



# Department of Health

## Review of the Balance of Competences between the United Kingdom and the European Union: Health

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### 1. Introduction

The Academy of Medical Royal Colleges (the Academy) brings together the voices of its 20 member colleges and faculties, speaking for safe, high quality care for patients on behalf of over 200,000 doctors. The purpose of the Academy is to promote, facilitate and where appropriate coordinate the work of its member medical Royal Colleges and their Faculties (as defined in their respective charters) for the benefit of patients and healthcare.

In developing this response to the call for evidence, the Academy has drawn on the experience of its individual members and its own collective knowledge and understanding of current and developing issues. This response supports the individual responses made directly by medical Royal Colleges, and focuses on the overarching questions as set out on page four of the November 2012 document calling for evidence.

### 2. How does the EU's competence in health affect you/your organisation

The Academy and our member colleges and faculties are affected by the EU's competence in health, both in the UK and in countries where the medical Royal Colleges have Members and Fellows, though its impact on:

- a) health service delivery (e.g. sharing good practice and learning through European networks);
- b) patient safety (e.g. device and drug standards and research); and
- c) medical training (e.g. equivalency of qualifications, working hours)

### 3. What evidence is there that EU action in health advantages or disadvantages:

- **The UK national interest**
- **Business and industry**
- **Patients and citizens**

Advantages include:

- a) Acceptable safety standards for clinical supplies (technology and pharmaceuticals) sourced across the EU
- b) EU-wide response to control of infection and identification of disease
- c) EU-wide safety and control measures for blood, tissue and organs
- d) Access to clinical care across EU for EU citizens
- e) EU directives (such as those on tobacco packaging) that support the UK's own approach and allow flexibility for the UK to make provisions for higher standards (e.g. introducing picture warnings on packs).
- f) Providing ability for sharing knowledge at European level and collaboration (e.g. key disease research, management of drug misuse)
- g) Supporting ability for Drs to enhance skills by working in different health systems across the EU

Disadvantages include:

- a) Additional complexities or limitations on UK choice (e.g. EU decisions on IT in healthcare; administrative burdens on information governance; working time)
- b) Concern at potentially lowering standards the UK wish to adhere to (e.g. language skills; medical training standards)

### 4. Please consider what evidence there is to demonstrate;

- **the extent to which the EU's role in public health supports member state actions effectively and efficiently**
- **the opportunities and costs for the delivery of health and social care in the UK that flow from wider EU competences and policies such as the free movement of workers or the single market generally**
- **the extent to which EU competence and policies intended to allow EU citizens to access healthcare across the EU are effective and proportionate**
- **the extent to which health objectives are effectively and proportionately taken into account in wider EU policies**

a) The EU's role in public health can help provide core minimum standards, which member states should be able to enhance if desired (e.g. alcohol or tobacco).

b) Health data should be proportionately governed, and clinical trial legislation further harmonised, to continue to encourage and support European based research and clinical trials.

c) Patient safety should be paramount in appointing health service workers, above country of origin / freedom of movement.

d) The health service implications of wider EU policies could be more strongly considered (e.g. unintended impact on quality of training as a result of EWTD)

### **How does the EU's competence in health affect you/your organisation**

1. This submission is from Action on Smoking and Health (ASH) a health charity set up in 1971 by the Royal College of Physicians to work towards eliminating the harm caused by tobacco. Funding for ASH is currently received from Cancer Research UK, the British Heart Foundation and from the Department of Health for work to support implementation of the DH Tobacco Control Plan.<sup>1</sup> ASH works collaboratively with its funders and other health and welfare organisations towards the goal of improving public health by reducing tobacco consumption. This response relates only to EU competencies related to tobacco. The key contact for this submission is Deborah Arnott, Chief Executive of ASH who can be e-mailed at [deborah.arnott@ash.org.uk](mailto:deborah.arnott@ash.org.uk).

### **What evidence is there that EU action in health advantages or disadvantages:**

- **The UK national interest**
- **Business and industry**
- **Patients and citizens**

2. Smoking rates have declined significantly in the UK over the last decade or so, by over one quarter in adults and one half in children.<sup>1</sup> This is as a result of a comprehensive strategy undertaken by the UK government and the devolved administrations and action on tobacco control taken at EU level has played a significant supporting role.

3. Measures introduced by the EU which help reduce smoking prevalence are greatly to benefit of the UK national interest, business and industry, patients and citizens. Reducing smoking prevalence is a UK government objective as smoking kills around 100,000 people each year and smoking related-diseases disable many more. Smoking remains the major cause of preventable premature death in the UK killing more people than the next six causes of preventable premature death put together.<sup>1</sup>

4. A report produced by the APPG on smoking and health<sup>2</sup> during the last spending review in 2010 estimated the following costs of smoking to the public purse and benefit to the public purse of a one percentage point reduction in smoking prevalence. The overall cost to the public purse, including NHS costs, reduced tax revenue from premature mortality, reduced tax revenue from workplace absenteeism and increased disability benefits due to poor health (taking into account reduced pensioner benefits as a result of premature mortality) was £9 billion. Each one percentage point reduction in smoking prevalence leads to a net revenue gain of £240 million.

### **What evidence is there to demonstrate the extent to which the EU's role in public health supports member state actions effectively and efficiently**

5. EU competence on tobacco issues has been helpful in setting a baseline but has also allowed the UK to go further where appropriate. Over the last decade EU directives on tobacco advertising and promotion, on TV advertising and on packaging and labeling have supported the UK in banning advertising promotion and sponsorship of tobacco products and in requiring larger health warnings on tobacco packs. Flexibility on EU competencies, for example within the TPD allowed the UK to go further and to introduce in addition picture warnings on packs,

6. Furthermore the UK has also been able to go further in areas not covered by EU competences, for example, to prohibit the sale of tobacco from vending machines and to prohibit displays of tobacco in retail outlets (a staged approach which will be fully implemented in 2015) as well as to introduce legislation to require all enclosed public places to be smokefree.

## **What evidence is there to demonstrate the extent to which health objectives are effectively and proportionately taken into account in wider EU policies**

7. All EU policies are required by the EU treaty to follow a “Health in all Policies” (HIAP) approach’ and this has proved useful when it comes to tobacco control. As the Consultation document states EU competence on tobacco control has been one of the Commission’s public health priorities in recent years. This is appropriate given that smoking remains the major preventable cause of premature death throughout the EU.

### **Tobacco Tax Directive**

8. One example of where this has occurred is the Tobacco Tax Directive<sup>3</sup> which contains a number of references to the importance of health protection, in particular:

*(2) The Union’s fiscal legislation on tobacco products needs to ensure the proper functioning of the internal market and, at the same time, a high level of health protection, as required by Article 168 of the Treaty on the Functioning of the European Union, bearing in mind that tobacco products can cause serious harm to health and that the Union is Party to the World Health Organization’s Framework Convention on Tobacco Control (FCTC).*

9. The current Directive has been helpful in enabling the UK to continue its policy of reducing the affordability of tobacco through tax increases while also increasing the minimum excise tax other Member States have to levy and reducing the differential between manufactured and fine cut tobacco.

## **What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?**

10. In certain circumstances non-legislative measures are an appropriate alternative and the EU can play a positive role. For example, under the General Product Safety Directive safety requirements can be introduced in MS through publication in the Official Journal.

11. In 2008 the European Commission defined the safety requirements for fire safety of cigarettes and then asked the European Committee for Standardisation (CEN) to develop the relevant standards. These came into force in November 2011 and are now used by national authorities to measure compliance with fire safety rules. The standard requires that no more than 25% of cigarettes shall burn through their whole length.<sup>4</sup>

12. Cigarettes are sold across borders and so setting a technical standard in this way for the whole of Europe is far more effective than if the UK had developed such a standard nationally which only applied to the UK and had to be introduced through legislation. Around 7% of fires and 30% of fire deaths in the UK are caused by smoker’s materials, primarily cigarettes and setting technical standards in this way is proportionate.<sup>5</sup>

### **Future Options and Challenges**

#### **How might the UK benefit from the EU taking more action in health?**

#### **How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?**

13. In the next review of the Tobacco Tax Directive we would like to see changes which take into consideration more appropriately the need for ‘a high level of health protection’. In particular further increases in the minimum taxes to be levied and a further decrease in the differential between manufactured and fine cut tobacco, for the benefit of health as well as the working of the internal market.

14. The UK would benefit from the revision of the Tobacco Products Directive currently underway which requires larger health warnings on the pack and that picture warnings be mandated. The proposal should, however, be revised to require all nicotine containing products to be authorized pursuant to Directive 2001/83/EC. The MHRA is currently examining how best to regulate nicotine containing products and ASH supports all such products being regulated by the MHRA.

15. The current proposal for the revised TPD should allow the UK to implement standard packaging at national level, as set out in the DH consultation in 2012, and we strongly support this.

### **Could action be taken at any other international level i.e. by the WHO?**

16. Action has been taken in the area of tobacco control by the WHO which has supported effective action in the UK. The WHO Framework Convention on Tobacco Control<sup>6</sup> is the world's first health treaty and sets out a comprehensive set of obligations for tackling the harm caused by tobacco. The EU and its Member States are all parties to the WHO FCTC and the EU negotiated the treaty as a bloc.

17. Parties are legally bound by the treaty's provisions, but the treaty is very much a framework. To summarise the key measures in the FCTC Parties are committed to:

- Establish a national coordinating mechanism for tobacco control (Article 5)
- Involve civil society in national and international tobacco control efforts (preamble and Article 4)
- Prevent the tobacco industry from interfering in the setting of public health policies (Article 5.3)
- Consider increasing tobacco taxes as a means of reducing tobacco consumption (Article 6)
- Protect citizens from exposure to tobacco smoke in workplaces, public transport and indoor public places (Article 8)
- Regulate the contents of tobacco products and disclosure of information about contents (Articles 9 and 10)
- Require large health warnings on tobacco packaging which should be 50% plus of the principal display areas but at least 30% of the principal display areas. To be done within 3 years of entry into force for that party (Article 11)
- Prohibit the use of misleading and deceptive terms such as 'light' and 'mild' within 3 years of entry into force for that party (Article 11)
- Promote public awareness of tobacco control issues, including the impact on health, using all available communications tools (Article 12)
- Enact comprehensive bans on tobacco advertising, promotion and sponsorship within 5 years of entry into force of the treaty for that party (Article 13)
- Include tobacco cessation treatment in national health programmes (Article 14)
- Implement specific measures to combat tobacco smuggling including pack markings to identify country of sale (Article 15)
- Prohibit sales of tobacco products to minors (Article 16)
- Support economically viable alternatives to tobacco growing (Article 17)
- Consider litigation to make tobacco companies pay for the harm caused by their products (Article 19)
- Develop and promote research into tobacco control and publish reports on implementation with a first report within two years of entry into force (Article 20 and 21)
- Support tobacco control in developing countries and countries in transition (Article 22)

18. Guidelines to the WHO FCTC have now been developed on Articles 5.3, 8, 9 and 10, 11 and 13 which can be found on the WHO FCTC Secretariat's website.<sup>7</sup>

19. Subsequently a protocol on the illicit trade in tobacco<sup>8</sup> has been negotiated and adopted and will come into force once it has been ratified by 40 parties. The UK government has publicly stated its support for the protocol.<sup>9</sup>

20. The UK has a very effective anti-smuggling strategy introduced in 2000 and regularly updated since then which has led to a dramatic reduction in the illicit trade over that time. A

widely ratified protocol will bring global standards up to those of the UK. In addition it will lead to greater international cooperation on tackling the illicit trade in tobacco and require comprehensive tracking and tracing of tobacco products.

21. The illicit trade in tobacco undermines public health and public finances and this protocol will play a major role in reducing the illicit trade globally and in the UK specifically with consequent benefits from increased tax revenues and reduced smoking prevalence which will accrue to the UK economy to business and industry and to patients and citizens.<sup>10</sup>

22. Negotiation at EU level has been effective and cost-effective for the UK and has ensured that the FCTC and subsequently the Illicit Trade protocol meet the needs of the UK and other Member States.

**Are there any published sources of information to which you would like to draw our attention for the purposes of this review?**

23. See references listed below.

<sup>1</sup> Healthy Lives, Healthy People: A Tobacco Control Plan for England. DH March 2011.

<sup>2</sup> APPG Smoking and Health. Inquiry into the effectiveness and cost-effectiveness of tobacco control:

*Submission to the 2010 Spending Review and Public Health White Paper Consultation process.* 2010

<sup>3</sup> COUNCIL DIRECTIVE 2011/64/EU

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:176:0024:0036:EN:PDF>

<sup>4</sup> Europa summaries of EU legislation. Product safety : general rules

[http://europa.eu/legislation\\_summaries/consumers/consumer\\_information/l21253\\_en.htm](http://europa.eu/legislation_summaries/consumers/consumer_information/l21253_en.htm) accessed 15 February 2013.

<sup>5</sup> DCLG. Fire statistics Great Britain 2011 to 2012.

<https://www.gov.uk/government/publications/fire-statistics-great-britain-2011-to-2012> accessed 15th February 2013.

<sup>6</sup> WHO FCTC. [http://www.who.int/fctc/text\\_download/en/index.html](http://www.who.int/fctc/text_download/en/index.html)

<sup>7</sup> WHO FCTC guidelines <http://www.who.int/fctc/protocol/guidelines/adopted/en/> accessed 12th February 2013.

<sup>8</sup> PROTOCOL TO ELIMINATE ILLICIT TRADE IN TOBACCO PRODUCTS. SEOUL, 12 NOVEMBER 2012

<http://www.who.int/fctc/protocol/en/>

<sup>9</sup> HMRC and UKBA. Tackling Tobacco Smuggling – building on our success. April 2011.

<sup>10</sup> Johnson, P. Cost Benefit Analysis of the FCTC Protocol on Illicit Trade in Tobacco Products. ASH. London 2009.

### **About the Alcohol Health Alliance UK**

The AHA brings together medical bodies, patient representatives, charities and alcohol health campaigners to work together to:

- Highlight the rising levels of alcohol health harm
- Propose evidence-based solutions to reduce this harm
- Influence decision makers to take positive action to address the damage caused by alcohol misuse.

The following response is consensus-based, following consultation with AHA members.

For more information about the AHA UK see: [www.rcp.ac/aha](http://www.rcp.ac/aha)

Alcohol is the world's number one risk factor for ill health and premature death among the 25-59 year old age group and Europe is the heaviest drinking region in the world.<sup>i</sup> Due to the scale and pervasive nature of alcohol misuse across the UK and Europe, it is essential that there is a comprehensive, coordinated response at the local, national and European level.

Alcohol is 'no ordinary commodity' and requires action equivalent to the current EU competence on tobacco control, which is exercised with clear public health objectives and which has supported national action and addressed cross-border issues such as advertising and sponsorship. Responsibility to ensure human health protection in all EU policies

The EU has responsibility to address public health problems such as alcohol misuse by complementing national actions, as stated in Article 168 of the Treaty. AHA notes that EU competence in health is not confined to actions by Directorate-General for Health and Consumers, rather the Treaty specifies that "a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities."<sup>ii</sup>

Currently public health protection is not given consistent weight across all EU policy areas.

There is clear evidence that effective alcohol strategies must address the price, marketing and availability of alcohol products, which requires concerted action from a range of policy areas such as such as trade, agriculture, enterprise and industry.

For example, the EC is currently reviewing the Scottish legislation that introduces a minimum unit price for alcohol. Failing to give adequate weight to the public health implications of this initiative could delay, or even prevent, Scotland from implementing a proportionate measure that evidence shows will target young and heavy drinkers.<sup>iii</sup> That said, a ruling in favour of minimum unit pricing would demonstrate how EU law can, and must, prioritise effective public health measures over commercial interests. This would provide a valuable precedent that could support member states in introducing other public health legislation, such as standardized nutritional labelling that addresses national dietary concerns.

### **Establishing a new EU Alcohol Strategy**

AHA UK supports the development of a new EU Alcohol Strategy for 2013-2020 that builds upon the

current progress by individual member states and the EU collectively to effect greater change.

There

are a number of ways that coordinated action through an effective EU strategy can contribute to reducing alcohol misuse. These include:

- Establishing baseline, non-limiting standards on the marketing and promotion of alcohol, equivalent to those that already exist for tobacco control under EU regulation. The exposure of young people to alcohol advertising and marketing, particularly digital

marketing, is a growing cross-border issue that cannot be solely addressed by individual member states and requires effective EU action.

- Providing a platform for organisations active at European level to share approaches and develop joint actions to tackle alcohol related harm
- Building understanding and awareness of the economic consequences of non-communicable diseases caused by risk factors such as alcohol misuse.
- Tackling the illicit trade in alcohol across Europe
- Ensuring that existing EU nutritional labelling regulations are expanded to include calorific labelling on alcohol.
- Creating greater flexibility for member states to vary VAT rates to support national-level fiscal measures based on volume that can curb harmful drinking.

i World Health Organisation Europe (2012) Alcohol in the European Union, Consumption, harm and policy approaches.

ii Official Journal of the European Union 2008. Consolidated Version of The Treaty on the functioning of the European Union

iii Purhouse, R et al, Modeling to assess the effectiveness and cost-effectiveness of public health related strategies and interventions to reduce alcohol attributable harm in England using the Sheffield Alcohol Policy Model version 2.0. Report to the NICE Public Health Programme Development Group, 2009.

## Alliance for Natural Health International

Please find comments from the Alliance for Natural Health International below. Our comments address primarily the following sections of the report: Nutrition and food labelling (Section 5), Health security (Section 8), Public health programmes (Section 10), Further legislation and case law (Section 19) and Non-legislative action (Section 20).

### **Impact on the national interest**

- *How does the EU's competence in health affect you/your organisation?*

ANH-Intl is a non-profit, non-governmental organisations working to help positively shape, with the cooperation of citizens, industry, academia and governments, the scientific and legislative framework that enables widespread adoption of sustainable approaches to healthcare. To be sustainable, it is our view that healthcare approaches should in the main be based on their compatibility with natural systems.

Accordingly, especially as a means of dealing with the burden of chronic diseases, they should be based on dietary and lifestyle approaches that are fully cognisant of the biochemical, physiological, psychological, emotional and physical requirements of human beings. This is a far cry from the current healthcare model which is dominated by use of new-to-nature pharmaceuticals that inevitably contribute to high rates of adverse reactions including death. Almost all the challenges faced by consumers requiring natural whole, unprocessed foods, effective food supplements or products associated with traditional systems of medicine, are created directly or indirectly by excessive EU competence. While laws regulation traditional medicines (Directive 2004/24/EC) or health claims (EC Regulation 1924/2006) were originally tabled owing to a perceived need for tighter regulation of their respective areas of scope, they have failed dismally in dealing with the original perceived problems, while introducing a range of new problems. These in turn lead to contravention of certain fundamental rights, as given in the Charter of Fundamental Rights, including adverse impacts on freedom of expression, freedom of choice and discrimination.

Accordingly, a large part of our work aim to remedy problems caused by disproportionate, unnecessary or ineffective EU regulation.

- *\_What evidence is there that EU action in health advantages or disadvantages:*

#### *The UK national interest.*

Good health and the wellbeing of UK citizens is the UK's single biggest asset. Yet chronic diseases place a massive burden on citizens' health. The UK has one of the highest levels of obesity

([http://epp.eurostat.ec.europa.eu/statistics\\_explained/index.php/Overweight\\_and\\_obesity\\_-\\_BMI\\_statistics](http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Overweight_and_obesity_-_BMI_statistics)), yet the EU Strategy on Nutrition, Overweight and Obesity related Diseases (2007-12) has failed to deliver any benefit to the UK, or any other EU member state, in terms of reducing the incidence of overweight and obesity.

There is little or no evidence that such top-down policy approaches will work, yet the UK continues to heap resources into such EU programmes. Non-governmental organisations and companies that seek to work with citizens to address obesity and overweight not only receive virtually no governmental support, they now have increasing difficulty delivering or recommending viable options owing to interference by policies, such as the EU Nutrition and Health Claims Regulation (1924/2006), that was born out of the EU 'obesity strategy'.

#### *Business and industry*

See above.

*Patients and citizens*

See above.

- *\_Please consider what evidence there is to demonstrate; o the extent to which the EU's role in public health supports member state actions effectively and efficiently*

The Novel Food Regulation (258/97) purports to provide an authorization system for foods or food ingredients deemed novel i.e. not used significantly within the EU prior to 15 May 1997. Given the very broad definition of a novel food, the regulation can easily be applied to altered or improved manufacturing processes. Accordingly, member states are increasingly regarding food supplements that are based on concentrated forms of botanical ingredients as unauthorised novel foods. Member States, including the UK, have been very unhelpful in their interpretation of the term "significant use" as contained in the Regulation, and there are several cases about which we are aware, where neither the Commission nor a Member State authority are willing to provide a definitive view despite having been provided with substantial evidence of sale prior to the May 1997 cut-off date. Also, such dates, being arbitrary in nature, are increasingly problematic given that accountancy records going back before the cut-off date have increasingly been disposed of.

*the opportunities and costs for the delivery of health and social care in the UK that flow from wider EU competences and policies such as the free movement of workers or the single market generally*

No comment.

*the extent to which EU competence and policies intended to allow EU citizens to access healthcare across the EU are effective and proportionate*

But what kind of healthcare are you referring to? Specifically only mainstream, Western medicine? In the case of the very significant numbers of EU citizens that choose to utilize complementary and alternative medicine (CAM) approaches, there are great differences in accessibility to citizens in different EU member states. Much of this is linked to different approaches to national regulation, or different levels of enforcement of EU laws, especially those relating to medicines (Directive 2001/83/EC, as amended) and novel foods (EC Regulation 258/97).

It is of paramount importance that there is a level playing field when considering access to CAM therapies, especially given their important role in disease prevention<sup>3</sup> and managing or reducing the risk of chronic diseases.

*the extent to which health objectives are effectively and proportionately taken into account in wider EU policies*

We are aware of no evidence that EU policies have led to significant reductions in chronic disease incidence, exposure to environmental chemicals or unsafe 'natural remedies'. Additionally EU policies are orientated to increase exposure of EU citizens to genetically modified (GM) foods and food ingredients along with harmful low frequency radiation from wireless technologies, despite increasing evidence of health and environmental risks from these sources.

EU policies seem to be more about protecting the interests of big businesses, rather than a genuine interest in consumer protection and wellbeing. Not least of all, the EU has no adequate definition of health. There is increasing medical consensus that health is much more than the absence of clinical symptoms of disease, and it is of paramount importance that the EU moves to a definition that takes into account the latest developments relating to health and resilience.

Suchwork is underway as part of a EU FP7 project, coordinated by the Dutch research organization TNO (see: [http://www.tno.nl/downloads/MSB\\_AgroFood.pdf](http://www.tno.nl/downloads/MSB_AgroFood.pdf) for more information)

### **Future options and challenges**

*How might the UK benefit from the EU taking more action in health?*

The EU could usefully provide value by improving the functioning of the single market and in the process removing barriers to trade. But the use of risk analysis in the field of nutrition and health, that ignores analysis of benefits, creates unnecessary barriers to trade. Focusing on risk alone and then developing policies to ensure 97.5% of the population is legislatively isolated from these risks, guarantees that a significant proportion of the population will be denied benefits. Refer to the following paper showing how risks and benefits in relation to micronutrients (vitamins and minerals) tend to overlap and why there is an urgent need for risk/benefit analysis:

Verkerk RH. The paradox of overlapping micronutrient risks and benefits obligates risk/benefit analysis. *Toxicology*. 2010 Nov 28;278(1):27-38. doi: 10.1016/j.tox.2010.02.011. Epub 2010 Feb 24. Review.

See also the following regarding the unscientific and flawed nature of existing EU risk analysis in relation to vitamins and minerals:

Verkerk RH, Hickey S. A critique of prevailing approaches to nutrient risk analysis pertaining to food supplements with specific reference to the European Union. *Toxicology*. 2010 Nov 28;278(1):17-26. doi: 10.1016/j.tox.2009.12.017. Epub 2009 Dec 23. Review.

• *\_How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?*

Greatly. The legislative history of the Traditional Herbal Medicinal Products Directive (Directive 2004/24/EC) indicates that this Directive was intended to prevent recurrences of poisoning of patients and consumers from Chinese herbal medicines<sup>4</sup> (Nortier et al, *N Engl J Med*. 2000; 342(23): 1686-92).

*How could action in this area be undertaken differently e.g. Are there ways of improving EU legislation in health, e.g. revision of existing legislation, better ways of developing future proposals, or greater adherence to the principle of subsidiarity and proportionality?*

Yes! Proportionality and subsidiarity are useful principles, but they are frequently ignored either by EU or UK regulators. The MHRA, for example, in making final determinations about herbal food supplement it deems to be medicines, does not take into account subsidiarity, ignoring data from other member states that allow the same products to be sold and consumed, with no evidence of harm. There appears to be a double standard in operation with regard to the precautionary principle. It is utilized with regard to bans on non-authorized novel foods which it deems may present a risk to humans if not authorized, yet the EC is happy to register over 50 GM crops following their green-lighting by EFSA, despite big question marks over the long-term consequence of mass-scale release of GMOs into the environment and into the human food supply. Surely the precautionary principle should dictate that there should be a moratorium on outdoor release of GMOs pending evidence of safety. We have been stunned by the unscientific, pro-GM approach taken by Dr Anne Glover, who acts as chief advisor to President Barosso (<http://news.sciencemag.org/scienceinsider/2013/02/new-science-body-to-adviseeurop.html?ref=hp>).

*Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest?*

It could demonstrate a more lenient interpretation of some EU laws to prevent negative impacts on the majority of responsible players in the food and natural health industry. The UK has currently the reputation in the EU of being a 'gold-plater' of EU laws. This reputation does the UK or its citizens no favours and should be altered.

*Could action be taken at any other international level i.e. by the WHO?*

The WHO has already done some useful work in diet and nutrition e.g. the Global Strategy on Diet, Physical Activity and Health. However, most of the recommendations have yet to be implemented by the UK. The UK was a signatory to the International Assessment of Agricultural Knowledge, Science & Technology for Development (IAASTD), yet most of the concerns expressed in this report have been ignored and successive UK governments, both Labour and Conservative. UK governments have in fact been outspoken proponents for globalisation of GMOs as a means of alleviating poverty, despite this report making clear GMOs could play no such role.

The UK needs to stop thinking that top-down solutions are the way forward. There needs to be a shift towards community and citizen engagement in healthcare—as well as a much greater emphasis on improving self-responsibility and self-care of individuals.

*What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?*

In dealing with disease prevention and chronic disease prevention, legislative<sup>5</sup> measures have failed abysmally and non-legislative measures have not been supported adequately by government, especially where they are intended to improve individual responsibility for healthcare and self-care.

*How else could the UK implement its current obligations?*

By more meaningful engagement with principles such as proportionality, subsidiarity, freedom of movement of goods and the precautionary principle.

*What future challenge/opportunities might we face in EU health competence and what impact might these have on the national interest?*

The unfolding series of pieces of law affecting food, food ingredients, labeling, health claims, traditional herbal products and related natural health products all involve removing competence of the Member States and handing these to the EU. EU health claims law (Regulation 1924/2006) is good example of how long-standing claims based on plausible science are in the process of being lost, to be replaced only by EC authorised health claims. The UK should maintain light enforcement of nonauthorised or unauthorised health claims, at least until such time that a successful judicial review of this very poorly orchestrated law resolves its many problems.

*What impact would any future enlargement of the EU have on health competence?*

Just make the EU's problems, and that of its citizens, worse.

## **General**

*Is there evidence of any other impacts resulting from EU action in health that should be noted?*

This is difficult to assess until the UK and EU have developed a suitable definition on health.

*Are there any general points you wish to make which are not captured above?*

No.

*Are there any published sources of information to which you would like to draw our attention for the purposes of this review?*

Some are given above.

## Alliance of UK Health Regulators on Europe

1. The Alliance of UK Health Regulators on Europe (AURE) brings together 9 of the health and social care regulators (competent authorities) in the United Kingdom to work collaboratively on European issues affecting patient and client safety. As regulators, our purpose is to protect and promote patient safety through effective regulation and ensuring proper standards in the practice of health and social care.

### Introduction

2. We welcome the opportunity to respond to the Department of Health's call for evidence on the Review of the Balance of competences between the United Kingdom and the European Union (EU). Our response focuses primarily on those sections in the consultation paper that impact on our work as regulators.

3. We believe that public protection and high standards of care should be at the core of any European initiatives in health.

4. As highlighted by the call for evidence, EU action in health is of a supporting nature. However legislative and policy initiatives in other areas often have implications for health policy and patient safety across Europe. This is partly complicated by the fact that different European Commission Directorate Generals (DGs) may not always work jointly to consider the specific requirements of the health sector.

### Section 13 – Implications of free movement of persons: healthcare professionals

5. As healthcare professional regulators in the UK, we are responsible for implementing the recognition of professional qualifications Directive (2005/36/EC).

6. According to the [Regulated Professionals Database](#), the UK receives almost three times as many European trained professionals than it sends out. As a net importer of healthcare professionals, both from Europe and internationally, the UK has significant experience with both the benefits and challenges of high levels of professional mobility.

7. Migrant healthcare professionals make a positive contribution to the provision of healthcare in the UK. However, the Directive has raised a number of challenges to public protection in the UK. Whilst we recognise that the current review of the Directive is intended to address some of these concerns, our response to this consultation outlines the opportunities and challenges of the existing legislative framework.

#### *Administrative cooperation*

8. The Directive has helped to initiate a dialogue and joint action with other competent authorities in the UK (as AURE), but also with our counterparts across Europe. The introduction and use of the Internal Market Information System (IMI) has helped us improve our interactions with competent authorities in other EEA countries.

9. As AURE, we share information, agree shared positions and jointly respond to relevant European initiatives, particularly the recognition of professional qualifications and data protection Directives.

10. In addition, the Healthcare Professionals Crossing Borders project, a European informal partnership between professional healthcare regulators launched in 2005, has enabled us to share best practices and improve information exchange between regulators for different health professions across Europe.

#### *Fitness to practise information sharing*

11. At present, the extent to which regulators exchange information about healthcare professionals is variable and there is no requirement for EEA competent authorities to proactively inform their counterparts on disciplinary issues. This presents a risk to patient safety.

12. We consider that a European legal duty for competent authorities to share disciplinary information is necessary and essential as it would provide greater assurances to UK regulators that the professionals they register are safe and fit to practise.

13. We hope that the introduction of an alert mechanism in a revised recognition Directive and the review of the data protection Directive will go some way to address these challenges to the benefit of UK patients.

#### *Language skills*

14. We strongly believe that the ability to communicate effectively with UK patients and colleagues is integral to the safe practice of all healthcare professionals and as such should be a prerequisite for access to the profession. However, the language requirements in the existing Directive are not expressed clearly enough and have led to different interpretations and implementation across the EEA to the detriment of patients in the UK.

15. We therefore welcome the European institutions' intentions to clarify Article 53 to enable healthcare competent authorities to assess the language competency of EEA applicants. This would ensure that patients are fully protected while increasing trust and confidence in the recognition system.

#### *Minimum training requirements*

16. There are some inherent tensions between member states' exclusive competence in education and the minimum training times set out in the Directive under automatic recognition. To ensure public protection, competent authorities, employers and patients must have better assurances that the qualifications included in the Directive are and remain genuinely comparable over time.

17. Furthermore, the minimum training requirements in the Directive are so broadly drawn and general that they provide little assurance about the standards of education and training of migrants. At the same time, their focus on duration of training rather than the outcomes of training has imposed constraints which have impeded the health sector from developing their education system in line with the UK's needs.

18. To ensure public protection, regulators, employers and patients must have better assurances that the qualifications included in the Directive are genuinely comparable. We therefore believe that there should be a European level review of the criteria for automatic

recognition and the minimum training requirements to better reflect current practice in education and training.

### *Competence assurance*

19. The Directive as it currently stands does not require professionals to provide evidence of recent practice or current competence as a condition for automatic recognition. We believe that automatic recognition must be linked with a requirement on professionals to demonstrate that they have been effectively maintaining and improving their knowledge and skills throughout their careers. This will address the unease competent authorities experience when they have to automatically recognise healthcare professionals that have not practised for many years.

20. Where professionals cannot provide this information, competent authorities should have the discretion to assess applicants under the general system and, if appropriate, apply compensation measures to ensure public protection. This process does not need to be burdensome and would increase trust in the mutual recognition system.

### *Unintended bureaucracy*

21. European initiatives such as the recognition Directive sometimes have a dissonance between intent and outcome. The intention of the legislation is to facilitate mobility but often generates bureaucratic outcomes that create perceptions of barriers.

22. For example, competent authorities' ability, under the general system, to compare an applicant's knowledge and skills against the national standards required for registration and the option to ask for successful completion of compensation measures before granting registration, is beneficial to patient safety, provides migrating professionals an opportunity to demonstrate their skills and facilitates mobility.

23. However, compensation measures pose some practical challenges for competent authorities. They can turn into an additional appeals point in the registration process if the migrant disagrees with the need for compensation or with the outcome of the measure. Compensation measures can also require significant stakeholder engagement in the UK for their delivery. Adaptation periods often take place in approved educational institutions and aptitude tests may require levels of bought-in expertise. European competent authorities with links to state ministries may have different abilities and ease with this aspect of compensation measures than an UK competent authority/regulator.

24. These outcomes have the effect of potentially increasing the regulatory impact of the competent authority and run the risk of confronting a migrant's expectations by appearing to be barriers to the recognition of their qualification.

25. Further examples of the discrepancy between intent and outcome include the inability to create a common training platform under the current Directive and the proposal to introduce a professional card under the revised framework.

### *Sectoral and general system professions*

26. The division in the recognition Directive of health professions into sectoral and general systems professions has led to policy inconsistencies in the way we regulate different health professions. For example:

- a. The use of the European Commission's Internal Market Information system has not yet been rolled out to all healthcare professions.
- b. For sectoral professions, the service is to be provided under the professional title of the host member state. For general systems professions, if a decision is made not to verify the qualifications of a would be temporary service provider, the service is to be provided under the title used in the member state of establishment and in the language of that state.

27. These discrepancies continue in the current review of the Directive. For instance, the Commission did not propose an automatic alert system to share fitness to practise information for general system professions and there is no derogation for these professions from partial access.

#### *Review of the Directive*

28. Despite the public protection issues highlighted above, AURE welcomes the review of the Directive and the attempt by the EU Institutions to address some of the concerns we have brought to their attention.

29. However, the adoption of the revised Directive might create some challenges for competent authorities including the implementation of the proposed European professional card (which serves no purpose in jurisdictions like the UK where there are web based searchable registers of healthcare professionals) and the application of partial access.

30. Moreover, it should be pointed out that any changes to the recognition procedures as part of the review of the Directive are likely to have financial implications for competent authorities which in turn may impact on the registration fees for healthcare professionals.

#### **Section 15 – Implications of free movement of services: cross-border healthcare**

31. AURE strongly believes that high-quality and efficient cross-border healthcare depends on accessible information. As well as having a right to receive healthcare anywhere in the EU, patients have a right to be confident that they will be treated by safe health professionals who are properly regulated.

32. In the context of regulation, patients need direct access to information about professional standards, assurance about the professional indemnity of those treating them, and information about complaints and redress if things should go wrong.

33. AURE members, for example, have publicly accessible and searchable web based lists of registered practitioners. This makes an important contribution to making regulation transparent and provides an easy way for members of the public, patients and health service contractors to check the registration status of practitioners. Therefore, we believe that all health regulators in Europe should be required to make up-to-date information about their registrants available to the public in this or a similar way.

## **Section 19 – Further case law**

### *ECJ case on temporary and occasional*

34. AURE is following with interest the ECJ case (C-475/11) brought by an employment tribunal for healthcare professionals in Gießen (Germany) against a Greek doctor registered under temporary and occasional mobility. The outcome of this case might have significant implications for healthcare regulation in the member states and has the potential to undermine the confidence of the professionals and the public at large in the mutual recognition system, should professionals working on a temporary and occasional basis not to be bound by the medical code of conduct of the host member state.

## **Section 20 – Non legislative action**

### *Patient safety and economic efficiency*

35. We consider that there are both economic and public safety reasons for treating healthcare professions differently from other professions. Concerns about healthcare professionals do not relate only to their competency, but also to their fitness to practise and professional behaviours, which are critically important when dealing with vulnerable patients. There are clear economic implications of healthcare professionals' misconduct for the NHS. Therefore, it is crucial to assure the fitness to practice of all healthcare professionals in the interest of both patient safety and economic efficiency.

## **Fresh Start Project**

### **THE EU AND THE NHS**

The impact of the Working Time Directive and language requirements on doctors in the NHS  
**November 2012**

**Andrea Leadsom MP, Charlotte Leslie MP, Chris Howarth 1**

#### **Foreword**

The NHS is rightly a treasured national institution in our Country.

Unfortunately, it is being damaged by the unforeseen consequences of EU legislation.

The Working Time Regulation, and in particular the SiMAP and Jaeger rulings of the European Court of Justice, are having a negative effect on junior doctor training, the continuity of patient care, waiting lists, NHS finances, acute specialties and doctors themselves, who report a negative impact on their working practices and fatigue.

Although valuable in promoting the exchange of healthcare professionals across the Union, the EU's directive on professional qualifications has led on occasion to doctors with insufficient language skills being able to practice in the UK, which has led to a number of serious incidents. This paper presents a robust analysis of these issues, and proposes a number of practical solutions that the UK could deploy. It draws on the contributions of the Royal College of Surgeons, the Royal College of Physicians, the Association of Surgeons in Training, the British Medical Association, the General Medical Council and other professional bodies during a roundtable in July 2012.

It is the responsibility of all politicians to ensure our healthcare system puts patient safety as its principal objective. EU regulation is failing to do that. The irony that a piece of health and safety regulation, the Working Time Directive, is now endangering patients should not be lost. And these impacts are all unintended. The EU has no competence over healthcare.

Whether europhile or europhobe we must object to the unintended consequences of legislation that puts patients at risk.

Andrea Leadsom MP Charlotte Leslie MP

#### **Executive summary**

Despite the fact that the EU treaties establish that it is the member states that have the responsibility for "the management of health services and medical care",<sup>1</sup> EU law still has a profound impact on the NHS.

EU legislation has had unintended negative consequences for the NHS, in part due to the particular structure of the NHS, which often differs to continental models of healthcare provision. The EU's impact on the NHS is particularly significant in the areas of staff qualifications, training and continuity of care, and has been shown to impinge on patient safety.

Although the NHS, like any large organisation, is affected by a broad range of EU regulations, this briefing will focus on two areas – the Working Time Directive and language testing of foreign doctors - and look at potential solutions to the problems faced.

#### **The Working Time Directive (WTD)**

The WTD's basic provision, limiting a working week to 48 hours, was introduced in 1998, following the UK Government's failed attempt to block the proposal in the EU's Council of

Ministers. Through subsequent amendments, the Directive now applies to almost all workers in the UK across all UK industry sectors.

As of 2009 the WTD now extends to all doctors and doctors in training except for those senior enough to set their own hours. In addition to the limit to 48 hours, the WTD also provides for mandatory break periods.

Two rulings of the European Court of Justice (SiMAP and Jaeger) have compounded the impact on the NHS by reducing doctors' flexibility as to when they take breaks, and deciding that time spent asleep, while on call within a hospital, should count as 'working time'. These rulings have severely disrupted doctors' working patterns and the ability of hospitals to organise rotas.

The WTD has had a serious and negative effect on the NHS in a way that even those who agreed it did not expect or intend. It has had a negative effect on junior doctor training, the continuity of patient care, waiting lists, NHS finances, acute specialties and the doctors themselves, who report a negative impact on their working practices and fatigue.

The WTD has led to junior doctors finding it hard to complete the hours needed for their training, with 84% saying they have had to come in during their spare time to make up hours and 86% saying it has led their "work-life balance" to deteriorate. Two thirds of surgical trainees reported deterioration in the quality of their surgical training as a result of the WTD.<sup>2</sup>

The Royal College of Surgeons has estimated that the WTD has led to a loss of 400,00 surgical hours per month. Likewise, the BMA has calculated it has led to the equivalent of the loss of up to 9,900 doctors. This adds additional costs to the NHS as new doctors have to be recruited to fill these hours.<sup>3</sup>

The application of the WTD has led to disruption in the continuity of patient care and an over reliance on handover notes. This has led to a number of publicised failings in NHS care including cases where the WTD has been cited by coroners as contributing to patient deaths.<sup>4</sup>

The UK is not alone in suffering the effects of the WTD, receiving support in raising concerns from a number of other member states. The European Commission has also realised that there is a need to remedy the worst aspects of the Directive, but due to the EU decision making process, including the intransigence of the European Parliament in relation to it, it is almost powerless to act.

The WTD's negative effects on the NHS cannot be ignored. If action is not taken, patient care will continue to suffer, with potentially disastrous effects in terms of insufficiently trained doctors, patient care and cost.

#### *Possible solutions*

It is clear that the UK would benefit from changes to the WTD. A desired outcome could involve a limited change such as a reversal of the two ECJ court cases, a higher limit on hours (c.60 hours), or a full opt-out from EU social legislation. Possible solutions to the problems of the WTD include:

- 1) Continue attempting to seek agreement at an EU level to amend the WTD and/or reverse the two court cases.
- 2) Attempt to avoid the Directive or manage a non-compliance with the rulings.
- 3) Seek a treaty change to opt-out completely from EU social and employment legislation.

#### **Language testing**

The EU's Directive on professional qualifications has led the NHS to treat doctors from the EU differently to doctors coming to the UK from outside of the EU. Whereas those wishing to practise in the UK from non-EU states have to demonstrate a use of the English language before being placed on the General Medical Council's (GMC) register, those from the EU do not.

The current system for doctors coming in from the EU, who make up 10% of all UK doctors, is that they can automatically have their medical qualifications recognised regardless of their standard of English and are then placed on the GMC's register. It is then up to the individual hiring hospital to ensure that the doctors they hire have sufficient English language skills. Systematic language testing is prohibited.

This has led to a number of serious incidents including death resulting from doctors with insufficient language skills slipping through the net. This is particularly the case with regard to locum doctors put forward by agencies at short notice.<sup>5</sup>

This problem is partly due to the system of registration in England and Wales, which differs to those in other EU member states in that there is no formal separation between registration for medical practice and recognition of qualifications.

There are a number of things that can and in some cases are being done in the UK to boost the GMC's powers and increase accountability for language testing. Negotiations on the Directive are also underway at the EU level and could be used to improve the situation. However, these improvements would still fall short of the tests imposed on non-EU health workers. Therefore, more can and should be done to ensure patient safety.

#### *Possible solutions*

1) The UK Government could use the current renegotiation of the EU Directive on qualifications to allow the UK to impose the same language testing for EU and non-EU health workers.

2) In the absence of EU agreement, the UK could formalise the separation between doctor registration and licensing that now exists, introducing language testing at the point of licensing, and extending this system to both EU and non-EU doctors to avoid discrimination.

3) Lastly, the UK could unilaterally extend its current system of testing non-EU health workers to all health workers and potentially face EU infraction proceedings.<sup>6</sup>

## **The Working Time Directive**

### **1.1. The Background**

The EU Working Time Directive (WTD)<sup>5</sup> came into force in 1998.<sup>6</sup> Its provisions are binding on the UK subsequent to the UK's agreement to the Amsterdam Treaty in 1997, which put an end to the UK's previous opt-out from the 'Social Chapter'. The UK Government was opposed to the WTD's introduction but failed in its attempt to block the proposal in the EU's Council of Ministers. Through subsequent amendments, the Directive now applies to almost all workers in the UK.

The 48-hour working week was extended to doctors in training on 1 August 2009, and after the expiry of a number of initial derogations, the Directive has now been applied in full.<sup>7</sup> The WTD was put into UK law via the Working Time Regulations, which require employers to grant most employees the following:<sup>8</sup>

- A 48 hour week (by an average calculated over a four month reference period).
- Eleven hours of continuous rest in a 24 hour period.
- A 20-minute break when working time exceeds 6 hours.
- 24-hour rest every seven days (or a minimum 48 hours rest every 14 days).
- Four weeks of annual leave.
- Maximum eight hours of work in 24 hours for night workers.

Subsequent European Court of Justice rulings in the *SiMAP* and *Jaeger* cases have had a particular impact on the NHS.

In the 2000 *SiMAP* ruling,<sup>9</sup> it was established that time spent resident on-call in a hospital (or any other workplace) must be fully counted as working time, even if the worker is asleep for some or all of that on-call time.<sup>10</sup>

The 2003 *Jaeger* ruling<sup>11</sup> has also provoked controversy, not least because it was clearly not what was intended by the policy makers who originally agreed to the WTD.<sup>12</sup> On that occasion, the ECJ ruled that the mandatory compensatory rest entailed in the WTD has to be taken immediately every time the minimum rest period is interrupted by an emergency.

This has meant that doctors unexpectedly required to work a longer shift have had to cancel appointments the following day.

In 2000, the British Medical Association estimated that the effect of the ruling would have been tantamount to losing between 4,300 and 9,900 junior doctors by 2009, when the full 48 hour limit for junior doctors was due to come into force (the UK later achieved a two year extension).

#### *Individual opt-out from the Working Time Directive.*

There remains an individual opt-out from the WTD, whereby an individual staff member can give their written consent not to be bound by the 48 hour week. However, no staff member, including junior doctors, can be compelled to opt-out making it impossible to plan on that basis. Senior consultants within the NHS do, however, tend to use the individual opt-out or take advantage of a separate derogation available to senior managers who set their own hours. However, the opt-out only covers the 48 hour week aspect of the WTD and does not cover other equally important aspects such as the enforced rest periods.

#### *Four month reference period for calculating the 48 hour week*

The WTD establishes that, when calculating limits to weekly working time, the hours worked can be averaged over a 'reference period'. In practice, this allows staff to work longer hours during certain weeks, provided that shorter hours are worked in other weeks during the same 'reference period' – so that the average remains below 48 hours per week.

Under the WTD, the 'reference period' cannot normally exceed four months – but national governments can unilaterally raise it to six months for certain activities (e.g. training doctors, dock or airport workers etc.). In theory, a further extension up to twelve months is possible, but only based on collective agreements between employers and employees.

## **1.2. The Problem**

Although the NHS's practices, such as the rigidity of the 'New Deal', have contributed to the problem, it is clear that the impact of the WTD has resulted in a serious and detrimental effect on the NHS, in terms of the continuity of patient care, the training of junior doctors and waiting times.

Although other EU states and the European Commission are aware of the problem and are willing to attempt reform, opposition from the European Parliament, and "social partners", both given power by the EU in this area, has so far made reform impossible.

The resulting issues are addressed in turn below:

- Lower standard of training of junior doctors.
- Disrupted continuity of care.
- End to organised rotas.
- Longer waiting lists – due to doctors enforced rest period leading to cancelled appointments.
- Increased cost to NHS.
- Doctors' welfare in terms of managing their non-working hours.

### **1.2.1 Impact on the training of junior doctors**

A combination of the limiting of trainees' hours, the counting of 'on-call' time as working time and the unpredictability created by enforced rest periods has had a major impact on the provision of training.

Firstly, the limiting of weekly hours has reduced the time trainees have to gain experience. Secondly, disruption to the traditional rotas has made it difficult for management to schedule individual training opportunities when supervisors and trainees are both present, in addition to decreasing the chances of trainees being present when unscheduled opportunities arise in the course of routine care. It is also difficult to schedule training events where a sufficient number of trainees are present. Lastly, due to trainees spending a larger proportion of their working time on 'out of hours' service provision, the value of their remaining time is further reduced.

As one doctor put it:

*“There is simply not enough time in the 48 hour week to get trained, particularly in the craft specialties so we all go in on our days off. If we don't, we don't get trained and it is us and our careers (but ultimately the patients) that suffer. Medicine is a competitive profession with only a limited number of desirable jobs in desirable locations to live so we simply have to get ourselves trained. This used to happen in our official working hours, now we work just as hard but get trained in our time off (unpaid) instead.”<sup>15</sup>*

This can be summed up by the diagram below.

**The effect that reduced hours can have on the time available for training**



Source: A review on the impact of the EUWTD on training by Sir John Temple<sup>16</sup>

This has been borne out in a number of surveys. The Association of Surgeons in Training, for instance, has found that over two-thirds of trainees reported deterioration in their surgical training due to the WTD.<sup>17</sup> 47.6% of Ophthalmologist trainees have found the same with similar results<sup>18</sup> for trainees in Obstetrics and Gynaecology (43%),<sup>19</sup> by the BMA (43%),<sup>20</sup>

The Royal College of Surgeons (66%),<sup>21</sup> and by the Scottish Academy which found that 65% of trainees in England and 81% of consultants felt the WTD's effect on training was negative.<sup>22</sup> Another serious factor resulting from the WTD is the trainee doctors' provision of services out of hours. Whereas time spent at night unsupervised could be supplemented by supervised training opportunities during the day, under the WTD, a larger proportion of a trainee's "training" will now be spent with inadequate supervision.

**1.2.2. Continuity and quality of patient care**

The overall effect of the WTD on the NHS has been to stretch staff availability to the limit and create more and shorter shifts. This in turn has led to more handovers, less continuity of care

and resulting mistakes as staff become unaware of patients' circumstances or they fall between the gaps.

A combination of the WTD (and the financial penalties imposed by the NHS's New Deal) has forced hospitals to move away from traditional resident on-call rotas towards shorter shift working or non-resident on-call rotas.

This has all affected the continuity of patient care. Patients will no longer have the same doctor who initially admitted them seeing them throughout their stay in hospital. This leads to more reliance on handover notes and patient care being broken down into individual procedures. It has also led to an expansion in the number and duration of the use of temporary locums in order to fill in gaps created by the WTD, thus breaking up patient care even further.<sup>23</sup>

The decrease in the continuity of care as a result of the WTD was brought to public attention recently with the sad case of Kane Gorny, who died of dehydration, after having even called the police to be given a glass of water.<sup>24</sup>

In her verdict the coroner at Westminster Coroner's Court put the blame for the deterioration in the quality of care on hospital waiting lists and the WTD which she said had affected Gorny's care. The Court specifically heard that many of the medical staff had not read Gorny's notes and did not even know that he suffered from a rare condition that required daily drugs to control it.<sup>25</sup>

This evidence that continuity of care has suffered as a result of the WTD is again backed up by the Association of Surgeons in Training survey, which found that 17% of trainees were aware of formally reported adverse critical incidents, directly arising from reduced working hours or increased frequency of handovers associated with WTD implementation.<sup>26</sup>

In this regards the *SiMAP* ruling over on call time has had a particularly bad effect, with one doctor writing that "the *SiMAP* ruling has, I think, had a devastating effect on acute care."<sup>27</sup>

### **1.2.3. Waiting lists**

Although difficult to quantify, the rulings in the *Jaeger* case have an impact on NHS waiting lists. This is because enforcing a rest period if a doctor has had to work longer than scheduled will mean that he has no option other than to cancel planned appointments at short notice.

### **1.2.4. Cost**

The combination of the *Jaeger* ruling and the 48 hour working week limit was estimated by the British Medical Association to amount to the equivalent of losing 4,300 to 9,900 junior doctors by 2009. The Royal College of Surgeons research and analysis of NHS workforce came up with an equivalent figure of 400,000 surgical hours lost per month due to the WTD.<sup>28</sup>

In addition to this cost, hospitals, as a result of the WTD, have been forced to hire more temporary locum doctors from agencies at a higher cost. These temporary doctors are not only a duplicate cost but due to demand and notice can end up costing far more. For instance, as a result of the need to be WTD compliant, North Cumbria University Hospitals NHS Trust has reportedly spent £20,000 on hiring a surgeon for one week and £14,000 on four days' cover for a gynaecologist. Mid-Staffordshire NHS Foundation Trust has also reportedly paid £5,667 for a doctor to cover one 24-hour shift in casualty—as the *Metro* newspaper points out, an equivalent salary of £1.36m a year.<sup>29</sup>

In addition to this is the cost of compliance with the WTD in individual hospitals, which can run into tens of thousands of pounds a year in terms of software and employee time. Responses to requests made under the Freedom of Information Act have shown, for instance, that some hospital trusts have engaged specific personnel to keep track of doctors' hours.

In 2010/11, University Hospital Aintree records having spent over £47,000 on WTD compliance, Rotherham NHS Foundation Trust over £41,000, Taunton and Somerset NHS Foundation Trust again over £36,000, to mention only three examples.

### 1.2.5. Doctors' welfare

The disruption to the residential on-call rota system and the introduction of shorter full shifts supplemented by enforced rest periods has paradoxically left many junior doctors with a more tiring and unpredictable working week. The Royal College of Surgeons concludes that the "move to working 48 hours a week through full shift rotas is exhausting surgical staff. We know from our members that working in a full shift pattern is more tiring when compared to working using an 'on-call' system, and creates a working environment that is impairing to patient safety."<sup>30</sup>

Likewise the Association of Surgeons in Training found that 67% of surgical trainees are attending work while off-duty to protect their training and gain adequate experience, and that 84% of surgical trainees are working in excess of their rostered hours to maintain the quality of the service provided.

It also reported that 86% of surgical trainees working a WTD-compliant rota have seen their work life balance deteriorate or remain unchanged with the theoretical reduction in working hours. For junior doctors in training, the strictures of the WTD can force trainees to make a difficult choice: comply the WTD and fail to accumulate sufficient training hours, or come in on their days off. Many end up working in their own time off.

### 1.3. Contributing factor: The NHS New Deal

The "New Deal" is essentially an employment contract that stipulates expected hours and pay bands. Despite predating the WTD (the New Deal was agreed in 1991),<sup>31</sup> the relevant parts came into force as a contract in 2000 and 2003. The New Deal awards staff financially for working more than 40 hours per week and sets a limit of 56 hours, which to some extent mirrors the WTD. <sup>32</sup>

Although the WTD is the main factor contributing to the disruption of doctors' working hours, the NHS' own New Deal is a contributing factor. Absent the WTD, the New Deal would continue to put cost and time restraints on the NHS.

### 1.4. Is the WTD a problem in other EU states?

It is important to understand that the implementation of the WTD and the ECJ rulings is not solely a UK problem - it has caused problems for healthcare providers across the EU. In addition, the European Commission has recognised this in its review of the Directive. It is therefore interesting to see how other states have coped with the WTD. To take a few examples below:

Belgium only enforced the 48 hour cap for training doctors into national legislation from February 2011.<sup>33</sup> Until then, training doctors were working up to 79 hours per week on average in Belgium. <sup>12</sup>

Despite transposing EU working time rules for training doctors into national law in 2004,<sup>34</sup> Ireland is still failing to apply them, and was last year threatened to be taken to the ECJ.<sup>35</sup> At the beginning of this year, the Irish government laid down a plan to ensure compliance with EU rules over the next three years, meaning that Ireland may not be fully applying the rules before the end of 2014.<sup>36</sup>

The following table outlines the level of compliance in Ireland: **Proportion of each grade of Non-Consultant Hospital Doctors (NCHD) compliant with EWTD provisions (2011) in Ireland**

| <b>Grade</b> | <b>Daily breaks</b> | <b>Daily rest</b> | <b>Weekly/fortni</b> | <b>Average 48-</b> |
|--------------|---------------------|-------------------|----------------------|--------------------|
|--------------|---------------------|-------------------|----------------------|--------------------|

|                               |            |            | <b>ghtly rest</b> | <b>hour week</b> |
|-------------------------------|------------|------------|-------------------|------------------|
| Intern                        | 79%        | 77%        | 97%               | 43%              |
| Senior House<br>Officer (SHO) | 72%        | 69%        | 93%               | 30%              |
| Registrar                     | 73%        | 67%        | 92%               | 31%              |
| Specialist<br>Registrar       | 73%        | 65%        | 94%               | 37%              |
| <b>TOTAL</b>                  | <b>73%</b> | <b>69%</b> | <b>93%</b>        | <b>33%</b>       |

1 Article 168(7) TFEU

2 Association of Surgeons in Training (ASiT) survey, *Optimising working hours to provide quality in training and patient safety (January 2009)* and British Orthopaedic Trainees Association (BOTA) survey, *BOTA position statement on EQTD and training in trauma & orthopaedic surgery (January 2009)*; <http://www.rcseng.ac.uk/policy/briefings/?searchterm=royal>

3 Royal College of Surgeon's briefing (August 2010);  
[www.rcseng.ac.uk/policy/documents/RCS%20EWTD%20briefing.pdf](http://www.rcseng.ac.uk/policy/documents/RCS%20EWTD%20briefing.pdf)

4 As in the case of the recent death of Kane Gorny, who attempted to ring the emergency services to receive a glass of water. The subsequent inquest cited the WTD as a factor leading to the lapse in care.

5 Directive 2003/88/EC

6 UK implementing legislation, <http://www.legislation.gov.uk/ukxi/1998/1833/contents/made>

7 The remaining derogation relates to doctors in critical areas or rural hospitals has also lapsed [http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH\\_099150](http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_099150)

8 There are limited exemptions for specific groups either unable to calculate their hours or senior enough to dictate their hours.

9 Case C-303/98 *Sindicato de Medicos de Asistencia Publica (SiMAP) v Conselleria de Sanidad y Consumo de la Generalidad Valenciana*. [2000] ECR I-7963

10 The ECJ rulings cover both periods where the worker is working in response to a call (i.e. 'active' on-call time), and periods where the worker is allowed to rest while waiting for a call (i.e. 'inactive' on-call time), provided that he/she does not leave the workplace. See *European Commission*, 'Report to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on implementation by Member States of Directive 2003/88/EC', 21 December 2010, p5

11 Case C-151/02 *Landeshauptstadt Kiel v Norbert Jaeger*. Judgment of 9 October 2003 <http://www.publications.parliament.uk/pa/ld200304/ldselect/ldcom/67/6706.htm>

12 In oral evidence to the House of Lords EU Select Committee in 2004, the then Health Minister John Hutton said: "To require compensatory rest to be taken immediately would potentially have a massively destructive effect across the NHS and might mean that doctors could not work the following shift or rota that they were required to do and that would have knock-on consequences right across the hospital. At the end of the day, the only people who would be negatively affected would be the patients and that is a ridiculous result.

House of Lords European Union Committee, *The Working Time Directive: A Response to the European Commission's Review*, 9th report of Session 2003-04, Volume II, answer to Q259

13 Other relevant ECJ rulings are: *Pfeiffer* (C-398/01) and *Dellas* (C-14/04)

14 See *Open Europe*, 'Time's up! The case against the EU's 48-hour working week', March 2009, p25, <http://www.openeurope.org.uk/Content/Documents/PDFs/wtdoptout2.pdf>

15 Mr Tom Palser MRSC, Surgical Trainee, email to Charlotte Leslie MP, 25 April 2012

16 [www.mee.nhs.uk/PDF/14274%20Bookmark%20Web%20Version.pdf](http://www.mee.nhs.uk/PDF/14274%20Bookmark%20Web%20Version.pdf)

17 Association of Surgeons in Training survey, of over 1,600 surgeons-in-training from all specialties ; [http://www.asit.org/news/wtd\\_implementation](http://www.asit.org/news/wtd_implementation)

- 18 Royal College of Ophthalmologists survey of 189 trainees in October 2009.
- 19 A review on the impact of the EUWTD on training by Sir John Temple
- 20 Ibid.
- 21 RCS survey of 980 doctors in 2010; <http://www.rcseng.ac.uk/news/impact-of-doctor-working-time-cap-on-patient-safety-and-training-getting-worse-says-new-survey> ;  
<http://www.rcseng.ac.uk/news/impact-of-doctor-working-time-cap-on-patient-safety-and-training-getting-worse-says-new-survey>
- 22 A review on the impact of the EUWTD on training by Sir John Temple.
- 23 Goddard A, Pounder R, McIntyre A, Newbery N. Implementation of the European Working Time Directive in 2009 – implications for UK clinical service provision and training for the medical specialties [http://old.rcplondon.ac.uk/professional-Issues/workforce/Workforce-issues/Documents/EWTDRCP\\_2009\\_surveys.doc](http://old.rcplondon.ac.uk/professional-Issues/workforce/Workforce-issues/Documents/EWTDRCP_2009_surveys.doc).  
*London.: Medical Workforce Unit, Royal College of Physicians, 2009.*
- 24 [http://www.publicservice.co.uk/news\\_story.asp?id=20312](http://www.publicservice.co.uk/news_story.asp?id=20312)
- 25 *Telegraph*, 11 July 2012; <http://www.telegraph.co.uk/health/healthnews/9391899/Kane-Gorny-inquest-medics-did-not-check-pulse-for-24-hours.html>
- 26 Association of Surgeons in Training (ASiT) and British Orthopaedic Trainees Association survey;  
[http://www.rcseng.ac.uk/news/docs/ASiT\\_BOTA%20EWTD%20Survey%20results.pdf/view](http://www.rcseng.ac.uk/news/docs/ASiT_BOTA%20EWTD%20Survey%20results.pdf/view)
- 27 Ibid
- 28 Royal College of Surgeon's briefing (August 2010);  
[www.rcseng.ac.uk/policy/documents/RCS%20EWTD%20briefing.pdf](http://www.rcseng.ac.uk/policy/documents/RCS%20EWTD%20briefing.pdf)
- 29 *Metro*, 18 March 2012; <http://www.metro.co.uk/news/893504-20-000-spent-to-cover-doctor-for-just-1-week>
- 30 Association of Surgeons in Training (ASiT) survey, *Optimising working hours to provide quality in training and patient safety (January 2009)* and British Orthopaedic Trainees Association (BOTA) survey, *BOTA position statement on EQTD and training in trauma & orthopaedic surgery (January 2009)*; <http://www.rcseng.ac.uk/policy/briefings/?searchterm=royal>
- 31 The New Deal: <http://www.dhsspsni.gov.uk/scujuniordoc-2>
- 32 Guide for Medical Students and Newly Qualified Doctors to the New Deal and European Working Time Directive;  
[http://www.healthcareworkforce.nhs.uk/working\\_time\\_directive/pilot\\_projects/new\\_deal\\_and\\_wtd\\_booklets/](http://www.healthcareworkforce.nhs.uk/working_time_directive/pilot_projects/new_deal_and_wtd_booklets/)
- 33 Loi du 12 décembre 2010 fixant la durée du travail des médecins, dentistes, vétérinaires, candidats médecins en formation, candidats dentistes en formation et étudiants stagiaires se préparant à ces professions, see <http://www.emploi.belgique.be/defaultTab.aspx?id=33092>
- 34 European Communities (Organisation of Working Time) (Activities of Doctors in Training) Regulations 2004, S.I. No 494/2004, <http://www.irishstatutebook.ie/2004/en/si/0494.html>
- 35 See *European Commission* press release, 'Commission requests Ireland and Greece to comply with the EU rules on limits to working time in public health services', 29 September 2011,  
<http://ec.europa.eu/social/main.jsp?langId=en&catId=157&newsId=1083&furtherNews=yes>
- 36 See *Irish government, Department of Health*, 'Plan for implementation of EWTD in Ireland – Doctors in training', 17 January 2012, <http://www.dohc.ie/press/releases/2012/20120117.html>
- 37 *Irish government, Department for Health*, 'Plan to progress measures required to ensure EWTD compliance', January 2012, p6,  
[http://www.dohc.ie/press/releases/pdfs/Plan\\_to\\_progress\\_measures\\_EWTD.pdf?direct=1](http://www.dohc.ie/press/releases/pdfs/Plan_to_progress_measures_EWTD.pdf?direct=1)

38 See Article R6153-2 of the French 'Code de la santé publique',  
[http://www.legifrance.gouv.fr/affichCodeArticle.do;jsessionid=8F04D356722BC1D93E769BDB4C952FB5.tpdjo02v\\_2?cidTexte=LEGITEXT000006072665&idArticle=LEGIARTI000022911373&dateTexte=20120807&categorieLien=id#LEGIARTI000022911373](http://www.legifrance.gouv.fr/affichCodeArticle.do;jsessionid=8F04D356722BC1D93E769BDB4C952FB5.tpdjo02v_2?cidTexte=LEGITEXT000006072665&idArticle=LEGIARTI000022911373&dateTexte=20120807&categorieLien=id#LEGIARTI000022911373)

39 In principle, there is no law which would prevent French junior doctors being asked to work longer than the eleven half-days. For further details, see *European Commission* staff working paper, 'Detailed report on the implementation by Member States of Directive 2003/88/EC concerning certain aspects of the organisation of working time', 21 December 2010, p33-34

40 *NHS*, Medical Education England, the impact of the EU WTD;  
<http://www.mee.nhs.uk/pdf/LiteratureReviewFINAL.pdf> p.26

## Anthony Nolan

### **Response to Call for Evidence: Balance of Competences: Health**

Date Thursday 28th February 2013

Anthony Nolan is a pioneering charity. Our primary purpose is to save the lives of people with blood cancer who need a haematopoietic stem cell transplant (HSCT). We recruit to and manage a register of potential haematopoietic stem cell donors, operate an umbilical cord blood donation programme and conduct research into HSCTs.

- We currently have over 450,000 people on our register and over 2000 banked umbilical cords
- Last year we helped to facilitate 933 HSCTs
- There are around 1,500 people waiting for an allogeneic HSCT in the UK
- Around 50% of Anthony Nolan searches result in a successful match and subsequent transplant
- Anthony Nolan imported 450 stem cell units from international registries for use in HSCT in 2012. We exported 170 stem cell units for clinical use for patients in international jurisdictions in the same year.

Anthony Nolan is the largest supplier of cells for allogeneic HSCT in the UK. Clinicians that have identified patients in need of allogeneic HSCTs contact Anthony Nolan. We then search the aligned registry of both our own and NHS Blood and Transplant's registered donors and UCB banks, and international registries and UCB banks, in order to find a matching donor or cord from which we can provide HSCs for transplant. Overseas-based registries are also able to search the Anthony Nolan register, and we export stem cells for transplant in other countries should their registries find a suitable match from the Anthony Nolan register.

Anthony Nolan is licensed by the Human Tissue Authority and regulated by the Care Quality Commission in the UK. We are also accredited by the UK Clinical Pathology Association, the World Marrow Donor Association and the European Federation of Immunogenetics.

### **EU COMPETENCE WITHIN HEALTH**

#### **EU Tissues and Cells Directives**

The EU Tissues and Cells Directives are the parent-legislation which governs the stem cell provision activity that Anthony Nolan carries out. We support the retention of EU competence in this area.

We feel that the co-ordination of standards across the EU for activities relating to stem cell provision is vital to ensuring the European market for cells functions effectively. It is imperative that there is cross-border governance of stem cell provision, given that the cross-border transfer of cells for clinical use is vital to ensuring as many patients within the EU are able to find a matching donor possible. We know that if we procure stem cells for a life-saving transplant from another Member State, the EU regulates the quality of those cells and the activities for which they are used. It acts as a kite-marking service. Similarly, should competence for regulating activities and quality in stem cell provision be moved to a UK-only basis, it may well impact on our ability to export cells to other Member States. This is an important source of income not just for Anthony Nolan, but for NHS Blood and Transplant. The ability to export stem cell units is a critical financial advantage, and that income stream in turn allows us where possible to keep our costs of domestic cell provision down when supplying to the National Health Service.

Should we need to navigate 27 diverging regulatory regimes across Europe, there would be significant cost implications for our provision of imported cells. More importantly, however, time is critical in HSCTs. There is potential that if our organisation sat outside the EU common

regulatory standards by virtue of our UK location, our stem cell import or export activity would be subject to delay caused by additional bureaucracy or lack of international trust in our 'product' caused by the absence of a recognised European 'kite-mark'. Such delays would undoubtedly have a significant impact on patient survival in the UK and for patients who require UK-sourced stem cells in other Member States.

HSCT standards are also within the EU competence. JACIE standards, which transplant centres are obliged to meet, are EU-wide standards. Similarly, in order for transplant centres to comply with JACIE, the cells they procure for transplant must come from a stem cell provider that is accredited by the European Federation of Immunogenetics. Again, given the cross-border aspect of stem cell provision, we believe it is right that the regulatory structure reflects this, and ensures that all EU providers meet similar standards in order to ease the flow of cells across the continent. It allows for consistency in standards, and reassurance for clinicians that we are sourcing safe and high quality cells for UK transplants, and that we provide high quality, safe cells for transplant in other Member States. The current EU-wide regulatory structure also provides for a full audit trail for stem cells, ensuring clinicians have all relevant information about the donor to inform their decision-making. We therefore support the retention of the status quo in relation to the European regulatory regime for both stem cell providers and transplant centres.

### **Support for Rare Diseases**

The stem cells that Anthony Nolan provides are used to treat a range of diseases that have one thing in common: they fall within the 'rare' category. EU work on rare diseases has led to the development of a rare diseases plan in the UK. We believe that to be a strong example of how EU competence in this area drives progress and supports the UK health framework. We fully support the retention of competence for rare diseases within the EU framework.

### **Clinical Trials Directive**

Clinical trial regulation is an EU competence, and is governed by the Clinical Trials Directive. The Anthony Nolan Research Institute conducts research that will ultimately lead to better HSCT outcomes for patients.

The patient populations for clinical trials relating to the diseases into which Anthony Nolan conducts research are typically very small in the UK alone. Therefore almost all clinical trials relating to these diseases require participation from patients in multiple countries. The Clinical Trials Directive, while in need of improvement, is a good mechanism by which to ease the bureaucracy involved in established cross-border clinical trials and ensures consistency in standards of research provided into central studies from EU member states.

We therefore support the competence for clinical trials regulation remaining with the EU.

**Response to Department of Health consultation on the review of the balance of competences: Health**

**How does the EU's competence in health affect you/your organisation?**

- This submission is made on behalf of ASH Wales, the leading voluntary organisation in Wales tackling tobacco use. Our main aim is to achieve a reduction in and eventual elimination of the health problems associated with tobacco use.

The Vision of ASH Wales is: "**ASH Wales is committed to achieving a life free from tobacco for all people in Wales**". The Mission of ASH Wales is: "**Towards a Tobacco Free Wales**"

ASH Wales works in collaboration with funders and other health and community organisations to improve public health through the reduction of tobacco consumption.

**What evidence is there that EU action in health advantages or disadvantages:**

**The UK national interest?**

**Business and industry?**

**Patients and citizens?**

Over the last decade, smoking rates have continued to decline in Wales and across the UK. However, in order to reach the ambitious targets set by the UK and devolved administrations, further progress needs to be made with the continuation of the comprehensive strategies that have been put in place in the nations of the UK during recent years. Supporting action on tobacco control, both in terms of legislation and non-legislative measures, has made, and should continue to make, a significant contribution to bringing smoking prevalence rates down further.

Measures taken at EU level to reduce prevalence rates, benefit the UK national interest, business and industry, as well as patients and citizens. Improving the health of patients and citizens through quitting smoking reduces the economic burden on the NHS and the person-hours lost to businesses through smoking-related illness and also smoking breaks. Reducing the level of smoking-related mortality and morbidity is in the interest of all groups identified.

**What evidence is there to demonstrate the extent to which the EU's role in public health supports member state actions effectively and efficiently?**

EU competence on tobacco control has set a useful baseline on important issues, whilst creating a flexible framework within which the UK has been able to take further measures where it has been deemed appropriate to do so. EU directives on tobacco advertising and promotion, TV advertising, packaging and labelling have supported moves by the UK in introducing bans and the requirement for larger health warnings on packaging, as well as allowing the UK to introduce pictorial warnings on packs. The UK and devolved administrations have also been able to take action in areas not covered by EU competences, such as smoke-free spaces legislation.

**What evidence is there to demonstrate the extent to which health objectives are effectively and proportionately taken into account in wider EU policies?**

ASH Wales believe that the 'Health in all Policies' approach adopted at EU level has been of use in terms of tobacco control as it serves to prevent steps that may undermine existing

tobacco control measures. This is appropriate given that smoking remains the major preventable cause of death both within the UK and across the EU.

### **What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?**

In the EU context, non-legislative measures can act as an appropriate alternative allowing the EU to play a positive role in public health promotion. As cigarettes are sold across borders throughout the single market, measures which allowing for the establishment of a technical standard across the EU are far more effective than if the UK had developed standards which only applied nationally.

### **How might the UK benefit from the EU taking more action in health?**

### **How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?**

The revision of the Tobacco Products Directive which is currently underway could benefit the UK through requiring large health warnings on the pack and the mandating of picture warnings. The proposal should, however, be revised to require all nicotine containing products to be authorised in accordance with Directive 2001/83/EC. The MHRA is currently reviewing how best to regulate nicotine containing products and ASH Wales supports all such products being regulated by the MHRA.

The current revision of the TPD should also allow the UK to implement standard packaging at national level.

### **Could action be taken at any other international level i.e. by the WHO?**

Action has already been taken by the WHO in the area of tobacco control in the form of the Framework Convention on Tobacco Control and the recent protocol on the illicit trade in tobacco.

The FCTC sets out a comprehensive series of obligations for tackling the harm caused by tobacco. The EU and its Member States are all parties to the WHO FCTC. Action should be taken by these signatories to ensure that they implement all provisions of the FCTC in full and as soon as possible. Examples of such commitments include:

Prevent the tobacco industry from interfering in the setting of public health policies (Article 5.3)

Protect citizens from exposure to tobacco smoke in workplaces, public transport and indoor public places (Article 8)

Require large health warnings on tobacco packaging which should be 50% of the principal displayers but at least 30% of the principal display areas., to be done within 3 years of entry into force for that party (Article 11).

The EU negotiated the FCTC as a bloc, both an effective and cost-effective step for the UK, ensuring that the FCTC and the subsequent Illicit Trade protocol meet the needs and concerns of the UK and its EU partner states.

## Association of British Healthcare Industries

Impact on the national interest

- How does the EU's competence in health affect you/your organisation?

The medical device industry is a global industry with a profile of (relatively) low volume and high technology/investment; consequently it is better, particularly for the relatively substantial UK based medical device industry, that there is as little variation between markets as possible. ABHI is therefore in favour of competency existing at EU Level where possible.

What evidence is there that EU action in health advantages or disadvantages

- The UK national interest  
Limiting the variations between markets means medical device industries benefit from economies of scale meaning it can provide more cost efficient devices to UK health-care. This is particularly relevant to the UK-based industry which has a large proportion of SMEs relative to European and global competitors.
- Business and industry  
Having access to a single market with little variation means industry can operate more efficiently with lower costs.
- Patients and citizens  
Patients benefit from the greater availability of cost effective devices that may not be available if markets were fragmented
- Please consider what evidence there is to demonstrate;  
the extent to which the EU's role in public health supports member state actions effectively and efficiently
- the opportunities and costs for the delivery of health and social care in the UK that flow from wider EU
- competences and policies such as the free movement of workers or the single market generally

Medical device design and manufacturing is a highly specialist activity and the ability to draw talent from as wide an area as possible is essential if the UK is to maintain the comparative advantage that has been identified by Government (BIS Economics Paper No. 18 - <http://www.bis.gov.uk/assets/biscore/economics-and-statistics/docs/i/12-1140-industrial-strategy-uk-sector-analysis>)

- the extent to which EU competence and policies intended to allow EU citizens to access healthcare across the EU are effective and proportionate
- the extent to which health objectives are effectively and proportionately taken into account in wider EU policies

## Future options and challenges

### How might the UK benefit from the EU taking more action in health?

Greater integration of the single market has the potential to reduce fragmentation between Member States leading to lower costs and easier marketing for UK-based companies.

### How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?

Unclear that there would be a benefit. Likely a heightened risk from greater fragmentation

**How could action in this area be undertaken differently e.g.**

**Are there ways of improving EU legislation in health, e.g. revision of existing legislation, better ways of developing future proposals, or greater adherence to the principle of subsidiarity and proportionality?**

Existing medical device legislation is currently under review. ABHI is working with its European partners to ensure that medical device legislation removes fragmentation, stimulates innovation and ensures patient and user safety.

**Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest? Could action be taken at any other international level i.e. by the WHO?**

The medical device industry is a global industry and consequently greater cooperation at global level would be welcome (for example as regards nomenclature) provided that it does not detract from cooperation at EU level..

**What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?**

The medical device industry is necessarily a heavily regulated industry. Recent experience would indicate that a move to non-legislative measures is not without risk.

**How else could the UK implement its current obligations?**

**What future challenge/opportunities might we face in EU health competence and what impact might these have on the national interest?**

With free movement of citizens across the EU it seems likely that there would be a drive for patient records to be accessed and intelligible from any Member State. This, as well as data and information from tele-health, e-health and m-health applications would require working seamlessly across the EU . This would suggest that more health competences would need to reside at EU level, with consequences for NHS operations.

**What impact would any future enlargement of the EU have on health competence?**

Recent experience shows that regulatory rigour can only be assured across the single market at EU level.

**General**

**Is there evidence of any other impacts resulting from EU action in health that should be noted?**

It should be noted that the EU has instigated the development of a network of Health Technology Assessment agencies ("EUnetHTA"). This is now at the stage of 'joint action 2', commenced January 2013 and running to September 2015 (joint action 1 ended last year). A permanent HTA network is scheduled to go live in October 2013 and a great deal of activity has

already taken place. In the round this will have had an impact on the development of HTA in the UK.

## Association of the British Pharmaceutical Industry

About the Association of the British Pharmaceutical Industry (ABPI)

The ABPI represents large, medium and small research-based biopharmaceutical companies, leading an exciting new era of biosciences in the UK. Our members are a major contributor to the economy of the UK, and supply 90% of all medicines used by the NHS. Member companies are researching and developing over two-thirds of medicines currently in development, ensuring that the UK remains at the forefront of helping patients prevent and overcome diseases.

Introduction

ABPI welcomes the opportunity to respond to your call for evidence on the EU Balance of Competence Review - Health Report. Whilst considering the context of your report and wherever the Balance of Competence related to health ultimately reside, it is critical to appreciate that investment in health is not a burden and that the healthcare sector has huge potential to improve the quality of life of citizens and to strengthen economies.

The healthcare sector has huge potential to contribute in terms of employment and improved health outcomes. Biopharmaceutical innovation is a source of huge investment in the UK and across Europe in university research, SME spin-offs. For example, members of the European Federation of the Pharmaceutical Industries and Associations (EFPIA) spend 27.5 billion Euros per annum on Research and Development in Europe, providing 660,000 jobs directly and generate an EU trade balance surplus of 48.3 billion Euros. In the UK the biopharmaceutical industry remains the leading R&D investor - £4.6 billion (ONS 2011) - and brings in an annual trade surplus of over £6 billion (HMRC 2011) whilst providing 67,000 highly skilled jobs (ONS, BERD 2011).

Patient access to a sustainable supply of value-adding medicines is a critical component of any healthcare system. Whilst ensuring that these innovative treatments are widely available, citizens can expect not only to live longer, but to live longer and be healthier.

Patient access to medicines is also vital to any successful long-term strategy for economic growth, contributing in two key ways;

- First it delivers a healthy population and therefore a more vibrant, productive workforce.
- Secondly it creates positive perceptions as a location for investment in high quality life sciences activity.

ABPI Response to the Call for Evidence – Review of the Balance of Competences (Health)

Whilst the responsibility for organisation, structure and funding of health services is a matter for individual Member States, the EU has an important role in co-ordinating, advising and organising information exchange, especially in relation to public health.

Raising and harmonising the standard of living and quality of life is an important responsibility of the EU. This includes ensuring that policies and actions provide a high level of health protection. Furthermore, given that health challenges and issues move across national borders, promoting cooperation and developing strategic frameworks in health is a key achievable for the EU, where member states cannot act alone. It is important that the UK Government remains an active, engaged and influential player in these discussions to promote UK interests.

Negotiated bilateral agreements on trade and economic relations are another area where the UK may benefit from EU economies of scale and encourages investment from global industries such as biopharmaceuticals. Such agreements should include principles on; regulatory harmonisation; market access; transparency of government pricing; intellectual property rights and enforcement; and third country engagement.

Biopharmaceuticals have traditionally been strongly and directly influenced by EU legislation and regulation. This includes the licensing of medicines by the European Medicines Agency

(EMA) and the network of national authorities, Intellectual Property (including European Patents, data regulatory exclusivity and the Supplementary Protection certificate), product liability, clinical trials, data privacy, integrity of the supply chain and the safety and quality of medicines.

The rationale behind European legislation on medicines is to allow medicines to be authorised, sold, and bought freely across the internal market of the EU whilst ensuring high level patient safety. Below we consider the impact of the current balance of EU/UK competence for the following areas:

- Proposed Clinical Trials Regulation
- EU Harmonisation of Good Manufacturing Process and Good Clinical Practice
- Medicines Regulation
- Pharmacovigilance
- Marketing Authorisation
- Falsified Medicines Directive
- Proposed Transparency Directive
- Member state (informal) collaborations and voluntary agreements e.g. EU HTA
- Cross –Border Healthcare Directive
- HTA Network
- Rare Disease
- Research and Development (recognising future call for evidence by BIS – during Semester 2)

### **Proposed Clinical Trials Regulation**

The implementation of the EU Clinical Trials Directive in 2004 was intended to harmonise the standard of clinical research performed in the EU. Unfortunately, different interpretations of the legislation across the Member States, different national laws and a general increase in the number of requirements greatly increased the administrative burden associated with performing clinical research. This increased the time taken to obtain key documents such as Clinical Trial Approvals (CTAs). This steep increase in complexity is considered to have contributed, along with other factors, to the steady decline in the number of clinical trials performed in the EU since 2004.

During 2012, the European Commission published its proposals for a draft Clinical Trial Regulation which aimed to rectify the situation by:

- Ensuring a consistent approach across the EU by adopting a regulation (directly applicable in all Member States) under which all clinical trials are approved via the same mechanism, even if they just take place in one Member State.
- Proposing more efficient mechanisms for performing key clinical trial activities such as applying for and obtaining CTAs and monitoring safety.
- Introducing competitive timelines for the clinical trial approval and trial modification processes and ensuring national level processes do not add unnecessary delays to EU level decisions.
- Introducing risk adaptation for some requirements to improve proportionality.

ABPI support the overall aims of the legislative revision and we strongly support an EU, rather than a national, system for clinical trials. Clinical research, regardless of who performs it (industry or academia) is of great benefit to Europe and to the UK. Thriving clinical research ensures clinicians are up to date on the latest treatments and patients have a chance to access

them; it also creates jobs and growth, particularly in the UK which is well known for the strength of its academic and research base. Without appropriate frameworks and consistent implementation, the EU can be a heterogeneous and a complex place to perform multinational clinical trials; simplifying the regulatory framework for clinical research, whilst maintaining or improving standards will make the EU more attractive as a location for this activity. This will have a positive knock-on effect on the UK as a location for such work.

Although not strictly in scope, it is extremely important that the UK complexity for setting up clinical trials is also addressed, or any gains from the EU level coordinated authorisation process may be limited nationally. We very much welcome the creation of the Health Research Authority (HRA) and related organisations across the devolved nations, but there is a lot of work to be done and ABPI request continued engagement on this topic going forward.

The number of patients taking part in UK clinical research has dropped from 6% to 1.4% of global patient recruitment between 2000 and 2010. Although there are a range of issues in this area, we would like to highlight the following:

- National Institute of Health Research (NIHR) funding needs to be sufficient to deliver on commitments to 70-day target to initiate studies and consistent delivery of patient recruitment to time and target.
- There needs to be a nationwide communication strategy and appropriate funding to engage patients and the public in clinical research.
- Initiation and delivery of clinical research in the UK should be seen as a collaboration between all parties to secure the health and economic competitiveness of the UK.
- The clinical trials regulation will be approved via the Ordinary (previously Co-Decision) Procedure, (please see comments in relation to the pharmacovigilance legislation below).

It is also vitally important that the aims of the European Commission in drafting this Regulation: maintaining or improving standards whilst reducing unnecessary administrative burden, introducing risk adaptation and competitive timelines, are not watered down during the approval process. We need a simple yet robust regulatory framework for clinical trials in Europe to help reverse the recent decline in the amount of clinical research performed at both European and UK level.

### **EU Harmonisation of Good Manufacturing Practice and Good Clinical Practice**

Harmonisation in relation to Good Manufacturing Practice (GMP) is clearly beneficial for organisations which manufacture and distribute medicines for Global supply. It provides a degree of certainty for companies of the standards that they will have to meet throughout the EU. Increasing application of ICH (International Conference on Harmonisation) guideline provisions into EU GMPs will also facilitate potential access to other non-EU markets which use those guidelines and can allow access on the basis of a single inspection by one EU member state.

Similarly to other topic areas, issues of variability in implementation between Member States can be a frustration for companies. However, the UK is fortunate that the MHRA is a highly respected agency in the area of GMP and is very influential in the framing and development of EU legislation whilst generally being pragmatic in its implementation.

Again, EU adoption of international standards of Good Clinical Practice (GCP) is an area which clearly benefits from EU and global harmonisation e.g. ICH GCP. Harmonisation of GCP requirements, across the world, facilitates the innovative biopharmaceutical industry and reduces duplication of effort and investment by allowing inspection of research facilities by a single EU state. This harmonised approach better ensures consistent public health protection and simplifies previously heterogeneous processes and regions, making it more attractive for global companies to invest within the EU and, by extension, the UK.

## **Medicines Legislation Pharmacovigilance**

Different local laws and different local interpretation of the text of EU legislation have, in the past, added unnecessary complexity to performing pharmacovigilance in the EU. The revised EU pharmacovigilance legislation (Directive 2010/84/EU and Regulation 1235/2010) was approved at the end of 2010 and had an implementation deadline of July 2012. The implementation of this legislation is complex and some elements will not be in place until 2015/16 or later. The key aims of revising the legislation were:

- To achieve more consistent approaches across the EU;
- To reduce the amount of unnecessary bureaucracy in the current system such as duplicative side effect reporting requirements, and
- To implement improvements to the current system, such as a greater focus on analysis of benefit : risk, rather than duplicative monitoring of data.

Industry supported the overall aims of the legislative revision and, for pharmacovigilance in general, we would strongly support an EU rather than a national system. A consistent approach to the monitoring of medicine safety and cooperation across the EU in this regard is in the interests of patient health protection. In addition, having a unified EU approach should greatly reduce complexity for companies, allowing resource to be refocused onto more value added safety monitoring activities. A simplified environment also makes the EU a more attractive location for companies to operate, which is extremely important as we are a global industry. Unfortunately, there have been some less positive experiences associated with the revision of this legislation which may have general relevance.

EU legislation is drafted by the European Commission and approved by the Co-Decision Procedure (approval in the European Parliament and Council). However, the later steps in this process involved closed trilogue discussions (Council, Parliament and Commission) to try and reach a quick compromise to allow the legislation to be approved. This resulted in some poorly thought out requirements, such as those in Article 57(2) (see below).

The implementation process was not well thought through by the EMA, which deprioritised implementation of many provisions which would have reduced administrative burden, such as central reporting of side effects to the EU database and rushed implementation of poorly thought out provisions such as those in Article 57(2). At present, attempts to comply with certain elements of Article 57(2) involve submitting large amounts of data to a not fully functional EU level database in addition to nationally submitting much of this information to the MHRA, duplicating work and adversely impacting local biopharmaceutical businesses, particularly if these are predominantly national in scope.

There are also concerns about the EU funding model as work is increasingly performed at an EU level, but often driven by national Agencies such as the MHRA. A funding model must be found that works well for the EU system but that recognises that this is best built around strong national level Agencies. All future funding models must take this into account and ensure appropriate national level support.

We are also unsure whether the legislative process itself has resulted in a simpler situation – we have gone from a Directive, a Regulation plus implementing guidance (Volume 9A), to a Directive, a Regulation, an Implementing Regulation, a 16 module Good Vigilance Practice guidance (not yet complete) and one Delegated Act to come.

## **Marketing authorisations**

The centralised procedure came into operation in 1995 and allows companies to obtain a marketing authorisation that is valid throughout the EU. It is compulsory for medicines manufactured using biotechnological processes, for orphan (rare disease) medicines and for medicines containing a new active substance not authorised in the EU before 20 May 2004 and which are intended for the treatment of AIDS, cancer, neurodegenerative disorder or diabetes.

Prior to the implementation of the centralised procedure, companies either licensed their medicines using national authorisation procedures or by processes coordinated by the Member States. These processes were unnecessarily burdensome as they required individual applications in each Member State, leading to individual authorisations in each country and information provided to patients which could be different in each Member State.

The introduction of the centralised procedure, along with the creation of the EMA, not only greatly simplified the above situation but also resulted in a system where medicines information such as the patient information leaflet are consistent across all EU Member States, which is good for public health protection. This is desirable from a business point of view as well because there is a single, robust system in place for marketing authorisations. The MHRA has played an important role in the success of the centralised procedure, by taking a high proportion of rapporteurships for marketing authorisations, and through its influence and leadership in EMA's committees and its Management Board. A system in which the UK did not participate in the centralised procedure as an EU Member State would reduce the UK's influence in European marketing authorisation decisions and could add unnecessary national level complexity. It may also risk products not being launched in the UK because global companies may not feel it was worth the effort for a relatively small market.

It is worth noting, that national level authorisation systems have remained in place, allowing companies the option of more agile national level authorisations if needed for some products. This optionality promotes competition, and adds flexibility and choice for companies and is also strongly supported by our members.

In addition, the basing of the European Medicines Agency in London has a positive effect on the UK economy, not least because some biopharmaceutical companies choose to base their EU regulatory departments in the UK for this reason.

## **Falsified Medicines Directive**

The EU has recognised that steps must be taken to tackle the threat from counterfeit medicines contaminating the legitimate medicines supply chain, potentially causing harm to those who take them. The Falsified Medicines Directive provides an opportunity to implement an EU-wide approach to combating counterfeiting. If successfully implemented, this could be a good example of beneficial and appropriate EU competence given that medicines, including fake medicines, move from country to country in line with the Internal Market. Recognising this free movement across borders, ABPI and EFPIA is promoting the concept of a European system of unique pack identification and scanning at pharmacies which will maximise the benefits of the Directive. Significant progress has been made at the European level to assess the feasibility of implementation; however, progress is much slower, with less proactive commitment in the UK, where the Department of Health appear to have concerns regarding the reading of pack codes at the point of dispensing.

Despite recent well publicised concerns and challenges in maintaining the integrity of other supply chains that can affect human health, the UK Government approach to this legislation is

somewhat contradictory. The MHRA is one of the most, if not the most, active and successful regulatory agencies in the world at detecting and bringing to prosecution counterfeiters of medicinal products. It has also launched a widely praised strategy on counterfeiting. Yet, as mentioned above, the Department of Health view on the proposed coding and reading systems makes the UK arguably the most reluctant of all the Member States to implement an effective way of product verification at the fundamental and critical time of supply to the patient. If the current UK view were to prevail the UK clearly would not benefit from the security provided by a harmonised system and indeed may compromise the integrity of the system for other parts of the EU.

### **Proposed Transparency Directive**

The current Transparency Directive was introduced in 1989. Its stated objective is to “obtain an overall view of national pricing arrangements, including the manner in which they operate in individual cases and all the criteria on which they are based, and to provide public access to them for all those involved in the market in medicinal products in the Member States”. The purpose of the original Directive was not to interfere with Member States’ organisation of their healthcare systems, but rather the removal of potential disparities by introducing transparency of process (with some requirement to publicise prices).

On 1 March 2012, the Commission published a proposal for a revised Transparency Directive which would replace the current Directive.

“The overall objective of the proposal is to clarify the procedural obligations incumbent upon Member States and to ensure the effectiveness of the Directive both in avoiding delays in pricing and reimbursement decisions and in preventing barriers to biopharmaceutical trade” ABPI is supportive of the modernisation of the Transparency Directive provided that any legislation which emerges from the exercise balances the needs of the Member State, the industry and the patient in the final outcome. The result should be

- That industry can rely on transparent and equal processes;
- That patients benefit from speedy and equal access to medicines across the EU; and
- That Member States play their part in ensuring a level playing field with timely decisions on pricing and reimbursement.

It is also vitally important that the original aims of the European Commission in drafting this revision:

“to clarify the procedural obligations incumbent upon Member States to avoid delays in pricing and reimbursement decisions and in preventing barriers to biopharmaceutical trade”, are not watered down during the approval process.

ABPI believes that any new Directive must ensure that patent owners are not prevented from:

1. Bringing patent actions before competent national courts against premature pricing and reimbursement applications or from invoking their patents against decisions and measures affecting the pricing and reimbursement of originator products; and
2. Defending themselves against decisions that change the pricing and reimbursement status of their own medicines.

### **Cross-Border Healthcare Directive**

This Directive clarifies citizen’s rights to access healthcare in another Member State of the EU and sets out the grounds on which they can claim re-imbursement of the eligible costs of treatment from their home health system and the limits that Member States may place on patients who wish to access their healthcare in another EU State. This allows patients to obtain

healthcare in another European country where there may be better expertise available, lower costs, better availability of certain highly specialised treatments or where waiting times for treatment are shorter.

Its main objectives are to;

- Clarify and simplify the rules and procedures applicable to patients access to cross-border healthcare;
- Provide EU citizens with better information on their rights;
- Ensure that cross-border healthcare is safe and high quality; and
- Promote co-operation between Member States.

The ABPI eagerly waits to understand the proposed UK approach to the implementation of this soon to be adopted Directive.

The Directive identifies the importance for biological medicines to be prescribed by brand name and not by International Non-proprietary Name (INN) and also makes it easier for patients to get their prescription recognised across borders, something which benefits many UK citizens who either travel frequently or spend longer periods of time abroad, for example in Spain and elsewhere in the EU.

The Directive also promotes co-operation and collaboration between Member States e.g. HTA Network (Article 15), as well as strengthening messages of pan-European co-operation and treatment of rare disease (Article 13), whilst advocating a platform for challenging R&D (e.g. Antibiotics). For example:

### **HTA Network**

There has been much work done over many years at the EU level to identify the components of health technology assessment (HTA), which could be “harmonised” at an above country level. Progress has been made on defining some of these components, which include undertaking evaluations of relative effectiveness, in other words direct or indirect clinical assessments of a new technology against relevant comparator treatments.

This work has been progressed by EUnetHTA which is an informal and growing network of collaborating HTA agencies, which includes NICE. A core HTA model has been developed which is modular in form and the content for modules has been the subject of public consultations. EUnetHTA is now set to become established by the EU as a “permanent” network going forwards.

However, if further and formalised harmonisation of HTA is to be developed across the EU, care needs to be taken to ensure that:

- Member States’ responsibility for the organisation, financing and management of national health systems is not compromised;
- A harmonised approach must reflect and recognise that different Member States and health systems utilise HTA in different ways;
- Economic analysis is acknowledged as being country specific
- All stakeholders are fully engaged in both formal and informal consultation over the degree and design of harmonisation (e.g. via public consultations); and
- Overall time to market is not lengthened by an “additive” international collaboration in HTA.

Taking into account the above concerns, ABPI recognises the potential benefits for NICE to share appropriate information with the EUnetHTA forum of its work relating to clinical effectiveness, but not UK specific economic analysis.

ABPI supports in principle harmonised assessment processes for relative clinical efficacy / effectiveness only, provided that:

- It did not lengthen the current EU licensing and regulatory process;
- It improved speed of access for NHS patients to new medicines;
- It reduced bureaucracy and costs; and
- Existing HTA processes were reengineered to accept, as a starting point, EU level assessments of relative clinical effectiveness.

### **Rare Disease**

Recognising that there is no immediate legislative requirement for Rare Diseases within the Cross Border Directive, its inclusion strengthens the expectation for pan-European co-operation and treatment of rare disease.

The specificities of rare diseases: a great heterogeneity of diseases and of expression of diseases without predominant symptoms; a limited number of patients; and a scarcity of relevant knowledge and expertise, singles them out as an important domain for EU level action. The European Commission (EC) defines a disease rare when it affects fewer than five per 10,000 people in Europe and recognises that such life-threatening or chronically debilitating diseases, many inherited, which affects so few people, requires a combined effort to:

- Reduce the number of people contracting the diseases;
- Prevent newborns and young children dying from them; and
- preserve sufferers' quality of life and socio-economic potential

The biopharmaceutical industry is also committed to developing new treatments and medicines in this area. However, there are number of issues and barriers unique to developing treatments for orphan diseases that biopharmaceutical companies' face and which are often not well understood.

One of the main problems is, because of the small number of people with a particular orphan disease, running meaningful clinical trials is very difficult. This poses significant problems in gaining a license for a new medicine, where evidence from significant trials is key, and collating sufficient evidence to prove clinical and cost effectiveness for HTA assessment. Conducting these trials in the UK, Europe or across the world, can also take many years to complete, which in turn impacts the timelines for making a medicine available. This is the rationale for offering welcomed additional incentives to develop products for rare diseases in Europe; through free advice from the European regulator (the European Medicines Agency) and a longer time period for intellectual property (IP) protection to allow companies to re-coup high R&D costs.

To facilitate even greater productivity in this area, further EU harmonisation of regulatory frameworks may be useful. Although a number of national competent authorities have some experience with rare diseases, some have not developed the required competence which alongside the need for several Ethical Committees to be consulted for each trial protocol causes significant but avoidable bottlenecks.

However, despite 68 medicines being approved for use in Europe by the end of 2011 (Committee for Orphan Drugs and the European Medicines Agency Scientific Secretariat), concerns remain that there is inconsistent access to these medicines within the UK.

### **Antibiotics**

The problem of increasing antibiotic resistance is well recognised and requires concerted action between civil society, industry and governments. To effectively manage this problem, it requires all countries to act together, as no one country can solve the problem alone - bacteria do not recognise national boundaries. Though much can and should be done

at the national level (tax incentives, patent box, a fair evaluation of the value of new treatment options), such action is insufficient to fundamentally change the return of investment (ROI) proposition in this area.

Europe however, with its 500 million inhabitants, provides an excellent platform to drive progress; it has critical mass and could have a tangible impact on ROI if governments, industry and civil society worked together; it has strong academia and well developed health care systems; and the last decade has seen several positive initiatives at EU level, such as the Council recommendation on prudent use of antibiotics, the creation of ECDC, and ground-breaking collaborations like the 'New Drugs for Bad Bugs' project under IMI.

The benefit this brings to UK patients, to UK society as well as the life-science industry is obvious. There may be global institutions which could arguably provide an alternative arena for progress, but the effort it would take to get concerted action across the globe might be extraordinary. The EU, in contrast, consisting of a group of reasonably homogeneous Member States might be just what the doctor ordered.

### **Research and Development**

The biopharmaceutical industry is the leading industry investor in R&D in the UK - £4.6 billion annually (ONS 2011), and brings in an annual trade surplus of over £6 billion (HMRC 2011). Industry R&D expenditure in the UK is greater than in any other EU member state, and provides for 67,000 highly skilled jobs (ONS, BERD 2011).

Investment in research and innovation is vital to securing economic growth through the life science industries. The life science sector is a recognised strength of both the UK and EU and therefore should be a strategic area of EU focus for growth, particularly during a climate of financial austerity in EU member states. This sits against a backdrop of historically low EU-27 investment in research – 2% GDP (OECD 2010), a shortfall against the Lisbon target of 3% GDP. Maintaining the Commission investment target into EU2020, and full adoption of Horizon2020 will be critical.

The biopharmaceutical industry increasingly operates in a complex R&D ecosystem of mixed actors, and companies increasingly participate in public-private research partnerships (PPP), particularly in precompetitive R&D. We support the renewal and creation of public-private partnerships in the Horizon 2020 strategy to leverage investment in research and innovation and enhance the EU's global competitiveness.

There are several EU programmes of relevance to the biopharmaceutical industry. For example, the Innovative Medicines Initiative (IMI) is a flagship PPP supported by the European Commission and the European-based biopharmaceutical industry under the Seventh Framework Programme (FP7), totalling a joint investment of €2 billion over 7 years from 2007. It is estimated that midway through the IMI, projects thus far have generated 1,500 jobs in the EU[1]. The European Commission's Management Plan 2013, issued by the

[1] [http://ec.europa.eu/research/health/pdf/imi-ppp-expert-panel-report\\_en.pdf](http://ec.europa.eu/research/health/pdf/imi-ppp-expert-panel-report_en.pdf)

Directorate-General for Research and Innovation, reports that "IMI has achieved a substantial leverage effect on industrial investment in R&D and has promoted collaboration between large-scale industry, SMEs, research organisations, patients and regulators. Therefore, it contributes to reinforce the EU's competitiveness in this critical sector" Across Member States, UK organisations have so far won the largest proportion of IMI funding (€140 million), with the greatest number of participants. The UK has therefore secured substantial value from IMI. In order to maintain the biopharmaceutical industry and the EC plan to renew IMI as a Joint Technology Initiative in Horizon2020 essential features need to be retained. These include

engagement with industry at the earliest stages and a focus on addressing the bottlenecks facing industry in drug development, through high quality science.

The UK also has good domestic research programmes, and these should continue – of note, national initiatives have the potential to be much more agile, adaptive and less bureaucratic than EU programmes. For example, the MRC-ABPI research consortia in immunology and inflammatory disease; establishing the Centre for Drug Safety Science. However, there remain areas in basic and collaborative research which benefit from a critical mass across the EU, recognising that individual Member States cannot do everything in isolation. For example, some key important achievements have been delivered in areas of antimicrobials, cancer, pain and asthma research. The benefits of working collaboratively include securing funding and utilising companies' resource contributions from different EU member states; whilst enabling the training and mobility of academic and industry talent across the EU. For example:

The promise of stem cell research is enormous, but the field is incredibly complex. No single source of stem cells is likely to provide all the necessary knowledge and therapeutic options required to realise the promise of new treatments. Competition to develop capacity in stem cell research around the world is intense. Some European countries such as the UK, Belgium, the Netherlands and Spain have been very active for some time in stem cell technologies, but Europe's position is not secure. The USA is in the lead, Japan and others are fast advancing programmes in stem cell research and support for new stem cell based companies. Europe should continue to be a leader in stem cell research with a critical mass of activity in basic research, translational and clinical studies on stem cell technologies that includes EU, academic, charitable and industrial partners. The harmonisation across Europe under the Directive 2004/23/EC which complements National and EMA regulations in this area is to be welcomed. However, it is critical that the regulation of stem cell research within Horizon 2020 does not become too complex and that the current position in FP7, which allows funding of stem cell research in those countries where such use is not prohibited, is maintained.

There remain other areas where care needs to be taken in the revision of EU legislation to avoid unintended consequences for EU and UK R&D. For example:

The inconsistent application of privacy requirements impedes our industry's ability to conduct the meaningful biomedical research that leads to the discovery of new medicines, and it creates particular challenges for the collection and reporting of safety data concerning medicines. Industry initially welcomed the Commission's efforts to reform the 1995 Data Protection Directive by further harmonising data protection requirements in the EU. This recognised that the public interest in medical research warrants special rules on the collection and use of personal data for medical research purposes. However, recent proposed amendments would appear to cause significant problems for research, specifically research re-using patient data or tissue samples (both anonymised and under appropriate governance frameworks). These proposals appear to introduce a requirement for 'specific, informed and explicit' consent for the re-use of data for research, and bring in key-coded data within the scope of the legislation (with possible implications for both the re-use and transfer of data). If accepted these proposals could be interpreted as creating barriers to re-using data in electronic health records through valuable UK initiatives such as the Clinical Practice Research Datalink.

Similarly,

The protection and welfare of animals is an area covered by a wide range of EU legislation. This includes the protection of wildlife, zoo animals, farm animals, animals in transport and animals used for scientific purposes. Animal studies, including for the development or production of new medicines, for physiological studies has to be carried out in compliance with EU legislation. Since 1986, the EU has had in place specific legislation covering the use of animals for scientific purposes. In 2010 the EU adopted Directive 2010/63/EU which updates and replaces the 1986 Directive 86/609/EEC on the protection of animals used for scientific purposes. The aim of the new Directive was to strengthen legislation, and improve the welfare of those animals still needed to be used, as well as to firmly anchor the principle of the Three Rs, to Replace, Reduce and Refine the use of animals, in EU legislation.

However, the proposed revision of Directive 86/609 initially put out by the European Commission was highly unbalanced and lacked substantial evidence in many areas, detrimental to EU science and competitiveness, without increasing animal welfare. It would have impacted negatively on the development of innovative medicines for patients and unmet medical need, including for dementias and infectious disease. There is value in awareness-raising with the Commission before the next periodic review of the Directive, and a role for Health Departments in this process due to the impact on health care.

## Association of Directors of Public Health

The Association of Directors of Public Health (ADPH) is the representative body for Directors of Public Health (DsPH) in the UK. It seeks to improve and protect the health of the population through DPH development, sharing good practice, and policy and advocacy programmes. [www.adph.org.uk](http://www.adph.org.uk)

ADPH has a strong track record of collaboration with other stakeholders in public health, including those working within the NHS, local authorities and other sectors.

### ADPH response to specific consultation questions

#### Overview

#### ***How does the EU's competence in health affect you/your organisation?***

The Association of Directors of Public Health seeks to improve and protect the health of the population through DPH development, sharing good practice, and policy and advocacy programmes. We believe that EU policy should be influenced by current evidence and best practice and should be incorporated and supported by all sectors concerned with the health and wellbeing of the population.

#### ***What evidence is there that EU action in health advantages or disadvantages: The UK national interest?; Business and industry?; Patients and citizens?***

Direct benefits of EU action in health include:

- Improving health outcomes by supporting work to address key health challenges and the wider determinants of health
- Health policy and practice supported by EU recognised standards
- Increasing collaboration between member states
- Enabling high quality research

In response to the recent Defra consultation on the provisions of Regulation (EU) no. 1169/2011 on the provision of food information to consumers, ADPH highlighted concerns that a deregulatory approach presented a potential public health risk. Taking tobacco control and action on smoking as one example, smoking rates have declined significantly in the UK over the last decade or so, by over one quarter in adults and one half in children. This is as a result of a comprehensive strategy undertaken by the UK government and the devolved administrations and action on tobacco control taken at EU level has played a significant supporting role. Measures introduced by the EU which help reduce smoking prevalence are greatly to benefit of the UK national interest, business and industry, patients and citizens. Reducing smoking prevalence is a UK government objective as smoking kills around 100,000 people each year and smoking related-diseases disable many more. Smoking remains the major cause of preventable premature death in the UK killing more people than the next six causes of preventable premature death put together.

A report produced by the APPG on smoking and health during the last spending review in 2010 estimated the following costs of smoking to the public purse and benefit to the public purse of a one percentage point reduction in smoking prevalence. The overall cost to the public purse, including NHS costs, reduced tax revenue from premature mortality, reduced tax revenue from workplace absenteeism and increased disability benefits due to poor health (taking into account reduced pensioner benefits as a result of premature mortality) was £9 billion. Each one percentage point reduction in smoking prevalence leads to a net revenue gain of £240 million.

***Please consider what evidence there is to demonstrate;  
The extent to which the EU's role in public health supports member state actions  
effectively and efficiently***

The EU's competence on health and health topics allows policy and practice within the UK to be guided by best practice and internationally recognised standards. In the UK this has a direct impact on health and health related policies linked to the wider determinants of health i.e. diet and nutrition, transport, employment.

EU competence on tobacco issues has been helpful in setting a baseline but has also allowed the UK to go further where appropriate. Over the last decade EU directives on tobacco advertising and promotion, on TV advertising and on packaging and labeling have supported the UK in banning advertising promotion and sponsorship of tobacco products and in requiring larger health warnings on tobacco packs. Flexibility on EU competencies, for example within the TPD allowed the UK to go further and to introduce in addition picture warnings on packs.

Furthermore the UK has also been able to go further in areas not covered by EU competences, for example, to prohibit the sale of tobacco from vending machines and to prohibit displays of tobacco in retail outlets (a staged approach which will be fully implemented in 2015) as well as to introduce legislation to require all enclosed public places to be smokefree.

***The extent to which EU competence and policies intended to allow EU citizens to access  
healthcare across the EU are effective and proportionate***

All EU policies are required by the EU treaty to follow a "Health in all Policies" (HIAP) approach and this has proved useful when it comes to tobacco control. As the Consultation document states EU competence on tobacco control has been one of the Commission's public health priorities in recent years. This is appropriate given that smoking remains the major preventable cause of premature death throughout the EU.

One example of where this has occurred is the Tobacco Tax Directive which contains a number of references to the importance of health protection, in particular:

*(2) The Union's fiscal legislation on tobacco products needs to ensure the proper functioning of the internal market and, at the same time, a high level of health protection, as required by Article 168 of the Treaty on the Functioning of the European Union, bearing in mind that tobacco products can cause serious harm to health and that the Union is Party to the World Health Organization's Framework Convention on Tobacco Control (FCTC).*

The current Directive has been helpful in enabling the UK to continue its policy of reducing the affordability of tobacco through tax increases while also increasing the minimum excise tax other Member States have to levy and reducing the differential between manufactured and fine cut tobacco.

The Commission's original proposal for the third community programme in health – Health for Growth programme<sup>1</sup> – illustrates an increasing tendency for EU action to be focussed on matters related to healthcare organisation and delivery. This can potentially extend beyond the current EU competence in health, which is primarily concerned with Public Health issues (health promotion and health protection in particular) and legislation stemming from completion of the internal market. However, concerted UK national action was effective in reorienting the Health for Growth proposal towards public health.

<sup>1</sup> Regulation establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020 [http://ec.europa.eu/health/programme/docs/prop\\_prog2014\\_en.pdf](http://ec.europa.eu/health/programme/docs/prop_prog2014_en.pdf)

The Europe 2020 strategy<sup>2</sup> presents a framework for boosting growth in the Union during the current decade. As such the strategy is focussed on smart investment and job creation plans, with health viewed as a cross-cutting priority in the strategy. The strategic priorities of the key flagship initiative related to health under strategy – the pilot European Active and Healthy Innovation partnership<sup>3</sup> - demonstrates how the focus of Europe 2020 has led to framing the EU's health competence under economic parameters, neglecting areas such as health promotion that are more in line with the treaty obligation for health.

***The extent to which health objectives are effectively and proportionately taken into account in wider EU policies***

The UK presidency of the European Union in 2005 pioneered the consideration of health inequalities as a policy priority at the EU level. Following this, the Finnish Presidency of 2006 launched Health in All Policies (HiAP) as one of its key priority areas for its Presidency programme. The European Commission's impact assessment process compels EC directorates to take health into consideration within the consideration of all policies. However, the delay to which the recently adopted EC proposal for a revision of the tobacco and related products directive was subject in the EC inter-service consultation raises a number of worrying questions regarding how seriously the HiAP principle is applied to EU legislation.

The present framework for Cohesion Policy [2007-2013] earmarks €5 billion for health infrastructure investment. Moreover, the European Social Fund deals directly with a number of key social determinants of health, such as labour market mobility, social inclusion etc. In the UK, use of the Structural Funds for health improvement has been traditionally low, despite the significant potential for investment in projects designed to address the social determinants of health.

The Commission proposal for structural funds for the next programming period includes a priority on reducing health inequalities, whilst the potential to harness the Structural Funds remains feasible in all thematic areas of concentration. The challenge is for the UK to systematically apply a health equity lens, building on the Marmot review, to integrate the consideration of the potential positive impacts of health over the long term that these significant investments can make, for example, through application of sustainable active labour market policies and accessibility strategies for vulnerable groups.

We welcome that the EC has financed several important projects on these topics – EUREGIO III, Health Gain, Equity Action - and continues<sup>4</sup> to stress the importance and relevance of health to Cohesion Policy. However, the responsibility lies with Member States and regions to implement these funds in an equitable manner.

The Common Agricultural Policy (CAP) has contributed to maintenance of good health across Europe (including in the UK) by ensuring security of food supplies, and by protecting and supporting rural economies. However, there is a strong case for further reforms of CAP to be agreed, in the interests of health promotion, for example by removing subsidy from production of saturated fat-rich foods to healthy alternatives, such as fruit and vegetables.

**What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?**

In certain circumstances non-legislative measures are an appropriate alternative and the EU can play a positive role. For example, under the General Product Safety Directive safety requirements can be introduced in MS through publication in the Official Journal. In 2008 the

European Commission defined the safety requirements for fire safety of cigarettes and then asked the European Committee for Standardisation (CEN) to develop the relevant standards.

These came into force in November 2011 and are now used by national authorities to measure compliance with fire safety rules. The standard requires that no more than 25% of cigarettes shall burn through their whole length. Cigarettes are sold across borders and so setting a technical standard in this way for the whole of Europe is far more effective than if the UK had developed such a standard nationally which only applied to the UK and had to be introduced through legislation. Around 7% of fires and 30% of fire deaths in the UK are caused by smoker's materials, primarily cigarettes and setting technical standards in this way is proportionate.

2 Europe 2020 Strategy <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:2020:FIN:EN:PDF>

3 EC Communication - Taking forward the Strategic Implementation Plan of the European Innovation Partnership on Active and Healthy

Ageing: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52012DC0083:EN:NOT>

4 Health and Structural Funds in 2007 - 2013 : Country and regional assessment,

[http://ec.europa.eu/health/health\\_structural\\_funds/docs/watson\\_report.pdf](http://ec.europa.eu/health/health_structural_funds/docs/watson_report.pdf)

### **General**

#### ***Is there evidence of any other impacts resulting from EU action in health that should be noted?***

Benchmarking between EU member states, both in terms of health outcomes and health expenditure, has been a significant driver for policy change in the UK leading to increasing investment in, for example, comprehensive cancer care. Whilst this process can be potentially sensitive for competent authorities involved, the practice of benchmarking services and outcomes can be invaluable for stimulating positive change. In addition, voluntary targets agreed upon at the EU level can also be a useful tool for improving service delivery, such as with the Digital Agenda target for the digitisation of patients health records by 2015.5

Comparing UK services in this area with EU counterparts and engaging in shared learning can lead to significant improvements and the avoidance of replicating costly errors previously made elsewhere in the EU. [For example, the North West of England has benefited from several EU funded projects along these lines; an example is the very successful Healthy Stadia project, which was led by a North West organisation, with sports-related partners (such as UEFA) as partners, and which developed systems for health promotion aimed at populations using sports stadia]. The UK should consider closely the implications for health presented via the European Semester, through which the EC issues country specific recommendations on public budgets, including national healthcare budgets. Consideration should be given to any effect this may have in the future on developed administrations.

5 Lloyd-Williams F, O'Flaherty M, Mwatsama M, Birt C, Ireland R and Capewell S (2008)

#### **Estimating the cardiovascular mortality**

**burden attributable to the European Common Agricultural Policy on dietary saturated fats.** Bull World Health Organ vol 86 issue

7 535-541

7. CA Birt, M Mwatsama, M O'Flaherty, S Capewell, R Ireland. (2008) **Improving health through reform of European agricultural**

European Journal of Public Health vol 18 issue Supp 1 pp 128

8. <http://ec.europa.eu/digital-agenda/en/pillar-vii-ict-enabled-benefits-eu-society/action-75-give-europeans-secure-online-access-their>

## Public health

### Nutrition and food labelling

#### ***How might the UK benefit from the EU taking more action in health?***

One of the main benefits for the UK existing as a member state of the EU is the free market, which enables food production companies to trade freely in Europe. With this internal market, other EU countries can freely import food products to the UK. It is important that quality of foods brought into the UK are well regulated to ensure that nutritional components are clearly marked and foods are produced and transferred safely to prevent transmission of infectious agents (e.g. E. Coli). Strong legislation must be in place to ensure that food brought into the UK is safe and of a high quality. Obesity is on the increase in the UK and is reaching epidemic levels. There are a number of interventions that should be considered, both at UK and EU level to reduce obesity levels in the UK:

Food traffic light systems are in place in the UK to provide a simple tool to assist consumers to choose healthy options, although these are currently voluntary. Evidence shows that traffic light food labelling is effective and cost effective<sup>6,7</sup>;

Taxing junk food has been shown to be effective and cost effective;

Restriction of trans fats has recently been implemented through legislation has shown to reduce transfat consumption<sup>8</sup>; reducing consumption of industrial TFAs by even 1% of total energy intake would be predicted to prevent 11,000 heart attacks and 7000 deaths annually in England alone<sup>9</sup>;

Reductions in salt in food reduces blood pressure and prevents cardiovascular disease. Voluntary labelling on food regarding salt would lead to a 15% relative reduction in salt intake whereas legislative action to ensure a reduction of salt in processed food with appropriate labelling would lead to a 30% relative reduction in salt intake<sup>10</sup>

ADPH would welcome further legislation at EU and UK level in these areas to assist the population to reduce obesity levels in the UK, and reduce the burden on our health services.

#### ***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

In the modern world it is becoming increasingly difficult, if not impossible, to control epidemics of either communicable or non-communicable diseases within the boundaries of any relatively small European country. For example, the problem of obesity will require action at every possible level. Obesity is not simply a UK problem and therefore increasing legislation at EU level is welcomed<sup>11</sup>.

#### ***Could action be taken at any other international level i.e. by the WHO?***

As this is a global epidemic, action is needed in partnership across the EU and other international bodies. This will encourage a strong evidence base to be built, thereby enabling strong guidance to be developed and legislation to be taken at EU and country levels.

6 G Sacks, J L Veerman, M Moodie and B Swinburn. 'Traffic-light' nutrition labelling and 'junk-food' tax: a modelled comparison of cost-effectiveness for obesity prevention. *International Journal of Obesity* (2011) 35, 1001–1009

7 FSA. Citizens' forums on food: Front of Pack (FoP) Nutrition Labelling

<http://tna.europarchive.org/20100910172942/http://www.food.gov.uk/multimedia/pdfs/citforumfop.pdf>

8 Angell SY, Silver LD, Goldstein GP, Johnson CM, Deitcher DR, Frieden TR, et al. Cholesterol control beyond

the clinic: New York City's trans fat restriction. *Ann Intern Med* 2009;151:129-34  
9 Mozaffarian D, Katan MB, Ascherio A, Stampfer MJ, Willett WC. Trans fatty acids and cardiovascular disease. *N Engl J Med* 2006;354:1601-13  
10 WHO. 2002. The world health report 2002 - Reducing Risks, Promoting Healthy Life [online]. Available from <http://www.who.int/whr/2002/en/>  
11 Hastings G. Why corporate power is a public health priority. *BMJ* 2012;345:e5124

***Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest?***

As already stated above, there is a clearly demonstrable need to reform the CAP so as to ensure that subsidies are used to promote production and consumption of foods that will promote healthy nutrition, and to remove such subsidies from production of unhealthy foods (such as those which are saturated fat-rich).

***How could action in this area be undertaken differently e.g. Are there ways of improving EU***

***legislation in health, e.g. revision of existing legislation, better ways of developing future proposals, or greater adherence to the principle of subsidiarity and proportionality?***

The Commission should release without delay the proposed setting of nutrient profiles foreseen under Regulation 1924/2006 on nutrition and health claims made on foods and envisaged in the 2013 Commission Work Programme [4th quarter]. Nutrient profiles will provide the criteria which foods and/or categories of foods must respect in order to bear claims. The profiles will, primarily, be based on the levels of nutrients intake of which in the overall diet are shown to have incidence on health and in particular on obesity and non communicable chronic diseases.

## **Tobacco**

***How might the UK benefit from the EU taking more action in health?***

ADPH welcomes the EU's directives on advertising and sponsorship of tobacco products. UK citizens travel to other EU states and therefore, it is important that these directives on advertising and sponsorship are maintained in order to prevent initiation of smoking in younger people. The recommendation on smokefree places is disappointing and stronger legislation should be encouraged within the EU to protect vulnerable populations living in the EU and UK citizens during travel<sup>12</sup>.

Counterfeit and smuggled cigarettes are thought to hold 8-18% of the tobacco market in the UK, with one in six cigarettes smoked being illicit<sup>13</sup>. In addition, illicit cigarettes are more commonly used by younger people and those in lower socioeconomic groups due to lower costs.

Therefore illicit tobacco may increase health inequalities and continue to encourage young people to start smoking.

Health warnings on packages makes smoking less attractive<sup>14</sup>. Health warnings should be on all cigarette packs, including cigarettes from other member states. This would ensure that imported cigarettes and those purchased abroad will carry similar messages as UK cigarette packets. In addition, strong legislation at UK and EU levels should be implemented to introduce plain packaging on cigarette packages. Plain packaging has been shown to reduce the appeal of tobacco products, increase the effectiveness of health warnings and reduce initiation of non-smokers, in particular young smokers<sup>15</sup>.

***How might the UK benefit from the EU taking more action in health?***

***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

In the next review of the Tobacco Tax Directive we would like to see changes which take into consideration more appropriately the need for 'a high level of health protection'. In particular further increases in the minimum taxes to be levied and a further decrease in the differential between manufactured and fine cut tobacco, for the benefit of health as well as the working of the internal market.

The UK would benefit from the revision of the Tobacco Products Directive currently underway which requires larger health warnings on the pack and that picture warnings be mandated. The proposal should, however, be revised to require all nicotine containing products to be authorized pursuant to Directive 2001/83/EC. The MHRA is currently examining how best to regulate nicotine containing products and ASH supports all such products being regulated by the MHRA. The current proposal for the revised TPD should allow the UK to implement standard packaging at national level, as set out in the DH consultation in 2012, and we strongly support this.

### ***Could action be taken at any other international level i.e. by the WHO?***

The EU and the UK are separate parties to the WHO Framework Convention on Tobacco Control,<sup>16</sup> which is an effective method of working in respect of the relevant balance of competences between the UK and EU.

12 Daniel F. Mackay, Scott M. Nelson, Sally J. Haw, Jill P. Pell. Impact of Scotland's Smoke-Free Legislation on

Pregnancy Complications: Retrospective Cohort Study. PLoS Med. 2012;9(3):e1001175.

13 North of England: Tackling Illicit Tobacco for Better Health. 2009. North of England (NoE) 'Tackling Illicit

Tobacco for Better Health' Programme Action Plan (2009-2012).

14 Hammond, D, et al., "Impact of the graphic Canadian warning labels on adult smoking behavior," Tobacco

Control 12(4): 391-395, December 2003

15 Moodie C, Stead M, Bauld L, McNeill A, Angus K, Hinds K, Kwan I, Thomas J, Hastings G, O'Mara-Eves A.

Plain Tobacco Packaging: A Systematic Review. 2011.

[http://www.plainpacksprotect.co.uk/assets/pdf/plain\\_tobacco\\_packaging\\_systematic\\_review.pdf](http://www.plainpacksprotect.co.uk/assets/pdf/plain_tobacco_packaging_systematic_review.pdf)

16 [http://www.who.int/fctc/signatories\\_parties/en/index.html](http://www.who.int/fctc/signatories_parties/en/index.html)

Action has been taken in the area of tobacco control by the WHO which has supported effective action in the UK. The WHO Framework Convention on Tobacco Control is the world's first health treaty and sets out a comprehensive set of obligations for tackling the harm caused by tobacco.

The EU and its Member States are all parties to the WHO FCTC and the EU negotiated the treaty as a bloc.

Parties are legally bound by the treaty's provisions, but the treaty is very much a framework. To summarise the key measures in the FCTC Parties are committed to:

- Establish a national coordinating mechanism for tobacco control (Article 5)
- Involve civil society in national and international tobacco control efforts (preamble and Article 4)
- Prevent the tobacco industry from interfering in the setting of public health policies (Article 5.3)
- Consider increasing tobacco taxes as a means of reducing tobacco consumption (Article 6)

- Protect citizens from exposure to tobacco smoke in workplaces, public transport and indoor
- public places (Article 8)
- Regulate the contents of tobacco products and disclosure of information about contents (Articles 9 and 10)
- Require large health warnings on tobacco packaging which should be 50% plus of the principal display areas but at least 30% of the principal display areas. To be done within 3 years of entry into force for that party (Article 11)
- Prohibit the use of misleading and deceptive terms such as 'light' and 'mild' within 3 years of entry into force for that party (Article 11)
- Promote public awareness of tobacco control issues, including the impact on health, using all available communications tools (Article 12)
- Enact comprehensive bans on tobacco advertising, promotion and sponsorship within 5 years of entry into force of the treaty for that party (Article 13)
- Include tobacco cessation treatment in national health programmes (Article 14)
- Implement specific measures to combat tobacco smuggling including pack markings to identify country of sale (Article 15)
- Prohibit sales of tobacco products to minors (Article 16)
- Support economically viable alternatives to tobacco growing (Article 17)
- Consider litigation to make tobacco companies pay for the harm caused by their products (Article 19)
- Develop and promote research into tobacco control and publish reports on implementation with a first report within two years of entry into force (Article 20 and 21)
- Support tobacco control in developing countries and countries in transition (Article 22)

Guidelines to the WHO FCTC have now been developed on Articles 5.3, 8, 9 and 10, 11 and 13 which can be found on the WHO FCTC Secretariat's website. Subsequently a protocol on the illicit trade in tobacco has been negotiated and adopted and will come into force once it has been ratified by 40 parties. The UK government has publicly stated its support for the protocol. The UK has a very effective anti-smuggling strategy introduced in 2000 and regularly updated since then which has led to a dramatic reduction in the illicit trade over that time. A widely ratified protocol will bring global standards up to those of the UK. In addition it will lead to greater international cooperation on tackling the illicit trade in tobacco and require comprehensive tracking and tracing of tobacco products.

The illicit trade in tobacco undermines public health and public finances and this protocol will play a major role in reducing the illicit trade globally and in the UK specifically with consequent benefits from increased tax revenues and reduced smoking prevalence which will accrue to the UK economy to business and industry and to patients and citizens.

Negotiation at EU level has been effective and cost-effective for the UK and has ensured that the FCTC and subsequently the Illicit Trade protocol meet the needs of the UK and other Member States.

***What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?***

The Commission should continue in full cooperation with Member States its efforts to combat cigarette smuggling, address the illicit and counterfeit tobacco trade.

The Tobacco Tax Directive contains a number of references to the importance of health protection.

The current Directive has been helpful in enabling the UK to continue its policy of reducing the affordability of tobacco through tax increases while also increasing the minimum excise tax other Member States have to levy and reducing the differential between manufactured and fine cut tobacco.

## **Alcohol**

### ***How might the UK benefit from the EU taking more action in health?***

It is vital that the future progress reports and evaluations of the EU Alcohol strategy are shared with member states. We support the revision and extension of an EU alcohol strategy and EU support to implement policy in member states. Competence in this area would continue to ensure that policies are derived from best available evidence and reflect effective interventions to reduce the impact of alcohol on health. The UK will benefit from on-going research and evidence collated from member states to guide country level policies to tackle a key public health priority. ADPH supports stronger legislation on advertising and promoting of alcohol products and this should be linked to implementation of the EU alcohol strategy.

### ***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

As price and availability are key determinants of consumption we would want to ensure that any proposal, if suggested in the future in a manner compliant with EU law, for harmonisation of alcohol duties across the EU should not hinder the ability of individual Member States to set higher alcohol duties designed to tackle the harmful consumption of certain products, especially amongst young people.

### ***Could action be taken at any other international level i.e. by the WHO?***

The global alcohol strategy supported by WHO should co-exist with the EU Alcohol strategy and both provide recommendations for members states to implement relevant alcohol reduction strategies. EU action should take into account and implement feasible elements from the WHO Europe Action Plan to reduce the harmful use of alcohol 2012-2020.17

### ***Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest?***

The EU should be encouraged by member states to take more effective measures through internal market legislation to address the harmful use of alcohol, for example with targeted taxation policies. In light of this, the EU should also allow Member States such as the UK to implement Minimum Unit Pricing for alcohol in order to meet priority health objectives. With regards to a UK Alcohol Strategy, the Association of Directors of Public Health believes that:

- a reduction in alcohol consumption at population level is needed, with UK government strategies, legislation and regulation to reduce alcohol-related harm;
- there should be greater consideration of public health and levels of alcohol-related harm when processing licensing applications;
- national policies should support partnership working to ensure implementation of existing laws on sales of alcohol including to those underage, supported by the introduction of education on alcohol-related issues at a younger age;
- a minimum unit price for alcohol of \*50p (at 2009 prices) is required, with no alcohol sold at less than \*50p per unit (index linked). In a survey conducted by ADPH in December 2009, 83% of Directors of Public Health said that lobbying for a minimum price of \*50p per unit of alcohol was one of their top priorities. [\*at 2009 prices. It should be noted that due to inflation since the SchARR (University of Sheffield) model in 2009, this figure is now equivalent to 54p];
- measures should be developed that narrow the gap between the on and off trade;

- the Public Health Outcomes Framework should give more support to outcome-focused delivery in relation to alcohol related harm.

17

[http://www.euro.who.int/\\_data/assets/pdf\\_file/0006/147732/RC61\\_wd13E\\_Alcohol\\_111372\\_ver2012.pdf](http://www.euro.who.int/_data/assets/pdf_file/0006/147732/RC61_wd13E_Alcohol_111372_ver2012.pdf)

***What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?***

The EU alcohol strategy expired in 2012 and as yet, despite a joint call from the UK, Ireland and Sweden, the Commission is reluctant to propose a follow up strategy for 2013-2020. We support the UK in its call for a renewed strategy and one which will focus upon internal market levers at the disposal of the EU to address marketing, labelling and pricing issues. It is regrettable that the EC has yet to consent to renewing the strategy.

**Health security**

***How might the UK benefit from the EU taking more action in health?***

It is vital that a mechanism exists to share health intelligence on threats to human health and security within EU states. Particular benefits of such an approach can be seen from the European wide response related to recent health threats i.e. pandemic influenza 2009 and E.Coli 0104:H4 outbreaks in 2011, in Germany. A joint response from the Health Protection Agency and international partner organisations i.e. Koch Institute in Germany is vital in outbreak responses with a wide impact on the health of UK citizens and citizens of other EU countries. The supervisory role of European Centre for Disease Control (ECDC) and internal mechanisms of the EU enabled this to be facilitated and should be continued.

***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

Less action from the EU would result in a lowering of standards and of security for all states. Cross country mechanisms for collaboration and cooperation would be impaired if competence is reduced. This could pose a high level of risks to UK citizens. We would support the ability for member states to implement actions in extreme cases of need related to emergency situations, and any change in EU competence needs to ensure this capacity remains. Possible improvements in this area would arise from altering the mandate of the European Centre for Disease Control to include the surveillance and monitoring of non-communicable diseases. This would allow for comprehensive data collection on a whole range of key mortality and morbidity indicators that can be used to effectively design and shape evidence based policy, both in individual member states, as well as at the EU level.

***Could action be taken at any other international level i.e. by the WHO?***

Attention should be paid to the risk that duplication of function between EC apparatus and the WHO might cause confusion in this field; such duplication should be avoided.

**Public health programmes**

***How might the UK benefit from the EU taking more action in health?***

We would support the continuation of support for the EU Public Health Programme. Continued funding for voluntary sector organisations, health service organisations and academic institutions to work in collaboration on health research and development related to health determinants, thus supporting HIAP, Health security and health information is key to the success of this programme.

***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

Reduction in competence and therefore loss of opportunities for innovation and collaboration within member states and across member states could potentially result in a loss of momentum of current projects and partnerships built successfully, and impact on health determinants, health security and health information.

***How could action in this area be undertaken differently e.g. Are there ways of improving EU legislation in health, e.g. revision of existing legislation, better ways of developing future proposals, or greater adherence to the principle of subsidiarity and proportionality?***

The principle of subsidiarity could be better taken into account into the development and implementation of the programme though enhanced consultation with competent authorities at the sub-national level, which can be conducted in full cooperation with the member state level. Priorities should be linked to medium-long term public health goals with the over-arching objective of reducing health inequalities between and within EU member states.

***Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest?***

The Public Health Programme is the only dedicated public health funding programme at the EU level and the UK has consistently been one of the highest member states recipients of the programme. Therefore, it is highly important to support and value the opportunities presented by this programme.

Potentially all other funding structures at the EU level are applicable to health concerns if the Health in All Policies principle is applied. However, too often little attention is paid other funding programmes and their possibilities for UK organisations to harness their funding for health improvement.

The Public Health programme could be improved by gearing it towards taking the outcomes and findings from other EU funding programmes e.g. FP7 and implementing this in practice at the national and local level in the EU. This will require an enhanced role of the Executive Agency for Health and Consumers which could assist with aligning programmes related to health, thus avoiding duplication of topics across work programmes.

***Could action be taken at any other international level i.e. by the WHO?***

The WHO is not primarily a funding organisation and so it is not appropriate to consider them as an alternative. However WHO guidelines and recommendations should feed into the design and implementation of the programme's work plan as part of the broader consultation with experts.

**Rare diseases**

***How might the UK benefit from the EU taking more action in health?***

A move from recommendation to shared competence would encourage member states to prioritise rare diseases in line with the EU Public Health programme recommendation. EU competence should encourage collaboration for research across member states. The UK national policies and implementation plans for rare diseases should be shared with other member states.

The RARE DISEASE PLATFORM is a Seventh Framework Research Programme (FP7) funded project created a set of tools for collaboration in the field of rare disease. Current competence at EU level was crucial in enabling this project to succeed; identifying key stakeholders and

partners, information sharing on OrphanXchange and developing platforms for dissemination of information.

***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

Less action would be detrimental. Rare diseases are few in numbers, with low incidence and prevalence and shared learning and collaboration opportunities within the PH programme would be limited and dissolved if further EU action was reduced.

***Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest?***

The use of EU structures and resources in this field is both appropriate and logical. Careful attention should be paid to the presence and influence of external lobby groups to ensure transparency and accountability exists within decision making in this field.

**Others Areas:**

**Chronic Diseases / Non-Communicable Disease**

***How might the UK benefit from the EU taking more action in health?***

The EC, in cooperation with member states, has begun to prioritise the issue of the rising burden of chronic disease by undertaking a reflection process in the European Council, which is set to conclude in 2013.

The UK can benefit by encouraging the EU to take further action on innovative health promotion strategies for the prevention of the major chronic illnesses. This approach can leverage existing EU resources with the cooperation of member states to tackle common societal challenges, such as childhood obesity, in a collaborative manner. The redesign of DG SANCO to incorporate Chronic Disease more firmly into its organigram should be welcomed and can lead to more focused efforts in this field. However, efforts should be focussed on primary prevention and health promotion in the first instance in order to engender long-term and meaningful change for society. The UK should be wary of external lobbying (for example, from pharmaceutical industry interests) under the umbrella term of chronic disease management; this would tend to push for the inclusion of a wide range of conditions, thus decreasing the focus and impact of the EU efforts. It would also be likely to lead to increased emphasis on treatment and care in the short term, which will not lead to the significant long term societal changes needed to deal with the growing burden of chronic disease.

***Could action be taken at any other international level i.e. by the WHO?***

This area is an example of where effective collaborative working between international bodies, the EU and member states respectively can yield positive results. The EU should be encouraged to integrate the recommendations and approaches contained within the WHO Health2020 strategy across of its policy domain but especially regarding the prevention of non-communicable/chronic diseases. Consideration should also be given to the UN declaration on non-communicable diseases of September 2011.

***What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?***

Non-legislative items such as the reflection process and its' subsequent activities [for example the future joint action on chronic disease and healthy ageing] are highly valuable and should be encouraged and maintained. The value lies in bringing competent authorities and their

counterparts together from across Europe to address common problems and to find appropriate solutions for their respective populations.

Legislative items primarily are related to internal market legislation, such as advertising, marketing, labelling etc., and should be harnessed in tandem with effective non-legislative items to improve population health as top line priority.

Non-legislative measures should not be seen as a substitute for legislative measures such as directives and regulations. Without effective hard law from the EU level, where it has the competency to act, the non-legislative items will be ineffective and lead only to the exchange of practice and opinions with minimal effect upon population health.

## **eHealth**

### ***How might the UK benefit from the EU taking more action in health?***

E-Health is one of the EU lead market initiatives<sup>18</sup> and as such has been earmarked as one of the sectors in which the EU as trading block can become a global leader in the field. eHealth policies offer significant opportunities for health systems and for quality of care at the patient level.

18 <http://ec.europa.eu/enterprise/policies/innovation/policy/lead-market-initiative/>

Sustainable investments are possible at the EU level through multiple funding instruments, joint procurement programmes and collaborative working between member states on matters of mutual concern [such as the digitisation of medical records, holistic patient records, implementing telecare / telemedicine], and also with industry in effective and mutually beneficial partnerships. This approach can see innovative technology clusters which are emerging domestically particularly, in the growing field of eHealth, access a wider market.

## **Statistics**

### ***How might the UK benefit from the EU taking more action in health?***

The European Community Health Indicators projects, and others that have contributed and are contributing to the development of an EU health information system, have proved to be extremely useful and valuable initiatives. These information systems will considerably contribute and facilitate the planning and evaluation of better-targeted health-related services in future, at national level, as well as at regional and urban levels. These developments should be implemented, sustained and developed, as they promise considerable benefits to member states and to improved health of their citizens. The new EU health information systems have been developed so as to supplement, rather than to duplicate, existing WHO systems, and this principle should be sustained.

## **Research**

### ***How might the UK benefit from the EU taking more action in health?***

The current proposal for the next multi-annual financial framework for the EU 2014-2020, envisages a 50% increase in the funding for the EU research budget. This would see approximately €11 billion allocated to health, wellbeing and life sciences research. In 2011, the UK had the second highest number of applicants retained in FP7 proposals,<sup>19</sup> illustrating the strong research infrastructure and capacity that the UK has. There is significant potential to increase the participation and success rates of EU research funding in the UK and to leverage these funds as matched funding to existing national sources of funding for priority topics such as dementia research.

## **Association of Directors of Public Health**

**February 2013**

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[http://ec.europa.eu/research/evaluations/pdf/archive/fp7\\_monitoring\\_reports/fifth\\_fp7\\_monitoring\\_report.pdf](http://ec.europa.eu/research/evaluations/pdf/archive/fp7_monitoring_reports/fifth_fp7_monitoring_report.pdf)

### Key points:

- **The EU has a strong influence on the UK medical research sector.**
  - **Science is international. Coordination and collaboration across Europe is important to foster research and innovation. The EU can play an important role in facilitating this.**
  - **Medical research charities are keen to engage with the EU and have valuable insights into policy development. However there are challenges that both charities and the EU must overcome. Increased transparency of EU processes and well-publicised consultations would increase participation, leading to more effective research and innovation proposals.**
  - **The UK is a European leader in many research and technology areas, notably the life sciences, attracting international investment. It is important that the UK engages effectively in EU policy-making to ensure the UK and Europe can continue to attract global investors.**
1. The Association of Medical Research Charities is a membership organisation of the leading medical and health charities funding research in the UK and overseas. We welcome the opportunity to respond to this consultation. Our vision is charities delivering high-quality research to improve health and wellbeing for all. Securing the best environment for medical research in the UK and EU is key to achieving this. We will confine our remarks to those points most relevant to charity funders.
  2. In 2010-11, AMRC members invested over £1 billion into health research in the UK alone. This money comes from a variety of sources, including personal public donations: in 2011/12, 33% of donors giving every month chose to donate to a medical research charity, donating approximately £1.4 billion in total.<sup>1</sup> This high level of charitable support for research is relatively unique across the EU, the UK being second only to the Netherlands in scale of giving to medical research.<sup>2</sup>

### **Impact on the national interest**

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<sup>1</sup> NCVO CAF, *UK Giving 2012* (2012) - <https://www.cafonline.org/publications/2012-publications/uk-giving-2012.aspx>

<sup>2</sup> European Commission, *Eurobarometer on Science & Technology* (June 2010) - [http://ec.europa.eu/public\\_opinion/archives/ebs/ebs\\_340\\_en.pdf](http://ec.europa.eu/public_opinion/archives/ebs/ebs_340_en.pdf)

3. EU legislation, communications, initiatives and programmes have a strong influence on the UK medical research environment, and therefore medical research charities. These influences can be positive, such as EU Rare Disease policy (case study 1), and negative – the 2001 Clinical Trials Directive (case study 2). The medical research environment – including for example, infrastructure, a skilled workforce, the regulatory regime and diverse funding sources – affects the ability of our members to fund the highest quality research. Some charities have found that the UK is not internationally competitive in certain research areas and consequently invest some of their funds in research overseas (case study 3).

4. **CASE STUDY 1:** Rare diseases is a policy area where leadership from the EU has been hugely valuable for patients and industry. Rare diseases are those that affect less than 1 in 2,000 people. Europe-wide policies and legislation have been implemented to support the development of “orphan” drugs which offer promising treatments for rare diseases but have a low commercial value.<sup>3</sup> This support includes market exclusivity, licensing fee reductions and R&D grants from the EU and enables these drugs to be developed by charities and industry to benefit patients. The European Commission has also developed a Communication on Rare Diseases which sets out proposals for a comprehensive, EU wide strategy on issues including research, diagnosis, treatment and care for rare disease patients. This recommendation called on all EU member states to develop plans or strategies for rare diseases by 2013 to increase integration of strategies across Europe. The UK government is currently developing a UK plan.

5. **CASE STUDY 2:** It is widely accepted that the Clinical Trials Directive 2001/20/EC<sup>4</sup> has led to delays in trial setup due to inconsistent implementation of the Directive by Member States, increased bureaucracy and inflexible regulation. Cancer Research UK coordinated a joint position across UK, pan-European and other European organisations to demonstrate a common position shared by the medical research community on proposals by the Commission for a new EU Clinical Trials Regulation.<sup>5</sup> The response to this has been positive and so far, helpful. The Commission ran several consultations on plans to revise the 2001 Directive and associated guidance and the draft legislation showed they listened to the concerns and viewpoints that were raised in the joint statement. This is an example of good practice in an important policy area.

6. **CASE STUDY 3:** In 2007, the UK spent £1.34 on research into hearing loss for every person affected. This compares to £14.21 for sight loss, £21.31 for diabetes, and £49.71 for

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<sup>3</sup> AMRC, *Opportunities for medical research charities to engage with Europe* (2011) [http://www.amrc.org.uk/news-policy--debate\\_engaging-with-europe](http://www.amrc.org.uk/news-policy--debate_engaging-with-europe)

<sup>4</sup> <http://www.eortc.be/services/doc/clinical-eu-directive-04-april-01.pdf>

<sup>5</sup> [http://www.cancerresearchuk.org/prod\\_consump/groups/cr\\_common/@nre/@pol/documents/generalcontent/cr\\_077460.pdf](http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/cr_077460.pdf)

cardiovascular research.<sup>6</sup> Charitable funding for hearing loss research is therefore meeting an area of high unmet need. Action on Hearing Loss funds £1 million of hearing research each year but a lack of hearing research capacity in the UK means that they are often forced to make investments outside the UK. For the period 2009/10 to 2011/12, 44% of their research budget has been invested overseas.

7. All health research is an international activity; collaboration, peer review and research dissemination all take place in an international context. This is especially important for research into rare diseases, which many AMRC members have a focus on (case study 1 and 4). The EU supports the activities philanthropic research funders, either directly through grants (case study 4), or by supporting research capacity – for example, by making it easier for skilled scientists to work across borders or by funding infrastructure, such as the European Molecular Biology Laboratories in Cambridge (UK) and Heidelberg (Germany).
8. EU legislation can bring huge advantages if drafted and implemented correctly, but can also disadvantage the UK and Europe as a whole if done badly (case study 2 and 5).

9. **CASE STUDY 4:** The AKU Society<sup>7</sup> works internationally to enable research into the rare disease Alkaptonuria (AKU). With 81 affected individuals identified in the UK and only a further 325 across the rest of Europe, an international collaborative approach is the only way to recruit enough participants for the study of the disease and to test potential treatments. The AKU Society, founded in 2003, has established several sister arms, including ALCAP in France, AIM AKU in Italy and DSAKU in Germany. In 2013, the AKU Society and the Royal Liverpool University Hospital will be launching clinical trials to assess the use of the drug nitisinone in AKU patients, funded through a grant from the European Commission. The trial will take place across Europe at centres in the UK, France and Slovakia. This exemplifies the strength of charities in coordinating research for the benefit of patients, often in areas of high unmet need, but also demonstrates the crucial role of the EU and other public agencies in providing financial support for projects that are prohibitively expensive for charities to undertake alone.

## **Future options and challenges**

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<sup>6</sup> Action on Hearing Loss (2010) *TRIH: Hearing matters* <http://www.actiononhearingloss.org.uk/supporting-you/policy-research-and-influencing/research/hearing-matters.aspx> [accessed 19 September 2012]

<sup>7</sup> The AKU Society is a registered charity but not currently a member of AMRC.

10. As described above, EU legislation, communications, initiatives and programmes can benefit the UK; its researchers, citizens and the economy. Greater investment and further coordinated action by the EU will benefit UK research. And consistent regulation, which can be greatly enhanced by EU activity, will attract global investors.
11. Effective national engagement with EU policy making is vital to ensure these activities benefit the UK. Medical research charities with their unique links to both patient groups and researchers, have valuable insights into unmet need and the actions needed to address health problems. Their engagement in policy making can avert unintended consequences and ensure policy delivers for the public, clinicians and researchers (case study 5 and 6). However monitoring and inputting into EU policy development is a resource-intensive activity that many are unable to undertake individually. There is a role for umbrella groups such as AMRC and also for the government to facilitate this engagement but there are also a number of steps EU institutions, or national representatives in some cases, could take to make it easier for stakeholders to engage:
- **Communication** of policy areas that the Commission intends to look at, and of the purpose of proposals at their outset, will allow charities to be better prepared to respond to consultation, development and implementation.
  - **Increased transparency** to make it easier to follow policy-making processes and see where, when and with whom to engage (case study 3). This should include being open to engagement with national organisations.
  - **Impact assessment** to identify where legislation in one field may impact on others and ensure that relevant stakeholders are consulted.
  - **Realistic consultation timeframes and engagement** to ensure relevant stakeholders are aware and are able to respond.
  - **Responsiveness** to address changes in the research environment

12. **CASE STUDY 5:** Personal health records are a valuable resource for clinicians and researchers alike. The information contained within them can reveal the most effective ways to care for someone and allows us to better understand the causes and frequency of disease. The Data Protection Regulation currently under debate in Europe will impact on the UK's ability to access NHS patient data for medical research. This could even jeopardise the government's own initiatives: the *Strategy for UK Life Sciences*<sup>8</sup> included a £60 million investment to establish a new secure data service, the Clinical Practice Research Datalink, to service the needs of the research and life sciences community, amendments in the Regulation could severely hinder this project. UK representation on the Council of Ministers scrutinising this Regulation is being led by the Ministry of Justice. It is important that it is fully aware of the impacts on medical research and hence UK research and innovation as it negotiates in Europe.

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<sup>8</sup> BIS OLS *Strategy for UK Life Sciences*, 2011

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/32457/11-1429-strategy-for-uk-life-sciences.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/32457/11-1429-strategy-for-uk-life-sciences.pdf)

13. **CASE STUDY 6:** The European Parliament is currently debating the Horizon 2020 funding proposals, including deciding which areas of research the money will be spent on. Following the European Court of Justice's ruling in *Brüstle vs. Greenpeace*<sup>9</sup> that technologies that require the prior-destruction of embryos are not patentable, the EU Parliament's legal committee (JURI) recommended that research involving human embryonic stem cells should not be funded through Horizon 2020. Regenerative medicine based on this research has huge therapeutic potential and George Osborne recently named it as one of eight key areas for UK economic growth<sup>10</sup>. The medical research community responded quickly to engage with MEPs to protect this important area of research. Without their engagement, a valuable stream of funding for UK research may be lost, however, the complex and unfamiliar system of the EU Parliament is a challenge for UK medical research funders to engage with. Clearer communication of the legislative process and opportunities to input may have facilitated this engagement.

14. The EU can play a leading role in addressing challenges faced at an international level. Medical research is evolving rapidly; as we move towards more stratified medicines, the processes of research and licensing must adapt to enable us to trial new treatments on smaller populations and explore how we can facilitate earlier access to life-saving treatments. We are already addressing these issues at a national level but the EU can take a valuable lead in bringing together multiple stakeholders to shape policy and move all EU states together towards a more adaptive licensing model. If achieved successfully, the EU can become a global leader in this field.
15. The EU can also take a leading role in addressing concerns around the accessibility of research data and findings. The international nature of research, and in particular clinical trials, means that action to address these concerns must occur at an international level. Without such cross-boarder harmonisation, any action will only serve to drive research activities elsewhere. The EU is well placed to facilitate pan-European agreement and represent Europe's interests on the global stage.
16. The Horizon 2020 programme, running from 2014 to 2020, is very welcome to continue to support effective and collaborative research and innovation across Europe. Larger medical research charities report that their researchers have had positive experiences accessing EU funding, which is a valuable and complementary source of money. However, European funding processes are complex and many small charities with valuable project proposals have little resource to invest in understanding the system. Bodies established to help them navigate the system – such as the national contact points – are welcome but can themselves be a challenge for individuals new to the system to know to approach them. It is

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<sup>9</sup> <http://curia.europa.eu/juris/liste.jsf?language=en&num=C-34/10>

<sup>10</sup> [http://www.hm-treasury.gov.uk/speech\\_chx\\_091112.htm](http://www.hm-treasury.gov.uk/speech_chx_091112.htm)

notable that universities have become very successful at securing EU funds but only through employing staff specifically to support researchers through the process. There is a role for umbrella organisations such as AMRC in demystifying the system, and AMRC has ongoing work in this area. But it is important that accessibility of funding is considered as research and innovation proposals are developed in Europe. As outlined above, effective stakeholder engagement, facilitated by a more transparent process on behalf of the EU, is vital to develop successful research and innovation proposals.

17. The UK has a world-leading position in the life sciences. Effective policy for research & innovation at a European level can help us maintain and grow this, pooling resources to build effective pan-European collaborations.

## Brighton and Sussex University Hospital NHS Trust

The Question needs to be asked why are we, the UK more vulnerable to exploitation than some EU countries that have equal as good medical services providers.

The fact that the NHS is 'free at the point of use' is problematic. Whilst in theory with the exemption of A & E, this is meant for those legally residents in the UK. The Guidance states that NHS treatment is free to those who are 'ordinarily resident' in the UK, 'on a lawful, properly settled basis'. For which there are so many exemptions and interpretations. A & E along with GP referrals is often the gateway (loop hole) for all care. Even though this is at the tax payer's expense, is rarely challenged by politicians for fear of infringement of the patient's human rights.

The Guidelines for the eligibility for free NHS care provided by the Department of Health is sometimes difficult to implement. With grey areas that may be open to misinterpretation. Although this has improved in some parts of the recent DH Guidance published last year, there are loop holes re EU rights to treatment in the UK. These anomalies are often identified by the health tourists (including Ex-pats) who are blatant enough to try and often succeed in accessing our NHS. Often for a serious pre-existing condition, not just minor ailments. This is not reciprocated by other EU countries for UK nationals.

### **Why can EU members apply for a UK EHIC just based on residency?**

EU members often go home to their own country for treatment charging this care back to the UK on the basis that they are in possession of an UK EHIC. Whilst this in some cases may actually be more economical for some care, (I think maternity care in Poland is cheaper than the UK)

This is not reciprocated by all EU countries for UK nationals.

If/when there is an EU country that does provide an EHIC based on residency.

Do UK nationals/British passport holders use this system to access care in the UK.

The answer is no. Most will come back to the UK claiming that have now come back to the UK for the foreseeable future, receive the care required and then leave the UK. Some may access care outside the UK, but as health care in so many EU countries is not completely free of charge, this again is unlikely.

The administration systems in place in the UK are not adequate within the NHS to identify these groups of people. This is hindered by the fact the Primary care and Secondary care do not have rules and guidelines that run parallel with each other.

However the responsibility cannot just lie with the patient/the Health tourist/the opportunist. The Trusts, DH etc needs to take some responsibility for not providing/being able to fund the resources and enforcing the appropriate administration systems to identify those who are not eligible for free NHS.

Identifying a non eligible patient when they are part of the way through or near the end of their treatment, be it surgery, dialysis, fertility treatment or on a waiting list for organ transplant is not adequate and may lead to court action if care is delayed, postponed or withheld.

Never the less, none of this can be achieved without funding and support from government level. Not just from a financial aspect, but also when we are faced with legal challenges.

We are unable to provide statistics or costs for EEA members as the data on OASIS (our PAS patient administration system) whilst the nationality maybe recorded, we do not have the facilities to pull reports for this data.

## British American Tobacco

British American Tobacco is grateful for this opportunity to contribute to the Department of Health call for evidence in the context of the government's review of the balance of competences between the EU and the UK.

Our contribution will be limited to commenting on the EU's competence to regulate tobacco products and this paper will therefore focus on section 6 of the consultation document and section 1 of the legal annex thereto, and respond only to directly related questions.

### **Introductory remarks**

Section 6 of the consultation document would, in our view, require a slightly more nuanced heading in the sense that there is, as such, no "EU competence on tobacco control". As rightly stated in the legal annex, the EU's competence as articulated in Article 168(5) TFEU is limited to adopting "incentive measures" to protect public health in respect of tobacco, and this provision expressly excludes any harmonisation of the laws and regulations of the Member States.

In this context, we would disagree with the statement in paragraph 1.11 of the legal annex that Article 168(5) TFEU sets out a shared competence since Article 2(5) TFEU clearly states that where the EU has competence to carry out supporting actions this does not supersede the Member States' competence in these areas.

This does not mean that the EU has no power at all to regulate tobacco and it can do so on the basis of Article 114 TFEU although recourse to the internal market legal basis – which is a shared competence – has limitations spelt out by the Court of Justice. The Court has clearly stated that Article 114 TFEU does not vest in the EU legislature a general power to regulate the internal market as this would be incompatible with the principle of conferral.

The Court has further ruled that other Treaty provisions (such as Article 114 TFEU) may not be used as a legal basis in order to circumvent the express exclusion of harmonisation laid down in Article 168(5) TFEU. Moreover, a measure adopted on the basis of Article 114 TFEU must genuinely have as its object the improvement of the conditions for the establishment and functioning of the internal market and must actually contribute to eliminating obstacles to the free movement of goods.

The EU's competence to regulate tobacco is thus strictly limited by law and it is of interest to this review of the balance of competences to note that this is an area where the principle of conferral is being breached by abusive reliance on purported internal market objectives.

### **How does the EU's competence in health affect our organisation?**

In the light of the above comments, we would submit that the current Commission proposal for the revision of the Tobacco Products Directive goes far beyond the EU's limited competence in this area and constitutes a clear attempt to circumvent the express exclusion of harmonisation laid down in Article 168(5) TFEU.

It is however not our intention to develop in this submission the whole legal argumentation this proposal raises in our view. Rather, our purpose is simply to highlight how a lax implementation or interpretation of Treaty rules – possibly for reasons of political expediency – can unsettle the balance of competences between the EU and its Member States.

In a nutshell, we believe (i) that there is no legal basis for most elements in this Commission proposal as the conditions for resorting to Article 114 TFEU are not fulfilled, (ii) that, even if there were a genuine internal market objective the proposal breaches the principles of subsidiarity and proportionality, as well as fundamental rights and the Constitutions of most Member States.

Against this legal background, it should be noted in practice that there is actually no free movement of tobacco products in the internal market: product can only be sold in the Member State of intended marketing because the packaging is manufactured to comply with the health warnings' linguistic requirements of the country concerned, and the tax markings are clearly specific to each Member States. The free movement of tobacco products in the internal market is therefore limited to purchases for own use and in limited quantities by the individual travelling consumer. Cross-border movement on a commercial scale would amount to illicit trade.

Using the revision of the Tobacco Products Directive as an example, the point we would like to make in the context of this consultation on the balance of competences is that there has for many years been a constant drive towards gradual expansion of EU competences, a process usually referred to as “competence creep”.

The two institutions most likely to drive this process are the European Commission and the European Parliament. It is therefore clearly the role of the Member States in the Council and in their national parliaments to resist this constant erosion of their power to define their own policies at national level. We will revert to this assessment in our concluding remarks below.

What evidence is there that EU action in health disadvantages the UK national interest, business and industry and/or patients and citizens?

The above comments will have indicated that, where there is no genuine internal market objective to a piece of EU legislation in the health area and where – as in the case of tobacco products – there is no true free movement of goods, EU-wide regulation is not only unnecessary, it is also detrimental to the balance of powers.

- It is not in the UK national interest to concede EU competence where there is none as this ultimately deprives the government of this country of the right to devise its own policies. If a shared competence such as that grounded on Article 114 TFEU is asserted without due justification and this is not opposed by the Member States, the latter can no longer exercise their competence until such time as the EU decides to cease exercising its competence [Article 2(2) TFEU] – a highly unlikely occurrence.
- Regarding the impact on business and industry, we will limit our comments to the tobacco sector. As indicated above, since there is no free movement of tobacco products on a commercial scale in the internal market, sweeping regulation aimed at “levelling the playing field” is unnecessary and constitutes over-regulation thus hampering the freedom for business to compete and innovate. The current proposal would result in the European Commission regulating in its finest details an area where it has no competence to harmonise the laws of the Member States.
- Finally, as far as citizens are concerned, and still limiting our comments to experience with the EU public health competence as applied to tobacco, we believe that the current, very strong tendency to “homogenise” EU citizens is not in their interest. This is why EU Heads of State two decades ago coined the term “subsidiarity” and defined its principles: the peoples of Europe are diverse and this diversity must be respected if citizens are to respect the EU institutions.

### **How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than the EU level**

We believe that, from a broad constitutional viewpoint, it is crucial for the UK and for EU Member States in general to resist repeated attempts to expand EU competence beyond those explicitly conferred by the Treaty. This unsettles the delicate balance of powers and ultimately disregards the diversity and freedom which the peoples of Europe are clearly attached to.

### **How could action in this area be undertaken differently?**

EU legislation in the public health area should not only respect the boundaries defined by the Treaty, it should also adhere more strictly than is currently the case to the principles of subsidiarity and proportionality.

As public health is an area of supporting competence, EU action should generally speaking take the form of recommendations, not legislative initiatives, thus acknowledging Member States' freedom to define their own policies.

### **Concluding remarks**

The UK government is to be commended for its effort to review the balance of competences between the UK and the EU.

Our assessment is that, while the Treaty provisions generally provide an appropriate balance, this is undermined by lax implementation or interpretation of Treaty provisions, and in particular by excessive and unjustified use of Article 114 TFEU as a legal basis for EU initiatives in areas of supporting competence such as health.

The concept of internal market is often misconstrued and taken to equate uniformity of conditions throughout the 27 Member States. This is not the case: diversity is a reality and must be respected, and it is the Member States' responsibility to resist undue pressure to impose uniformity upon their citizens.

There are two ways of achieving this objective. One is to ensure that national parliaments effectively use the power granted them under the Lisbon Treaty to scrutinise respect by the EU regulator of the principle of subsidiarity. The other is for Member State governments to dare to speak up in Council meetings and question the EU's competence to legislate and/or the purported need for further regulation every time this is warranted.

## British Dental Association

### Introduction

1. The British Dental Association is the representative organisation for dentists in the UK, with over 18,000 dentist and 4,000 student members. We welcome the opportunity to respond to this call for evidence, and will outline some of the positive and the more problematic effects of EU regulation affecting the area of dentistry.
2. The United Kingdom is a full member of the European Union (EU). Matters of health service provision and policy remain within the competence of individual members states; however, EU policy influences other areas which in turn affect the field of health, as the call for evidence states.
3. At the same time, the UK influences EU policy through the relevant EU organisations, with EU legislation often mirroring common practice already in existence in the UK. There have, however, been examples where the interest of the internal market might take precedence over other interests, resulting in issues being caught up in EU legislation that should not have been (see tooth whitening). These cases then take an inordinate amount of time and effort to correct.
4. The British Dental Association also works with European dental organisations, such as the Council of European Dentists (CED) and the Association of Dental Education in Europe (ADEE) to influence policy decisions at EU level affecting dentistry.

### Medical devices

The system of regulation of medical devices and the CE mark set EU common standards and clarify responsibilities. It generally works well and is well-understood by professionals. The PiP implant failure revealed weaknesses which require addressing, but the system is worth retaining.

5. Medical devices legislation and guidance are currently under review. The proposals contain some concerns for dentistry, such as the introduction of greater controls in the area of custom-made devices. We are working with the Council of European Dentists (CED), a European not-for-profit association composed of national dental associations and chambers across Europe, to find a solution and influence the legislative framework.
6. In relation to tooth whitening, The EU cosmetics directive has caused great difficulty in relation to tooth whitening. Advances in dental whitening materials and treatment techniques mean that practitioners cannot always act in the best interest of patients and stay within the law. The process for amending the EU cosmetics directives is laborious. It took nearly 15

years to amend this directive, and the result only provides a partial solution. Outstanding issues include regulation of high concentration products, restrictions on products used on under-18s, and unsafe products not included in the directive, so outside the control of regulators. Given its structure, as whitening products evolve amendments to the Directive will be needed constantly.

## **Public health**

7. The EU Blood, Tissue and Cells and Organ Directives are benchmarks for standards, which have already been transposed into UK law and ensure traceability from donor to recipient. As a shared UK/EU competence, this does not affect national provisions on the uses of donated tissues. Dentistry is not affected by the regulations, except for dental pulp stem cell banking in which the donor and potential future recipient are the same (this removes some concerns about cross-infection, though traceability is still essential).
8. The recent launch of the EU Rapid Alert platform for human tissues and cells (RATC) is a secure alert platform aiming to improve the safety of patients undergoing transplantation and medical procedures involving human tissues and cells transferred across borders. In addition to quality and safety defects of tissues or cells, the RATC can be used to raise the alarm on illegal and fraudulent activities in this field, as well as on developing epidemiological situations that may have cross-border implications.

## **Nutrition and food labelling**

9. The EU Food Information for Consumers (FIC) regulations came into force in the UK in December 2011. These will make it mandatory (from 2016) for most pre-packaged foods to carry nutrition labelling. In practice, this will bring the rest of Europe into line with the UK, where nutrition information has been provided on a voluntary basis for some time. This should compel any currently non-compliant UK manufacturers to provide labelling.
10. The EU FIC regulations outline the content and presentation of the voluntary repetition of nutrition information front of pack (FoP), including which nutrients must be covered (either the energy value alone, or the energy value plus amounts of fat, saturates, sugars and salt). The regulations have sufficient flexibility to allow much of the variable practice currently seen within the UK market to continue, however, including the use of differing formats and the ability to provide nutrient information on a per-portion-only basis. Without any further harmonisation of FoP labelling, such variation could continue to make it difficult for UK consumers to compare products and to use FoP labelling as effectively as possible. The BDA advocates mandatory, consistent FoP labelling requirements including amounts of fat, saturates, sugars and salt and combining colour coding, high/medium/low text and GDAs.

## **Tobacco**

11. Three EU Directives relate to tobacco:

- The Tobacco Products Directive (TPD), which aims to align member states on manufacture, presentation and sale of tobacco products and covers maximum levels of tar, nicotine and carbon monoxide plus health warnings on packaging. We await the adoption of the updated TPD this year, reflecting changes in products and markets over the last decade.
  - Directive 2003/33/EC, covering advertising and sponsorship including the ban on print, radio and information society services advertising plus event sponsorship involving multiple member states.
  - Directive 2010/13/EU, covering the television advertising ban, plus other audiovisual/commercial communications.
12. The BDA notes the non-binding EU agreement on smokefree places, and welcomes the anti-smoking communications and marketing activity carried out by the EC.
  13. The BDA also welcomes the provision for health protection as a consideration in the tobacco control regulations (Article 114(3) TFEU). The UK's tobacco controls are more stringent than those of some other EU member states, and we believe that public health considerations should take precedence over the EU competence to address internal market barriers where a conflict arises in relation to tobacco – that is the UK should not be required to relax its controls in favour of removing the internal market barrier.
  14. UK tobacco regulation is at least as stringent as that required by the EU – in particular, we welcome the UK's initiative on smokefree work places, the ban on vending machines and the point-of-sale display ban. The UK government is still considering the possible introduction of standardised tobacco packaging; we support this measure and urge a swift decision.
  15. Since we are still awaiting the revised TPD, it is difficult to comment on any specific provisions. In the 2010 consultation, the BDA advocated: including regulation of new smoked tobacco products; maintaining the ban on snus; excluding electronic nicotine delivery systems; making pictorial warnings mandatory on packaging; replacing misleading machine-based tar, nicotine and carbon monoxide yield labelling with descriptive information; placing health warnings on water pipes; requiring a common reporting format; and introducing an EU-wide ban on vending machines, cross-border internet sales and retail displays.
  16. The updated TPD should be beneficial to UK population in regulating the tobacco that people import themselves when travelling to other member states.
  17. The EU's tobacco advertising and sponsorship Directives reduce exposure of UK citizens to promotional material when travelling in the EU or watching televised events for which sponsorship was previously permitted.

## **Alcohol**

18. The BDA welcomes Directive 2010/13/EU, covering television advertising of alcohol (this must not be aimed at minors or depict minors drinking; must not imply any enhancement in performance after drinking; and must not encourage immoderate consumption). Labelling is also covered by Directive 2000/13/EC. The UK already meets or exceeds these requirements, so they have minimal impact domestically. As for tobacco, the EU regulations on alcohol are beneficial to UK citizens importing alcohol from other member states or travelling to other countries where they might otherwise be exposed to advertising or promotion that is not permitted within the UK.

## **Public health programmes**

The BDA welcomes the fact that EU action aims to complement national policies and promote cooperation. We note that the EU has acted mainly through community health programmes; the third programme of EU action for 2014-2020 ("Health for Growth") is currently being negotiated and intends to assist member states to respond to economic and demographic challenges facing health systems and enable citizens to stay healthy for longer.

19. The EU encourages the formation of groups such as the Platform for Better Oral Health in Europe, which works to promote oral health and the cost-effective prevention of oral diseases in Europe.

## **Free movement of persons: healthcare professionals**

20. There are a number of areas where dentistry is affected by the free movement of healthcare professionals.

## **Automatic recognition of dental degrees**

21. The system is straightforward and generally works well. The UK is a popular destination for EU-qualified dentists to work, but many UK dentists have also gone to places such as Spain, often working with the expatriate UK population there.

22. The ease with which EU dentists can register and work in the UK has helped in the past to address workforce shortages, particularly in the NHS. In 2004, the UK government actively recruited dentists to the UK, although induction into the system was variable, putting patients and professionals at risk. In the current economic climate, competition for jobs from EU graduates affects UK dentists, however.

## **Quality of training**

23. There are some concerns over the level of practical dental training in some EU countries. While training programmes may be compliant with the PQD, they might not provide

adequate clinical hands-on training in the treatment of patients to the extent usual in the UK. This results in a need for remedial/top-up training in the UK to ensure patient safety, but there are no formal provisions for this.

### **Dental foundation training (DFT)**

24. Dental foundation training (DFT) is a paid one-year post-registration training period in general dental practice which all graduates of UK dental schools must undertake in order to work in the NHS. EU legislation exempts EU nationals (including UK citizens) who have graduated from an EU dental school outside the UK from undertaking dental foundation training. In the past, this exemption has helped to address workforce shortages.
25. In the current economic climate, however, an increasing number of EU dentists are keen to apply to the training programme despite being exempt from the formal requirement, as it provides a guaranteed income for a year and a sound basis for future careers.
26. In spite of the fact that the dental undergraduate course is thought to produce 'safe beginners', EU legislation does not permit the UK to ringfence training posts for UK graduates, who must do DFT to work in the NHS and to gain essential experience and knowledge. Ringfencing is not possible because DFT is subject to employment law regulations. In medical foundation training, the UK government now gives a guarantee to all UK graduates to obtain a place, but such a guarantee is not forthcoming in dentistry because dental foundation training is undertaken *after* full professional registration.
27. This means that every year a number of UK-trained graduates, whose training has been funded by the taxpayer and who themselves have taken on significant levels of debt to undertake the five-year course, are unable to participate in dental foundation training, endangering their career development and reducing their chances of working in the NHS. The BDA strongly believes that every UK dental graduate wishing to do DFT should be given the opportunity to do so.

### **Language testing**

Currently, the dental regulator cannot ask EU graduates to demonstrate their language proficiency at registration point due to the wording of the professional qualification directive (PQD) and resultant UK legislation. This issue is now being addressed as part of the modernisation of the PQD, and we believe that this is a positive development which aids public protection.

### **Fitness to practise warning system**

28. The UK has an online register of all dental practitioners. If a dentist is erased following a fitness-to-practise decision, it is made clear on the register, is press-released, and other regulators within the EU are informed. Not all EU countries provide this information; instead,

some regulators are reluctant to confirm registrant removals, citing national data protection laws. There is a move to address this issue in the modernisation of the PQD, which we welcome if it is implemented. At the time of writing, it is not clear whether the issue has been fully resolved.

29. Regulators must also improve their usage of the Internal Market Information system for this and other purposes. Currently, we understand usage to be variable. Again, the PQD considerations are expected to address this issue.

### **Free movement of persons**

30. The cross-border healthcare directive has relatively little impact on dentistry as most of the relevant treatments would be provided on a private basis. Dental tourism is an issue in general, however. Patients often have a need for remedial work after having attended for elective dental treatments abroad, and access to redress may often not be available.
31. Partially as a result of the cross-border healthcare directive, the DH is currently consulting on the introduction of a mandatory requirement for all healthcare professionals to have appropriate indemnity cover as a condition of registration. While already a professional requirement for registered dental professionals, it is not currently required in law. We welcome the proposal in principle while we will provide comment on the detail through the relevant consultation.

### **eHealth**

32. A number of EU countries have moved forward with the eHealth agenda. In many countries, dentists are fully integrated into online systems of patient records, referrals and prescriptions. While good systems seem to be in place for UK doctors, the involvement of general dental practice in such systems has not been a government priority.
33. Consideration is now being given to the harmonisation of codification of diagnosis and treatment planning. While there is no move to make the use of such a system mandatory at the moment, non-participation could leave UK software producers less competitive on the EU market.

### **Heal**

34. EU funding is hugely beneficial and important to UK research, particularly in the context of the current domestic economic climate. The UK receives a substantial proportion (the largest of any member state in 2008-11) of the available funds for health research (predicted to be 1.2 bn Euros under Framework 7). The Framework fosters collaboration between both national and international institutions, which is essential for efficient progress. Although the application and administration process for EU grants can be onerous, collaborations enable the burden to be shared and individual project grants can be generous, which makes the process worthwhile.

35. The BDA supports the common framework (Regulation 1338/2008) for the systematic production of Community statistics on public health and health and safety at work. It is beneficial to have a harmonised and common data set, containing information required for EU action in the field of public health, for supporting national strategies for the development of high-quality, universally accessible and sustainable health care as well as for EU action in the field of health and safety at work.

### **External representation**

36. The EU aims to foster cooperation with third countries and competent international organisations – both by individual member states and collectively by the EU – in the sphere of public health. The competence of the UK/EU depends on the issue. The BDA supports international collaboration on public health matters, many of which need to be tackled on a global level. Interactions with the World Health Organisation (WHO) are particularly important, as it commands significant global influence and respect. The collective voice of EU is more powerful than that of individual member states, underlining the importance of UK involvement in the EU.

37. In addition to the WHO, the BDA also works with a number of dental-specific organisations in the EU and worldwide, such as the Council of European Dentists (CED) and the International Dental Federation (FDI). Such collaboration has recently been particularly effective in the area of amalgam. Following negotiation of the global legally-binding treaty on mercury, the EU will set the pace of amalgam phase-down across member states. Work will now be required by CED and other organisations to ensure that this is achievable and allows time for improvements in oral health and research into alternative materials.

38. Other areas of collaboration with these organisations include tooth whitening, non-communicable diseases, and any area of EU or international legislation affecting dentists. Voluntary organisations also make an important contribution, for example with projects helping developing countries in the area of dental health or by sending forensic dentists to crisis areas to help identify victims.

39. The BDA also works with the Association of Dental Education in Europe (ADEE), which promotes the advancement of high standards of dental education as well as peer review and quality assurance in dental education and training.

### **Non-legislative action**

40. The EU runs “joint actions” which are aimed to scope issues and consider best practice approaches. The Council of European Dentists participates in a number of them, working to develop best practice to support countries in developing their own policies, for example in patient safety aspects.

41. We are concerned, as are our European colleagues, that there appear to be moves within the European Committee for Standardisation (CEN) to consider the development of standards in healthcare provision, which we believe should be a national competence as it needs to be tailored to national needs.
42. The development of a standard on cosmetic surgery procedures could potentially have prohibited dentists from providing injectable cosmetic procedures, but the UK influenced this work to ensure dentists can continue to provide such treatments. The standard is, however, not yet finalised.

### **Public procurement**

In the health sector, European public procurement law, and in particular the way it has been interpreted by the Health Service in England, leads to unnecessary bureaucracy and destructive uncertainty for established providers and consequently for services. The need to publish the details of contracts awarded in the Official Journal of the EU has no real benefit in the case of small dental contracts; and the application of the requirement to tender for services, in spite of the exemptions which would cover most dental contracts, is unclear. Promoting value for money and market testing are acceptable in some cases, but the fact that the NHS feels in danger of legal challenge if tendering does not take place, even if the nature of the contract is such that tendering is not in fact required, leads to unnecessary waste and significant barriers for small dental providers who wish to expand or new providers wishing to enter the market but who do not have the resources to mount a professional bid for a tender process designed for large institutional providers. This restricts competition and is not in the best interests of patient services.

### 1. Summary

- BGMA fundamentally supports the UK's participation in the Single Market, as well as the common standards and EU-wide market authorisation that allows UK-based generic companies to easily move into other EU Member State markets, as well as for European-based firms to supply medicines to the UK market.
- This is not only key for economic growth, but contributes to a vibrant multi-source market in the UK which produces low generic prices, increased medicines accessibility and security of supply. This is in the interest of business, patients, taxpayers and ultimately, the UK national interest.
- In the area of pharmaceuticals policy, the development of EU regulation has not always given rise to the most cost-effective solutions. This can impact very negatively on EU Member States, who bear the price of a more expensive drugs budget, whether these are costs passed through the supply chain from excessive regulation or direct costs such as from the EU Paediatric Regulation (covered below).
- As a start, irrespective of the UK's long-term role in the EU, the UK Government should signal an early and clear political commitment to the UK's negotiating position regarding contentious measures, and in particular, to proposals which should be regarded as non-negotiable in the national interest.
- EU Member States' health systems, as well as their pharmaceutical pricing and reimbursement systems operate differently. Indeed, the EU's remit in this area is limited. However, as encapsulated by the Falsified Medicines Directive, we are concerned that 'one size fits all solutions' to issues such as anti-counterfeiting fail to take into account these differences and lead to the development of ineffective and even disruptive policy. Should the EU's future direction move to a more federal model, it may be necessary for Member States to develop more aligned health systems to ensure that EU and national policy and practice complement each other. Alternatively, should Member States continue to preference national sovereignty in policy areas such as health, it may follow for the EU's scope relating to these areas to lessen.

### 2. How does the EU's competence in health affect you/your organisation?

The EU's competence in the area of pharmaceuticals policy is more limited than in other sectors of the economy. This is because large elements of healthcare policy, pricing and reimbursement of medicines, and prescribing and dispensing rules are matters of Member State competence. (This is notwithstanding cross-cutting and relevant areas of EU-devised law such as the EU Public Procurement Directive and the EU Transparency Directive).

#### 2.1 The Single Market

The Single Market operates most strongly and effectively in medicines regulation, including marketing authorisation and other issues focused on ensuring the safety, quality and efficacy of medicines (such as rules governing GMP, GDP and pharmacovigilance). Whilst some UK-based generic manufacturers continue to seek authorisation from MHRA to market their products solely for UK usage, many others benefit from using the centralised and decentralised procedures to access the broader EU market. This is highly beneficial, enabling companies to expand, as well as contributing to a high level of competition in the UK that has delivered some of the lowest generics prices in the western world.

## 2.2 Regulatory scope

More recently we have seen EU legislation applying to areas of the medicines supply chain which, because they are issues of Member State competence, vary widely between Member States. An example is the Falsified Medicines Directive, which, though well intentioned, has sought to apply constraints to the way in which the supply chain operates without having regard to the different arrangements in the Member States. The European Commission's vision of how the so-called "safety features" should apply cannot be effectively or cost-effectively applied in the UK because of our unique national rules. EU legislation should focus more on the objective and less on the means of delivery.

Similarly, there is a disconnect between the Commission's apparent desire to move into more detailed areas and their lack of financial accountability. When we sought to discuss the costs of the FMD "safety features" provisions with DG SANCO, we were told that cost was a matter for the Member States. This mix of interference at a more granular level within Member States' systems sits uncomfortably with an indifference to the cost. This has also been seen, for example, in the EU Paediatric Regulation where the cost-benefit ratio is unsustainable.

We also question whether the European Commission is capable, due to lack of experience, expertise and/or resource, to undertake some legislative changes which it promotes. An example is the API quality provisions of the FMD, the objectives of which we support, where the Commission has palpably failed to negotiate the implantation of these provisions with the third countries' whose cooperation is vital to its success.

## 2.3 EU-wide patent policy

The EU's scope of competence in this area is set to grow with the very recent establishment of the Unitary Patent and the Unified Patent Court. Instinctively, the establishment of an EU-wide patent which seeks to extend the Single Market appears a sound idea. However, if the ability to challenge weak patents is not afforded equal status to rewarding genuine innovation as has been predicted through the bifurcated court structure, the budgets of European health systems will suffer as a result of limiting the generic market.

### **3. What evidence is there that EU action in health advantages or disadvantages the UK national interest, business and industry, and patients and citizens**

#### 3.1 Advantages to the UK national interest, business and industry, and patients and citizens

The Single Market, with common regulatory processes and requirements such as EU-wide marketing authorisation, makes it easier for UK-based generic firms to expand into national markets in the EU. It also makes it easier for EU-owned companies to serve the UK market which has advantages for, eg, the robustness of the medicines supply chain, as we comment below.

#### 3.2 The Single Market contributes to wider benefits beyond trade

Indeed, the Single Market is positive not purely for trade, but for patients and the country as a whole.

Low barriers to entry foster and maintain a competitive market place, which in turn creates low prices for the NHS and UK patients (through and outwith the NHS). A clear benefit is that this has helped deliver for the NHS among the lowest prices for generics in the western world. In 2011, by maximising generic savings, the NHS saved £10.25bn<sup>11</sup>, more than the overall NHS drugs budget. Additionally and just as importantly, this as a consequence also ensures that medicines are accessible. Lastly, strong competition through a multi-source market means that in the event of one or more suppliers having problems supplying a product, often another participant can 'step in'.

### 3.3 Disadvantages to the UK national interest, business and industry, and patients and citizens

Regulation is necessary and important so that the suppliers manufacture and transport medicines to high standards that the NHS and patients require. However, we have seen examples (some quoted above) where well-intentioned pieces of EU regulation have and could further lead to higher costs for the NHS.

### 3.4 Developing cost-effective regulation

We comment above on the Falsified Medicines Directive and the Paediatric Regulation. A further example of where EU legislation, though well intentioned, has acted against the interests of the NHS, British patients and our industry is the introduction of the requirement for braille to be applied to medicines' packs. Because of its introduction during conciliation<sup>12</sup>, there was no informed debate by the European Parliament or Council of Ministers about the cost effectiveness of the measure.

It is important to ensure that there is a greater focus on whether regulation is actually proportionate and practical at Member State as well as EU levels. However, these examples do point to a key disadvantage of the current balance of competence – that the EU Institutions do not pay for the policies for which they develop and legislate. As such, EU institutions, and notably the European Commission as the executive, may not fully consider the true financial cost of the measures they take forward. This can disadvantage UK taxpayers by effectively shrinking the drug budget from which UK patients benefit.

BGMA believes that a priority for the operation of the EU should be a determined focus on taking forward measures that can be evidenced to be cost-effective.

## **4. Please consider what evidence there is to demonstrate the extent to which the EU's role in public health supports member state actions effectively and efficiently**

The BGMA is not able to comment on this matter.

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<sup>11</sup> In 2011, if all medicines had been reimbursed at the average brand price (instead of the price for the generic version), the NHS drugs bill would have been £10.25bn higher.

<sup>12</sup> The mechanism to generate agreement between the different institutions of the European Union where discussion takes place behind closed doors.

**5. Please consider what evidence there is to demonstrate the extent to which the opportunities and costs for the delivery of health and social care in the UK flow from wider EU competencies and policies such as the free movement of workers or the single market generally**

The European Commission's (DG COMP) sector inquiry into the pharmaceutical industry, published in 2009, identified a series of practices and procedural deficiencies which delayed or prevented the launch of generic competition at expiry of originators' patents. The report made a number of recommendations on how the European market could work more competitively and European health systems could save more money. In this way, the European Commission's oversight view across the EU has provided the UK Government with an opportunity to improve healthcare delivery in the UK.

As mentioned previously, the Council of Ministers in February 2013 voted to establish a Unitary Patent and Unified Patent Court. Whilst it is important to note that companies could still choose to obtain national patents in relevant countries across the EU, this is of significance to the whole pharmaceutical industry. In many cases, a generic company will launch its product at patent expiry at risk of a legal challenge. Allowing a Court structure which gives preference to the upholding of weak patent claims over those seeking to launch equivalent products will not only damage the generics industry, but by limiting a competitive market place in some instances, could negatively impact on European health system budgets. BGMA hopes that the drafting of the Rules of Procedure (for consultation around Spring 2013), which are to govern how the Court operates, will create a balance between upholding intellectual property rights and promoting competition.

EU industrial policy can also play an important role in encouraging businesses to establish their manufacturing bases in Europe. Whilst it is unlikely to have an effect on traditional medicines production, the EU could target policies that incentivise the manufacture of biopharmaceutical medicines, which will be a key growth area in the pharmaceuticals market.

**6. The extent to which EU competence and policies intended to allow EU citizens to access healthcare across the EU are effective and proportionate**

6.1 Implementation

From the perspective of pharmaceutical policy, the EU's central role should be ensuring that European patients receive their medicines safely when they need them. However, unless a solution can be found by July 2013 (BGMA is working with MHRA, Department of Health and European Generic medicines Association to achieve this), the API quality provisions of the Falsified Medicines Directive threaten to have significant detrimental effect on the supply of generic medicines to the UK.

As we comment above, we support the intention of the legislation, but its highly prescriptive nature and the European Commission's failure to negotiate with API exporting countries could damage the interests of patients rather than protecting them. A less prescriptive and more realistic approach is needed, perhaps based on mutual recognition of Member States' implementation of principles established at EU level wherever possible.

6.2 Proportionality

As noted above, BGMA has concerns about the proportionality of some of the regulation devised by the EU. It is crucial that EU Institutions develop a focus on implementing policies that are cost-effective and practical.

### 6.3 How can European legislation fit with national health systems?

As noted earlier, EU Member States' national health systems, and medicines pricing and reimbursement systems operate in different ways. For example, regulations regarding stipulating the application of anti-counterfeiting measures may not take into account the different prescribing and dispensing routes in one country compared to another.

In BGMA's experience, this allows policies to develop where 'one size fits all' regulations are applied to different national health systems. This hinders the efficient delivery of UK health policy.

Indeed, we believe it is necessary to consider the future direction of the European Union project. If the UK is to remain in the EU – one which moves towards a more federal structure – then maybe Member States' health systems need to align to a greater extent in order for European policy to be truly effective in this area. If Member States do not support an increasingly federalised model, then in policy areas where States' systems or models are different, it may be more effective for the EU to retain only a very minimal sphere of competence beyond the enabling of the Single Market.

### 6.4 Consolidating the EU's approach to medicines regulation

Taking an increasingly federal approach regarding the regulation of medicines might deliver cost savings to business, which would bring down the costs of bringing a drug to market. In the US, the Food and Drug Administration (FDA) grants licensing authorisations and is the responsible regulatory authority across the US, operating a hub and spoke system. This compares with the EU where the European Medicines Agency (EMA) works through and with 27 national agencies (and the European Commission itself is a licensing authority). This clearly has inbuilt inefficiencies. The establishment of a single European medicines regulatory authority (expanding the EMA) operating through a much smaller number of centres of expertise based across the EU may enable the more efficient delivery of medicines.

## **7. The extent to which health objectives are effectively and proportionately taken into account in wider EU policies**

The BGMA is not able to comment on this matter.

## British Medical Association

The British Medical Association (BMA) is an independent trade union and voluntary professional association which represents doctors and medical students from all branches of medicine all over the UK. With a member of over 150,000 worldwide, we promote the medical and allied sciences, seek to maintain the honour and interests of the medical profession and promote the achievement of high quality healthcare.

### **Executive Summary**

The BMA welcomes the priority given to public health and patient safety at EU level and recognises that some issues are best addressed at the supranational level due to the free movement of patients, doctors and medical products across borders and the prevalence of public health threats across Europe.

European involvement in health must not replace successful activities already underway at the national or regional levels.

European activities should be used as an opportunity to evaluate what works well and to endorse and commend existing good practice.

Effective communication between stakeholders should be encouraged in order to ensure that EU actions add value.

It is essential that EU legislation fully respects the principle of subsidiarity and the right, enshrined in the EU Treaties, of member states to organise and finance their healthcare systems according to national practices. This is particularly important given the nature of the UK's publicly funded NHS.

### **How the EU's competence in health affects the BMA**

#### *Employment and professional issues*

The European Union (EU) has an important role to play in social and employment law. Health professionals benefit from EU health and safety legislation which in turn benefits patients in the form of increased patient safety. The European internal market guarantees that professionals can move and work freely throughout the EU by virtue of having their professional qualifications recognised in other EU member states. The shared competences with Member States on employment policy provides employees with important protections. Key areas of interest to the BMA are patient safety, safeguarding and enhancing professional mobility, the European Working Time Directive, European workforce for health and employment rights.

#### *Public Health*

The BMA has an interest in public health issues for the benefit of both patients and doctors. Through this work the BMA is committed to improving the health of people in the UK and across the world. Public health threats know no boundaries and with growing lifestyle changes and increasing mobility across European borders, member states must work together in order to combat serious public health threats to citizens with both infectious diseases and non-communicable diseases requiring transnational actions. Working towards a tobacco free society, reducing alcohol-related harm, tackling the obesity crisis, increasing rates of organ donation, adopting a health centred approach to tackling illegal drug addiction and working on the Social Determinants of Health are key areas of interest for the BMA.

#### *Adapting to changes in national healthcare delivery*

Medical staff have to meet the challenges of a rapidly evolving healthcare environment on a daily basis. Doctors are committed to embracing change for the benefit of patients. With increasing cross-border healthcare provision and ever increasing deployment of

telemedicine and eHealth solutions across Europe, it is essential that interoperability issues are addressed along with greater clarity about data protection across the EU. In the wake of the PIP breast implant scandal, and continuing concerns with metal-on-metal hip replacements greater consideration needs to be given to the regulation of medical devices and the rules governing clinical trials. The application of EU competition and procurement rules to the NHS could have significant implications for the stability of local health economies and the quality of patient care.

In this response these key areas of interest will be taken in turn and consideration will be given to the questions in the call for evidence document such as the advantages and disadvantages of EU action in each area and the extent to which the EU's role in public health supports member state actions effectively and efficiently.

## **1 Employment and professional issues**

### ***1.1 Safeguarding and enhancing professional mobility***

The aim of the Directive is to allow European professionals (in certain regulated categories) with recognised qualifications to practise their profession in any European country without unnecessary restrictions or difficulties.

The BMA supports, in principle, the free movement of doctors in the EU, so long as there are appropriate safeguards to ensure patient safety. The UK health system has benefitted from EEA and international doctors practising in the UK. Due to the changing nature of modern medicine, the BMA recognises that the Directive on the Recognition of Professional Qualifications (2005/36/EC) requires updating in order to meet the demands of modern medicine. It is

essential that the system is updated to emphasise a healthcare professional's continuing fitness

and suitability to practise in the host member state. It is vital that EEA doctors who exercise their right to free movement are able to demonstrate regularly to the host competent authority that they are fully qualified and fit to practise.

The BMA has already contributed to the debate on the revision of Directive 2005/36 and continues to engage with this process. This section will summarise our ongoing concerns with this Directive along with highlighting the challenges faced by the UK training system as a result of free movement.

#### Language Competence

The BMA believes that all doctors, whether they are from European Economic Area (EEA) countries or elsewhere, must have an acceptable command of English, both verbal and written, and acceptable clinical skills if they wish to practise in the UK. It is vital that, before granting access to the profession, a competent authority is able to satisfy itself that

an individual doctor has the necessary skills in order to practice medicine in that country. This includes language and communication skills and is important for all doctors but especially for those who are self-employed.

Current European legislation means that one-size-fits-all English-language tests of European doctors as a condition for working in the UK are not permitted. The BMA believes that both

regulators and employers must be able to verify the language skills of EEA doctors where legitimate doubt arises. The EU rules do not prohibit language testing per se, rather they state that testing should be proportionate and must not be part of the first stage process (i.e. recognition of the professional qualification). The competent authorities for the health professions should be able to verify language skills of applicants to the register either directly or indirectly by delegating this to another body. The BMA is now hopeful that the strength of concern around language testing has been recognised at a European level through improvements to the provision for language testing in the revised Directive.

Facilitating the movement of professionals is an important principle. It is essential that it does not restrict the actions of the General Medical Council and employers in undertaking essential language checks. The role of the EU should be to set the requirements that facilitate free movement whilst providing member states with the ability to implement additional controls where there is evidence that indicates there is a legitimate need.

#### Length of Basic Medical Training

Having provisions that set the length of Basic Medical Training are essential as long as these provisions recognise that longer training time does not necessarily equate to better trained doctors. The UK has proved with its four year graduate entry programmes that shorter more intense well designed and delivered and educationally challenging courses can also produce high calibre trainees and fully competent doctors. The BMA supports the move to clarify the current wording of the Directive from 6 years or 5500 hours to five years *and* 5500 hours. The move to 5 years *and* 5500 hours recognises that training practices are changing and that the length of training is far from the only factor that determines quality.

#### Oversubscription of the UK Foundation Programme

In 2012, for the third year running, the UK Foundation Programme was oversubscribed, with more applicants than posts in 2013. It is likely that this situation is going to repeat itself in subsequent years with the problem becoming more acute. It is vital that all medical students graduating from UK medical schools obtain a place on the Foundation Programme as without the opportunity to complete Foundation Year One (FY1) a doctor cannot secure registration with the GMC and cannot practise as a doctor in the UK or elsewhere. This would not only have a devastating effect on any affected graduates but would also result in the waste of substantial financial investment in educating and training doctors to work in the NHS. The causes of oversubscription are complex but there is no doubt that one

contributing factor is the unpredictable nature of applications from eligible EEA graduates. The impact on UK graduates of new states joining the EU on the Foundation Programme continues to be a real concern.

#### Content of specialty training curriculum

The Parliamentary Report on the Recognition of Professional Qualifications Directive includes a proposal which would give the European Commission power to adopt secondary legislation determining the content of specialist medical training across Europe. The BMA is approaching the move towards the setting of European wide curriculum with caution and has concerns regarding the proposed legal basis and the risk of undermining the UK medical training system. The BMA recognises that if this proceeds it is important that the UK engages in order to try to influence developments. The BMA supports the creation of high standards across Europe but there is a danger that UK standards, or the standards of those who are admitted to the medical register from Europe reduce in line with an EU minimum. The current UK specialty curricula have complex oversight systems but remain flexible to changes. There is a risk that this flexibility would be lost if it became EU-led. The BMA believes that the efforts required to reach a harmonised standard for specialist training would neither be worthwhile nor produce any meaningful or safe standard, and would ultimately add unnecessary complexity to the UK's system by replicating the work of the Royal Colleges and the GMC.

Under the rules of Directive 2005/36/EC, the UK would be required to recognise the qualifications of specialists who had qualified under these standards. Were the UK to remain one of the only countries not to adopt harmonised standards, there is a risk that UK qualified specialists would be hampered in their ability to have their qualifications recognised across the rest of Europe. The BMA would like to see the continual improvement in medical training across Europe and wishes to be actively involved in this, but at present the BMA has not been suitably reassured that patient safety will not be put at risk by the development of a common curriculum. Education and training remains a national competence' and the BMA strongly resists any moves towards European controls. The UK needs to ensure that qualifications are equivalent and comparable but this does not require a top-down approach.

The BMA has particular concerns around the use of delegated acts which would give the European Commission the power to supplement certain 'non-essential' elements of EU law. Delegated acts have supremacy over national laws and are approved through expert committees which are led by the commission. These delegated acts add an additional layer of complexity to the EU legislative landscape enabling the Council and Parliament to regulate a particular field only partially and to delegate power to the Commission to supplement the regulations. The BMA is particularly concerned about the potential use of delegated acts to determine the

content of harmonized training standards. It is essential that any process to develop a competency base is transparent and inclusive. All relevant stakeholders (member states, competent authorities, professional bodies) must be involved in this review and in the development of the subsequent delegated acts.

### Recognition of General Practitioners

The Directive is designed to facilitate the free movement of doctors within the EU and lists those medical specialties that are recognised within EU member states. In recent years, an increasing number of EU countries have introduced a specialty in family medicine as well as or instead of the traditional title of general practitioners. The current situation in which two tiers of general practitioner, operating under different provisions of the Directive, exist across the EU is hampering the ability of doctors to move freely across the EU contrary to a right that is enshrined in the EU's founding treaties. Doctors from those countries where general practice is not recognised as a specialty (as it is in the UK) are not able to join the specialist GP register in countries where general practice is considered to be a specialty (such as Germany). This creates a two-tier system of GPs and prevents UK doctors from practicing medicine under the same terms and conditions as their German counterparts. This has resulted in the creation of a barrier to genuine free movement of doctors across the EU. There is a lack of political will to address this situation, which the BMA would like to see addressed

### **1.2 The Bologna Process**

The Bologna Process is relevant when considering the education and training of doctors in the context of creating a modern, efficient health workforce. Whilst welcoming the Bologna Process as an opportunity to improve quality assurance and promote mobility of EU students, the BMA is concerned that it may impact on medical education in the UK. The introduction of a harmonised three cycle system presents specific problems for medical education with potential impacts on workforce planning and the flexibility of the medical degree. It may also have financial implications for medical students and may lead to the fragmentation of learning. The BMA does not want the Bologna Process to result in a potentially fragmented medical degree

which may challenge the integrity of the final medical qualification. This is an example of where involvement from the EU would not be welcomed and would not bring any significant advantages to the UK, unless there was evidence to suggest that not participating would have a detrimental impact on the status of UK universities internationally.

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<sup>1</sup> Under articles 165 and 168 TFEU

### **1.3 European Working Time Directive**

The European Working Time Directive (EWTD) is essential health and safety legislation that is necessary for both doctors and patients. Better rested doctors provide better patient care. The ability of doctors to learn is vastly improved when they are well rested. The EWTD, enshrined in UK law as the Working Time Regulations 1998, and the application to doctors, particularly

those in specialty training, is often used as an example of how European legislation is damaging to the UK. The BMA does not agree and continues to support the EWTD as it protects both patients and doctors and has the necessary flexibility to ensure a high level of training. The ability to average out the 48 hour week over 26 weeks means that it is not unusual for doctors to work longer hours when needed; if a patient requires care then that is given regardless of how many hours someone has already worked. The BMA is satisfied with the EWTD as it currently stands.

Where there are problems in balancing full implementation of the Directive with the demands of achieving a high level of training for junior doctors, the BMA believes that the problem lies with the design of training programmes and hospital rotas rather than with the Directive itself. The authoritative [Time for Training](#) in 2010 concluded that where improvements to training were required the answer was not to lengthen hours. If the Directive is to be revised the BMA would prefer the revision to focus on the issues of on-call time and compensatory rest. The revision must enshrine the SiMAP and Jaegar rulings in European legislation and must not dilute them in any way. The implementation of the EWTD in the UK through the Working Time Regulations has led to significant improvements for junior doctors in particular as it protects them from working dangerously long hours and improves patient safety. In the push to change junior doctor rotas by 1 August 2009 rota design often failed to consider doctors' education requirements. Good rota design is essential in ensuring that both the needs of the service and the educational needs of doctors in training are met. The role that the EU plays in protecting employees is essential and consideration should not be given to removing these protections from the UK workforce.

#### **1.4 European Workforce for Health**

To respond adequately to the challenges facing healthcare systems, member states require an efficient and effective health workforce. The 2008 Green Paper was an important first step in supporting member states in the creation of a modern, professional workforce. The BMA looks forward to future work on health workforce through the 2012 Action Plan and accompanying joint Action on forecasting health workforce needs and health workforce planning. This work should focus on the continuous professional development of healthcare workers and investment in recruitment and training. The BMA also calls for the development of an EU-wide set of principles for the recruitment of health professionals from developing countries in order to reduce the negative impact of migrant flows on vulnerable healthcare systems. The 2012 Action Plan provides an opportunity to share knowledge across Europe which benefits all.

#### **1.5 Transfer of Undertakings (Protection of Employment) (TUPE)**

TUPE implemented the Acquired Rights Directive in the UK. This is essential legislation that protects the rights of workers. Whilst TUPE is a complex piece of legislation the fundamental purpose is to protect employees if the organisation by which they are employed changes hands, or if an employee is transferring from one organisation to another. TUPE protects

employees' terms and conditions of employment during this transfer process. Employees of the previous organisation automatically become employees of the new employer on the same terms and conditions which provide an essential level of protection to staff employed in the NHS. The role of the EU in working alongside member states to protect employees across Europe through employment policy is an important principle and one that should be maintained and protected.

### **1.6 Patient safety and rights**

Patients should be the principle focus of any healthcare system and their safety must be guaranteed at all times. The European Union provides additional rights to patients that are often not provided under national law. This is an area where the EU adds demonstrable value to the lives of European citizens which should be promoted to the wider population. The BMA welcomed the

2008 Council Recommendation on Patient Safety which focused political attention on the importance of protecting patients. It is important that this momentum is maintained.

## **2. Public Health**

Climate change contributes to the global burden of disease and premature death and is having a growing impact on the health of EU citizens. Heatwaves and increasing air pollution have acute consequences for health particularly amongst the elderly and infirm whilst the health impacts of events such as flooding have effects on both physical and mental health. The EU needs to work cooperatively in global negotiations on climate change action because of the threat this poses to health. The rise of new infectious vector-borne diseases across Europe will require additional training for doctors and healthcare workers, particularly in southern member states.

More general directives concerning notification and early warning of infectious disease (TELLME Project) are helpful developments. Pharmacovigilance is commended although it is noted that many European medications do not appear in the BNF and there is an argument for keeping to that UK formulary. Europe is considering different strength insulins, for instance, which might result in prescribing problems for GPs and Pharmacists. The requirements for the shelf life of medicines could also be usefully addressed across Europe in order to reduce unnecessary wastage and the costs associated with this.

### **2.1 Working towards a tobacco-free society**

In the UK smoking is becoming less widespread, but it remains a leading cause of death and disease. NHS costs in the UK are estimated at £2.7 billion each year, with costs to the wider UK economy of around £2.5 billion in sick leave and lost productivity. The BMA welcomes the steps that have been taken at the European level to halt the prevalence of tobacco consumption, but argues that more needs to be done to protect EU citizens from the harmful effects of tobacco. Through the revision of the Tobacco Products Directive (2001/37/EC) the BMA stresses the need to introduce minimum pricing for tobacco products; to ensure that taxation on all tobacco products is standardised and increased at higher than inflation rates; and to prohibit the sale of packs of ten cigarettes. It is essential that further action is taken to promote a tobacco-free lifestyle that both 'deglamourises'

and 'denormalises' tobacco use. The BMA wants to see Europe go further in prohibiting the display of tobacco products at the point-of-sale and taking a much firmer stance towards the implementation of standardised packaging. The BMA also believes that the Directive should be revised to require all nicotine containing products to be regulated as medicinal products, taking account of Directive 2001/83/EC.

Import and cross-border distance sales continue to be a source of tobacco products. Without the wider involvement of the EU on this important public health issue the progress being made by the UK may be undermined elsewhere. The proposed Directive aims to regulate some of the issues around the ingredients and emissions of tobacco products and related reporting obligations, labelling and packaging of tobacco products, smokeless tobacco, cross-border distance sales and illicit trade. The main goal of this proposal is to regulate tobacco products in order to encourage young people to refrain from starting their experience with tobacco. The European Commission proposes to ban products (cigarettes, roll-your-own (RYO) tobacco and smokeless tobacco) with characterising flavours (vanilla, fruit flavours, chocolate or mint), including filters, papers or packages. The Directive also seeks to ensure that retailers engaging in cross-border distance sales must report on their activities to the competent authorities on the compulsory age verification mechanisms that monitor at the time of sale that the purchasing customer respects the minimum age foreseen under the national legislation across member states. It is essential that there is a firm response from across Europe to support the individual activities of member states and that the UK Government engages with this.

## **2.2 Reducing alcohol-related harm**

The BMA is concerned about the increasing level of alcohol use across Europe. Advertising strategies such as sponsorship of sporting and music events, as well as advertisements using celebrity endorsement all serve to reinforce a positive image of alcohol among young people and predispose them to start drinking well below the legal age to purchase alcohol. In its September 2009 report, the BMA called for a total ban on alcohol advertising and promotion and the introduction of minimum price levels for the sale of alcoholic products. The BMA believes that there should not be a reliance on voluntary codes to regulate the drinks industry as self-regulation is ineffective.

There is a clear need for stronger action on alcohol. One major plank of such action is to reduce its affordability. There is strong and consistent evidence that increases in the price of alcohol are associated with reduced consumption and alcohol-related harm at a population level. Heavy drinkers and young drinkers are known to be especially responsive to price. The Scottish and English proposals to introduce minimum pricing provide an ideal opportunity for the European Commission to demonstrate its commitment to improving the health of European citizens. Working with key European

stakeholders, the BMA will be lobbying the European Commission to secure its support for such proposals. This will also provide a clear signal of support to other Member States who are considering the need for a minimum price per unit

The EU alcohol strategy, which came to an end in 2012, was designed to help national governments and other stakeholders coordinate their action to reduce alcohol related harm in the EU. The strategy is an example of how the EU can have a positive role without the burden of legislation. Consideration is currently being given to what should replace the strategy and whether a new strategy should be established; the BMA would view the establishment of a new strategy as a positive step for all member states in reducing alcohol-related harm. Any new strategy needs to have a strong emphasis on regulatory action to reduce accessibility and availability, eliminate all promotional activities and limit industry involvement

In the UK the drink-driving blood alcohol limit is 80mg/100ml which is among the highest in Europe. It is essential that further measures are implemented to build on progress achieved over recent years in reducing the levels of drink-driving both in the UK and across the EU. The BMA calls for the EU to introduce a limit of no more than 50mg/100ml and to consider further reductions for all newly qualified drivers who are particularly at risk of alcohol-related road crashes as a result of their limited driving experience.

The BMA believes that the EU should be taking a stronger role in supporting member state actions to reduce alcohol-related harm. This would not only have significant public health implications but also reduce the high financial burden on health systems across Europe.

### **2.3 Tackling the obesity crisis**

The BMA is greatly concerned at the rising levels of obesity in the UK, particularly among children, and the significant health impact on the population. Tackling obesity requires commitment to a multi-disciplinary approach including the promotion of lifelong physical activity and an improvement in dietary behaviour. Improved and consistent food labelling is an important mechanism for enabling consumers to make informed dietary choices. The BMA was disappointed that in revising the rules on the Provision of Food Information to Consumers, the EU fell short of introducing a mandatory front-of-pack labelling scheme based on the traffic light scheme. The BMA has called on UK retailers to exercise their right to use this scheme on a voluntary basis but this is another example of where greater European involvement would have been of benefit to public health or where more responsibility should be taken at a national level to address the increasing obesity crisis.

Doctors have a key role in providing advice on dietary choices and physical activity patterns; this has to be supported by a comprehensive range of public health interventions to tackle the obesity epidemic. Addressing this key public health concern requires a comprehensive, EU strategy that promotes individual behaviour change across society as a whole, and seeks to remove or mitigate unhealthy and unhelpful influences

on behaviour. Central to this are policies that will create an environment that supports and sustains healthy eating and physical activity.

A coordinated approach is required to increase the popularity, understanding and acceptance of such policies among the general public across Europe. The consumption of saturated fat, salt and added sugar has been promoted by the ready availability of foods (often processed) and the voluntary commitment from the food industry to tackle these issues does not go far enough. The BMA would welcome greater influence from the EU in applying pressure on member states to introduce a legal obligation to reduce salt, sugar and fat in pre-prepared meals.

The BMA believes there is an urgent need to take action to create an environment that supports and sustains physical activity, and has repeatedly called for the UK Government to develop a strategy to encourage children and young people to take part in regular exercise and to increase and protect access to recreational facilities (eg public swimming pools and playing fields) regardless of socio-economic status and level of physical and psychological ability. The BMA would welcome the development of such a strategy at an EU level.

The Treaty of Lisbon, which entered into force on 1<sup>st</sup> December 2009, provides the basis for significant EU activity in this area as it can now support, coordinate and supplement the actions of Member States in the field of sport. The EU recognises the importance of physical activity in tackling the obesity crisis and has published EU Physical Activity Guidelines which recommend how policies and practices at EU, national and local levels can be used to make it easier for citizens to be physically active as part of their daily lives. The concept of health-enhancing physical activity (HEPA), covering a variety of sectors as diverse as sport, health, education, transport, urban planning, public safety and working environment, is another key pillar of EU policy and will be factored into future EU policy development across these sectors.

#### **2.4 Organ donation**

European legislation has contributed to ensuring high quality and safe standards for the donation, procurement, transportation, traceability and follow-up of human organs throughout the EU. Directive 2012/25/EU enshrined in legislation many of the systems and procedures that the UK had already been following. Whilst the Directive has introduced some additional requirements and bureaucracy this has been implemented in a sensible manner in the UK and does not appear to have been too onerous, although it is essential that this is monitored to ensure that this continues to be the case. If the EU was to consider any additional legislation in this area it would have to complement the systems that are already in place in the UK rather than introduce additional mechanisms. The BMA believes the role of the EU should remain within the confines of ensuring the quality and standards for organ donation. The UK must retain the right to control organ donation policy. Any significant policy change to increase organ donation rates will only succeed if it has both public and professional support and must be pursued carefully. It is essential that the UK maintains responsibility for public policy on organ donation.

## **2.5 Cross Border Healthcare**

The principle of subsidiarity needs to be respected with regards to cross border healthcare and it has to be acknowledged that EU healthcare systems differ across the 27 member states. In principle, patients want to and should be treated as close to home as possible. When it is not possible patients should have the option to travel to another EU member state for treatment

which is paid for by their home healthcare system providing greater choice for patients. Equality of access is a fundamental principle of healthcare systems and must be guaranteed.

The BMA believes that there needs to be a mechanism for sharing patient data between clinicians in both the patients' home country and the country where they receive treatment. Clinicians in both countries must be able to communicate effectively and to exchange medical records in the language of the patient's country of origin. Whilst high level recommendations are in place for cross-border interoperable systems the practicalities of delivering interoperable systems needs much more detailed consideration. There are also information governance and data quality issues which need further exploration. The BMA believes that a mechanism should be put in place in order to ensure that clinicians are able to systematically communicate in both the patient's home country and the country where they receive treatment and to exchange medical records in a language that is understood by both clinicians. Whilst the BMA welcomes EU initiatives such as the recent recommendation on the interoperability of e-Health systems and the related 'Smart Open Services' pilot project, we have concerns that e-Health systems will not be fully interoperable by the time that this Directive is implemented across the EU.

The BMA raised concerns when the Directive was revised that equal access to care abroad may be compromised by the need for a patient to pay up-front for care received abroad before seeking reimbursement. The BMA continues to have concerns regarding the possibility that healthcare may be more expensive abroad and that the patient would be expected to pay a 'top-up' in order to meet the costs. Whilst we agree with the principle that the level of reimbursement should be no more than the cost of treatment in the home healthcare system, we believe that the 'top-up' may have a negative impact on equality of access.

In the UK, the ability of NHS-funded patients to secure treatment abroad has implications for equity. Patients placed lower down a waiting list for reasons of clinical priority but who are willing to be treated abroad might not only get treatment more quickly than those higher up the list who prefer to be treated in the UK but, depending on reimbursement arrangements, might delay the treatment of UK patients. This directive must not compromise standards of care for people who choose to stay in their home country, or who are unable to travel abroad for treatment.

A further aspect of equity is that, under current NHS arrangements in the UK, patients in one part of the country are not free to seek treatment, as a matter of right, in another part

where waiting times are shorter. Yet they would be able to seek such treatment in another EU country. This is not only an anomaly, but also inequitable to those who might consider treatment elsewhere in the UK but who are denied that option by UK rules, and who for whatever reason will not contemplate seeking treatment abroad.

A further concern for the BMA is the lack of clarification regarding continuity of care. Whilst recognising the importance of continuity of care, we believe that the Directive does not adequately address the issue. Effective communication between clinicians and healthcare systems in both the sending and receiving countries must be ensured. Continuity of care should be ensured by a unified system of handover between clinicians as language problems and different decision making procedures may impact on patient safety. The BMA has particular concerns over the cross border treatment of certain illnesses such as mental health and chronic physical disability where the importance of the clinical relationship and knowledge built up over the course of several consultations cannot be overestimated. Patients must be aware of such concerns and they must be taken into consideration when opting for cross border treatment.

## **2.6 Health at the Heart of Drug Policies**

Drug policy has become an increasingly major topic for discussion following the Home Affairs Committee 2012 report *Drugs: Breaking the Cycle*, and the January 2013 All-Party Parliamentary Group on Drug Policy Reform publication, which called for a change of direction.

The BMA joined the debate by producing its own report- [\*Drugs of dependence: The role of medical professionals\*](#) that calls for health to be central in policies on illegal drug addiction. This reflects the view that the focus of drug policy as a crime prevention and law-enforcement issue has failed to deliver its intended goals of reducing illicit drug use. The report explores the role of medical professionals in dealing with illegal drugs of dependence. The BMA wants to reframe the debate to ensure drug policy is based on public health principles, and founded on rigorous scientific evidence.

The EU's policy in this area is detailed in the EU Drugs Strategy 2005-2012 which aims "to achieve a high level of health protection, well-being and social cohesion by complementing EU countries' national actions in preventing and reducing drug use, drug dependence, and drug-related harm to health and society". An external independent evaluation of the EU Drugs Strategy (2005-2012) is on-going and will inform the Commission's proposal for a new EU drug policy framework. The BMA supports the EU's efforts to support national activity, and would welcome further steps towards the adoption of a health-centred approach in the new drug policy framework.

## **2.7 Social Determinants of Health**

The BMA is committed to working on the Social Determinants of Health (SDH). Given that the WHO European Office has recently published the results of a review by Professor Michael Marmot and the UCL Institute of Health Equity on SDH across Europe the BMA

believes that the EU should make reducing health and wellbeing inequities a key element of its global health policy. We believe that a life-cause approach to this is essential and would commend a health impact assessment, looking particularly at the impact on SDH, on all new legislation, regulation and other EU wide policies.

### **3. Adapting to changes in national healthcare delivery**

#### **3.1 *Revision of the EU Data Protection Directive 1995/46/EC***

The BMA recognises that a comprehensive approach to data protection across Europe is necessary to take into account new technologies and the increasingly global nature of data flows. In January 2012, the European Commission proposed a comprehensive reform of European data protection rules, which will result in UK data protection law being directly updated. The proposed Data Protection Regulation will adapt the 1995 directive to take into account new data protection rights, developments in technology and the need for greater legal certainty.

It is a challenge to ensure that the benefits technology can bring to legitimate and appropriate information sharing are balanced with individuals' right to privacy and confidentiality. There can be a tension between ensuring respect for the rights to data protection whilst facilitating the free flow of personal data. The BMA is committed to ensuring that the highest standards of confidentiality in the use of identifiable health data are respected.

The BMA strongly supports the principles of the UK Data Protection Act 1998 and we believe that these remain valid as the backbone of the legislation in the UK. It is imperative that any changes to the legal framework do not undermine these principles. Our aim is to maintain the balance between confidentiality and allowing appropriate research to take place.

#### **3.2 *Clinical Trials***

The European Commission has published proposals for a new clinical trials Regulation in an attempt to remedy the problems of the 2001 clinical trials Directive. The main points of criticism relating to the current directive include the increased cost and reduced feasibility of conducting clinical trials. EU clinical trials legislation is an attempt to lay down common rules of procedure on aspects such as authorisation and performance of clinical trials, safety reporting, manufacturing and labelling of medicinal products used in clinical trials. The BMA is concerned by the lack of provision for clinical trials that go beyond the boundaries of the EU member states and include other nations. All clinical trials should be undertaken with the same rigour as those covered by the Directive otherwise it may be seen to be encouraging a two-tier system of research ethics. The World Medical Association Declaration of Helsinki, which is reflected in EU legislation, is widely recognised as the cornerstone document of research ethics and the global norm for protecting the rights and safety of research subjects.

#### **3.3 *Medical Devices***

It is imperative that protection of human health and the maintenance of patient safety are at the forefront of any change to the current legal framework. Following recent cases such as PIP implants and hip replacements it is essential to enhance transparency and ensure the safety of medical devices. With devices being used across Europe the approval process must be such that the quality of medical devices can be guaranteed. In 2008 when the Medical Device Directive was initially looked at the BMA raised concerns about expanding the scope of the legislation further to include products with no medical purpose such as cosmetic implants, tattoo equipment and other products used for cosmetic rather than medical purposes. Whilst we recognise the need to regulate such products in order to ensure consumer safety, this should be done under consumer law. To class such products as medical devices may impute a suggestion that such procedures are safe and medically sanctioned. It may also prompt consumers to expect such procedures to be classed as a medical procedure and to be included in a member state's package of healthcare.

### **3.4 Prescribing**

The BMA continues to have concerns regarding the interpretations of the European Medicines Directive 2001/83/EC on prescribing unlicensed or 'off label' medicines and the impact this Directive has in the UK. The BMA had hoped to see General Medical Council Guidance (GMC) guidance on prescribing off-label or unlicensed medication relaxed, in line with current medical practice in some areas, to enable doctors to prescribe a drug off-label where evidence shows it to be as safe and effective as a licensed alternative. The BMA is concerned that the decision to retain the old GMC guidelines, based on interpretations of the EU Directive, may prevent cheaper generic medicines being used off licence if a licensed medicine exists. The BMA is concerned about the impact of this Directive in the UK where use of generics is high, and the patient does not pay for the medicines directly. This situation is an example where EU regulations can have an impact on the rights of the UK to organise healthcare for UK citizens.

### **3.5 Public procurement and competition Jaw**

The Health and Social Care Act (2012) had radically reformed the NHS commissioning system. Both EU legislation and Government encourage commissioners to use procurement as a means to ensure competitiveness and plurality. Successive UK governments and the European Union (EU) have developed policy governing public sector procurement with the intention of ensuring cost-effective commissioning and increasing competition within public services. Procurement is governed by domestic and EU procurement and competition law, which outlines when procurement is appropriate and the process and timetables to be followed. Subject to these regulations, commissioners of NHS services may choose when to use procurement processes (they are not obliged to put every contract out to tender) but must be able to justify the decision taken. EU legislation distinguishes 'Part A' and 'Part B' services. Health and social care services are classified as Part Band subject to more flexible procurement rules and processes than Part A services. Non-clinical services, such as waste disposal, may be classified as Part A services and subject to more rigorous rules. EU procurement rules

pertain to public service contracts worth over £156,442. Department of Health procurement guidance stipulates that, in addition, all contracts worth over £100,000 (over the lifetime of the contract) must also be advertised and tendered.<sup>2</sup>

The BMA is concerned that the changes to the NHS in England may result in EU competition and procurement rules being applied to the publicly funded NHS. This could mean that bidders from across the EU would be given the same rights as local providers and that competition rules could apply to commissioning activities undertaken by clinically led consortia. The application of these rules could have significant implications for the stability of local health economies and the quality of patient care.

Value for money in public procurement is not achieved by giving preference to the most advantageous bid for a tender not least as it may undervalue quality of outcomes. Broader social, ethical and environment benefits should be considered in public procurement decisions. The provision of healthcare goods and services is big business; the NHS alone spends £30 billion on procurement every year. The market for such commodities is global, and increasingly is being outsourced to minimize costs. There is evidence that such outsourcing is harming basic labour rights, and also the health of populations elsewhere. This is not just an issue in the UK and the BMA believes that more should be done to change procurement practices and that this should be supported at a European level to support those that are already changing their practices and to recognise this. Effective ethical procurement is not easy and needs commitment from many levels; a commitment from Europe would be a positive driver for change. The International Market and Consumer Protection Committee is currently discussing amendments to the Public Procurement Directive. The BMA is heartened to see that support is growing for an amendment to the Directive that would see procurement contracts going to the most 'advantageous'

bidder, assessed on environmental or social criteria, not just the lowest bidder.

## **Conclusion**

The BMA is committed to improving the health of the UK citizens and welcomes EU activities which complement UK government work in this field. Future policy developments in this sector should continue to respect the principle of subsidiarity and the right, enshrined in the EU Treaties, of Member States to organise and finance their healthcare systems according to national practices.

The BMA believes that the European Union has a crucial role to play in safeguarding patients' interests and guaranteeing quality standards of care. The BMA will continue to engage proactively with European policymakers in order to protect the rights of both patients and health professionals, and to promote the highest possible standards of public health.

The continued improvement of health is of the utmost importance and, within the aforementioned parameters, the BMA calls on policymakers to work towards creating a safer, healthier Europe.

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<sup>1</sup> Procurement Guide for Commissioners of NHS-funded Services (Department of Health, 2010)

## British Nutrition Foundation

Please find below the British Nutrition Foundation's response to the consultation on the Balance of Competences Review.

The British Nutrition Foundation (BNF) was established over 45 years ago and exists to deliver authoritative, evidence-based information on food and nutrition in the context of health and lifestyle. BNF's work is conducted and communicated through a unique blend of nutrition science, education and media activities. BNF is a registered charity that attracts funding from a variety of sources, including contracts with the European Commission, national government departments and agencies; food producers and manufacturers, retailers and food service companies; grant providing bodies, trusts and other charities. Further details about our work, governance and funding can be found on our websites.

*We note that food is a shared competence within European treaties and because the EC has legislated extensively, existing EU food law leaves the UK with comparatively few opportunities to regulate nationally. Please note that we have commented just on the sections we felt were relevant to our expertise, namely section 5 on **Nutrition and food labelling** and section 17 on **Health research**.*

## 5. Nutrition and food labelling

### BNF Comments

- On balance, it is beneficial for both consumers and industry that regulation on nutrition and food labelling is controlled at an EU level as this helps to ensure consistency in the approach across member states.
- But there have been a number of issues with the nutrition and health claims regulation that may have had a negative impact on UK food businesses and on nutrition research.
- The food information regulation allows for national schemes e.g. for front of pack labelling. But it also prescribes against the use of terms that are in common use currently in the UK. The UK has been leading the way regarding provision of front of pack labelling and progress made to date with consumer understanding of on pack nutrition information may be compromised by the need to conform regarding use of the term GDA and the use of kilojoules rather than calories.
- While non-regulatory initiatives such as the EU platform for diet and health are potentially positive for the UK, we as an organisation have found it difficult to engage with them.

### **Legislation**

**Nutrition and health claims** in the UK are controlled by regulation EC 1924/2006. Previous to this regulation, there was no regulatory control of claims made on food in the UK, beyond the general responsibility of businesses not to mislead consumers, although there were voluntary guidelines developed by the Joint Health Claims Initiative (JHCI) for the UK. There is a clear benefit for the UK in being part of Europe-wide regulation of nutrition and health claims in terms of ensuring the scientific validity of claims and to support consumer confidence in claims, which

evidence suggests was low prior to the regulation<sup>13</sup>. This is also important in creating a level playing field for products that are exported to Europe by UK companies and imported into the UK. It is likely that many UK companies were already applying good practice in relation to nutrition and health claims as guidance from JHCI was available, which may not have been the case in many other member states.

However, there have been a number of issues with the implementation of the regulation that may have had a detrimental impact. An initial lack of guidance for those wishing to make claims meant that applications were not always made appropriately – and this has made the approval process for claims long and much more complex than may have been anticipated, with the potential unintended consequence of diverting businesses away from investing in research on nutrition and health and reducing innovation. There is also concern about the large number of claims, botanical claims in particular, which are currently ‘on hold’. These claims can still be made and are not subject to the controls that apply to rejected claims and so creates a loop hole that is not conducive to a ‘level playing field’ on health claims in Europe.

Food manufacturing is a source of many jobs in the UK and it is important that businesses have the support they need to remain operational in the UK and experience an environment that supports innovation. The British Nutrition Foundation (BNF) is currently involved in an EC Framework Programme 7 project *Bacchus*<sup>14</sup> to help address this in the area of cardiovascular health claims on polyphenols and bioactive peptides. Efforts have been made by the EC and EFSA to engage with stakeholders and it is important that this work continues with stakeholders in the UK, to help overcome some of the barriers that have been encountered. There is also the issue of the nutrient profile referenced in the legislation which, despite being scheduled for 2009, has yet to be finalised. UK consumers and businesses are dependent on the EC and EFSA to develop an appropriate model and it is vital that the UK is engaged with this process.

Other pertinent legislation is the European regulation on the **Addition of Vitamins and Minerals to foods**. This provides helpful guidance to UK food businesses on the amounts and formulations of vitamins and minerals that can be added to food, ensures this is harmonised within the EU and protects UK consumers from inappropriate addition of micronutrients to foods. However, to our knowledge, maximum levels have yet to be set and it would be helpful to UK stakeholders to have this in place. A difficulty for the UK in relation to EC regulation as described here, and in relation to nutrition and health claims, is that when implementation of certain areas is subject to a significant delay, the UK (and other member states) is left with a vacuum where there are no rules relating to these issues, yet at the same time, the UK cannot develop its own framework to address this because food is a shared competency in European treaties.

The new **Food Information for Consumers** regulation brings together food labelling regulations that were previously covered by a number of EC regulations. It makes nutrition labelling on back of pack compulsory from 2016 and sets out the format for voluntary front of pack nutrition labelling. The impact of this change in European regulation may be different for

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<sup>13</sup> Food Standards Agency (2007) *Review and Analysis of Current Literature on Consumer understanding of Nutrition and health Claims Made on Food*. London, <http://www.food.gov.uk/multimedia/pdfs/healthclaims.pdf>

<sup>14</sup> <http://www.bacchus-fp7.eu/>

the UK compared to other European member states, as both back and front of pack labelling was already widespread in the UK and a number of front of pack labelling schemes have already been in use in for some time. Harmonisation of nutrition labelling in Europe is likely to be positive for the UK as it will create a level playing field in terms of business and also the information provided for consumers. The regulation has also precipitated a move within the UK to harmonise the different front of pack labelling schemes which are currently used by retailers and manufacturers. However, the UK has been at the forefront of applying nutrition labelling in Europe, and the implementation of the regulation within the UK is creating challenges. While national schemes are accommodated in the articles on front of pack labelling, it is likely that the term 'Guideline Daily Amount', which has been used for 10 years or more in the UK, can no longer be used and will be replaced by the term 'Reference Intake'. It is likely that UK consumers will find the change in terminology confusing.

Overall, in relation to EC regulation of nutrition and food labelling, this is beneficial to the UK in terms of harmonisation and consistent standards. However, the position of the UK as one of the leaders in Europe on providing accurate information on the nutritional content of foods may actually put us at a disadvantage in some cases. In addition, significant delays to some parts of regulation in this area are going to have an impact on UK business and consumers.

**A new PARNUTs proposal** had recently been circulated and we agree that the proposed scope seems reasonable. Having a consolidated 'Union List' of substances that may be added to foods and the interpretation procedure is a positive step and the control of gluten free foods by the FIR and this regulation seems appropriate. We would also agree with the changes regarding dietetic foods, slimming foods, foods for diabetics, sports drinks and milk-based drinks for children.

### **Non-legislative action on nutrition**

We are aware of various activities, in particular DG Sanco's EU platform for action on diet, physical activity and health. However, despite being an organisation focussed on nutrition and health and as a participant in several EC-funded projects in this area, we have found it difficult to engage with and contribute to these activities. We welcome the voluntary initiatives on, for example, salt reduction, although it is likely that the UK is ahead of much of Europe in this regard. Perhaps if UK organisations such as ourselves could engage more with these platforms we could do more to feed into such programs and offer experience in areas where the UK has done more.

### **17. Health research**

We note that the Framework Programme is the main mechanism used by the European Commission to fund research across Europe, including health-related research and that negotiations for Horizon 2020 (which will replace FP7) are on-going.

In the 'Life sciences, genomics and biotechnology for health theme' of FP6, UK researchers have been effective in winning Framework Programme funding. For example, the UK received 16% of the total available funds (€380 million)

- The British Nutrition Foundation (BNF) has a longstanding involvement with European Commission (EC) funded projects (see examples below), going back to FP5, and EC funded projects provide a substantial proportion of BNF's project income.
- EC funded projects are an integral part of BNF's activities. Engagement with consortia over the past 10 years or so has allowed us to establish a wide network of European contacts and to promote the activities of the Foundation to stakeholders across Europe, and we are a sought after partner for our skills in the dissemination of nutrition information.
- EC funded projects are essential to enabling the integration of research within the EU. The opportunity for UK charities and SMEs to bid for EC funding is particularly important at a time when research funding from UK sources is increasingly scarce.
- We are also keen that UK organisations continue to be involved in EU-funded project work beyond the FP7 programme, with the new EC research programme, Horizon 2020.

### ***EuroFIR***

BNF was involved in the EC Framework Programme 6 (FP6) EuroFIR (European Food Information Resource) Network of Excellence, which ran from 2005-2010. BNF is now part of the extension to this work, EuroFIR Nexus funded under Framework Programme 7 (FP7), which began in April 2011. This builds on the previous work which created an online portal to all available online food composition data sets, both in Europe and internationally and created the non-profit organisation EuroFIR AISBL, based in Brussels. BNF has been responsible for dissemination and communication for both the FP6 and FP7-funded EuroFIR projects.

### ***ProSafeBeef***

BNF has had a supporting role in the dissemination activities for ProSafeBeef, a 5-year EU sixth Framework Integrated Project, which involves 41 leading research and industrial organisations across Europe. Through research and innovation, the aim of ProSafeBeef was to advance beef safety and quality across Europe. This project came to an end at the end of 2012.

### ***CommFABnet***

BNF began work on the CommFABnet project in January 2012, alongside four other partners. The aim of this project is to communicate the results of European research in the areas of food, agriculture, fisheries and biotechnology (funded under the FP6 and FP7 programmes of research) to stakeholders throughout the continent. This project will run until 2014 and provides various free services to FP6 and FP7 projects to support the communication of research results, such as media training, and dissemination activities aimed at different audiences, including the general public, young people and policy makers. BNF leads on the workpackage that targets young Europeans and has a joint role in leading on the dissemination workpackage.

### ***Bacchus***

Bacchus is the most recent project in which BNF has gained involvement. The aim of this project is to provide evidence to underpin health claims relating to beneficial effects of polyphenols and bioactive peptides on cardiovascular risk factors. This project runs for four years and involves 28 partners across Europe, including 15 SMEs. BNF's role is to monitor the progress of the health claims regulation and develop best practice guidelines for researchers doing studies on the health effects of polyphenols and bioactive peptides, with a view to making an application for a health claim evaluation.

### ***New applications***

We are part of 2 consortia bids submitted for FP7 funding in January 2013.

## British Society for Histocompatibility and Immunogenetics

### How does the EU's competence in health affect you/your organisation?

The EU's competence in health does not adversely affect Histocompatibility and Immunogenetics Services within the UK.

### What evidence is there that EU action in health advantages or disadvantages:

- **The UK national interest**
- **Business and industry**
- **Patients and citizens**

### Please consider what evidence there is to demonstrate;

- **The extent to which the EU's role in public health supports member state actions effectively and efficiently**

No comment.

- **The opportunities and costs for the delivery of health and social care in the UK that flow from wider EU competences and policies such as the free movement of workers or the single market generally**

Section 13.2 describes the Directive on recognition of professional qualifications facilitating the free movement of regulated professionals within the European Economic Area. Within Histocompatibility and Immunogenetics, progress has been made through the European Federation for Immunogenetics in the establishment of a novel European qualification in Histocompatibility which will be equivalent to the existing Fellowship of the Royal College of Pathologists in Histocompatibility and Immunogenetics (ESHI Diploma). This will demonstrate equivalence at this professional level between health professionals in Histocompatibility and Immunogenetics. There will be no financial implications with the introduction of the ESHI Diploma as the FRCPATH in Histocompatibility and Immunogenetics is a mandatory qualification for laboratory directors within the discipline.

Section 3 discusses Medical devices, including in vitro diagnostic devices. In 2010, the IVD Directive became operational. The Global Harmonization Task Force (GHTF) published a risk based classification system which classified HLA typing reagents as a Class C risk and outlined specific exemption for "in house" tests (<http://www.ivdtechnology.com/article/revision-europe%E2%80%99s-ivd-directive-9879ec>). Such "in house" reagents are subject to rigorous validation, verification and quality assurance testing required to maintain laboratory accreditation. It is essential that these tests retain exemption from the requirement for CE marking for two reasons:

1. In many cases, reagents of an equivalent quality and scope are not available commercially.
  2. No financial resources exist to cover the cost of CE marking all "in house" assays used within a laboratory providing Histocompatibility and Immunogenetics Services. This would have a significant impact upon the commissioning of services within the UK.
- **The extent to which EU competence and policies intended to allow EU citizens to access healthcare across the EU are effective and proportionate**

Section 4 describes the remit of the EU Blood, Tissue and Cells and Organ Directive, which is welcomed by the British Society of Histocompatibility and Immunogenetics and will present no problems to current clinical practise in the UK.

- **The extent to which health objectives are effectively and proportionately taken into account in wider EU policies**

No Comment

**Impact on the National Interest:**

**How does the EU's competence in health affect you/your organisation? What evidence is there that EU action in health advantages or disadvantages:**

**- The UK national interest**

Health care costs in the UK amount to nearly 20% of public expenditure. Strategic actions taken at EU level (in particular, e.g., actions targeting "Healthy Aging", neuroscience, dementia research, etc.) should help to reduce UK costs.

**- Patients and citizens**

The most important health benefit to UK citizens arising from EU membership is the provision of greater individual choice. This choice is particularly evident in the ready availability of advanced scanning (such as PET or MR scanning) in our near neighbours. Further choice is provided by the availability of capacity for operations such as hip replacements (where waiting lists are sometimes long). This availability of choice reduces the pressures on the NHS and should encourage emulation (of best practise) where it makes sense.

**Please consider what evidence there is to demonstrate:**

**- The extent to which the EU's role in public health supports member state actions effectively and efficiently**

The EU Medicines Agency through its efficient (central) scientific assessment of pharmaceuticals provides the bedrock information regarding pharmaceutical provision by the NHS. Replicating such an agency at national level would be costly and less efficient. The work of the EMA is enhanced through the Commission's research programmes on innovative medicines.

**- The opportunities and costs for the delivery of health and social care in the UK that flow from wider EU competences and policies such as the free movement of workers or the single market generally**

CT and MR scanners were invented in the UK but are no longer manufactured there. The opportunities provided through the EU Single Market for joint ventures etc. should be exploited more aggressively in the health care equipment sector where too often the rewards from UK research go elsewhere.

**- The extent to which health objectives are effectively and proportionately taken into account in wider EU policies**

The health objectives are manifest in the REACH Regulation (chemicals) – particularly in the way in which the Regulation deals with CMR chemicals (carcinogenic, mutagenic and reprotoxic) but also in the case of the various food laws (health claims, food additives, etc.) and

the various environmental actions that have been taken at EU level (air pollution, pesticides, smog, etc.).

**Future options and challenges:**

**- How might the UK benefit from the EU taking more action in health?**

Reducing costs; enhancing health in old age, cancer research at EU level, actions towards supporting the development of orphan drugs, etc.

**How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?**

**- Could action be taken at any other international level i.e. by the WHO?**

These are not mutually exclusive. Subsidiarity should be the guiding principle. A good example is the Commission's decision to review EU pollution laws in the light of recent WHO research indicating links between air pollution and a range of health conditions.

## Cancer Research UK

Every year around 300,000 people are diagnosed with cancer in the UK. Every year more than 150,000 people die from cancer. Cancer Research UK is the world's leading cancer charity dedicated to saving lives through research. Together with our partners and supporters, Cancer Research UK's vision is to bring forward the day when all cancers are cured. We support research into all aspects of cancer through the work of over 4,000 scientists, doctors and nurses. In 2011/12 we spent £332 million on research. The charity's pioneering work has been at the heart of the progress that has already seen survival rates in the UK double in the last forty years. We receive no government funding for our research.

The EU has an extensive remit in both funding research projects within Member States along with providing legislation to regulate it. It similarly has a role in legislating in some areas that affect health matters, although many areas of health remain national competencies. With regards to the EU competencies regarding health systems, we view this as a national issue and that it should remain so.

Cancer Research UK focuses on specific key issues that directly affect cancer patients or the research that we fund and have therefore focused our response on these issues. We have taken a leadership role in a number of areas, such as clinical trials and tobacco, and also undertaken efforts to coordinate a UK position and facilitate the sharing of information as believe this is useful to supporting UK health and science policy. We have done this through joint statements, involvement in pan-European groups such as Smoke Free Partnership and the European Public Health Alliance and the establishment and running of the EU-UK Health and Science Policy Group, which we established and has met once a quarter for the last two years for UK organisations to meet and share information about EU-related issues.

### **Research Funding**

Cancer Research UK funds research into all aspects of cancer from exploratory biology to clinical trials of novel and existing drugs as well as epidemiological studies and prevention research. We support research in a variety of different environments, including university research groups, core funded Institutes, and the Cancer Research UK Centres. We receive no Government funding for our research but some researchers we fund may receive funding from other sources, such as EU Framework Programme funding.

Research depends on co-operation across the scientific communities internationally. With cancer research and treatments becoming increasingly specialised, it is necessary for international teams to engage in collaborative working to share knowledge but also to achieve the number patients necessary to run clinical studies. EU legislation can promote harmonisation and some issues require international cooperation.

The EU funds substantial amount of research, as well as supporting cooperation and data sharing. The UK is also one of the primary beneficiaries of EU research funding and while

Cancer Research UK does not receive EU funding directly, the funding supports the wider research environment in the UK in which Cancer Research UK operates.

### **Clinical Trials**

The European Clinical Trials Directive was agreed with the intention of providing a standard for clinical trials in terms of both quality and safety. However, the Directive significantly increased the time lines and costs for setting up clinical trials in Europe. The need to revise the Clinical Trials Directive has been widely accepted.

We therefore welcomed the proposal for a Clinical Trials Regulation released by the European Commission. The Regulation appears to improve the legislation associated with running clinical trials. This will give researchers a better framework for developing and testing treatments, to benefit patients across Europe, while maintaining the high standards of patient safety that currently exist in European clinical research. The harmonisation of clinical trials legislation and the streamlining of the application process for starting trials should particularly benefit the set up and running of multi-national trials in Europe. The proposed Clinical Trials Regulation builds on the existing directive, while also addressing criticisms of the Directive and promises a much more efficient system. A regulation in this instance, which will ensure proper harmonisation across the EU, seemed the most appropriate legislative tool (rather than a new directive).

The UK was not the only Member State which raised serious concerns with the Clinical Trials Directive. Cancer Research UK worked with other over 25 national and pan-European bodies to produce joint statements calling for changes to clinical trials legislation which have proved to be effective tools. Cancer Research UK managed to work with other European groups to influence the Commission to adopt changes to the legislation which they believed to be solely UK issues. For example, co-sponsorship – a model used by the NHS and UK academia – was initially going to be excluded from the new Regulation, but through close working with European institutions and other organisations, the measure was maintained and enshrined in the draft legislation (subject to agreement in the European Parliament and Council).

### **Tobacco**

In terms of tobacco issues, we support the separate submission that has been made by Action on Smoking and Health (ASH). In summary, measures introduced by the EU which help reduce smoking prevalence benefit the UK national interest, business and industry, patients and citizens. Reducing smoking prevalence is a UK government objective as smoking kills around 100,000 people each year and smoking related-diseases disable many more.

Smoking remains the major cause of preventable premature death in the UK killing more people than the next six causes of preventable premature death put together.<sup>15</sup>

### **Data Protection**

The proposed Data Protection legislation demonstrates some of the difficulties with working with large pieces of legislation that cover the areas of several government departmental areas. The

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<sup>15</sup> Healthy Lives, Healthy People: A Tobacco Control Plan for England. DH March 2011.

legislation has been treated primarily an issue for justice ministries but data protection is also an issue that affects patients in both health and research settings. The broad nature of the data protection proposals means that it can be difficult to communicate the importance of research issues within the broader context of the legislation. We understand that the Department of Health has taken a leading role in this issue within Government, working closely with the Ministry of Justice, which we welcome.

### **Physical Agents Directive**

The introduction of the Physical Agents Directive was intended to protect workers in jobs where there was a potential exposure to radiation. The Directive, if it had been fully implemented, would have had the unintended consequence of suppressing the use of MRI in hospitals. The UK cooperated with other Member States to achieve a derogation on the implementation of the legislation and continues to work towards an exemption for medical use. This was a very unusual case in EU legislation, highlighting the impact of legislation where proper consultation has not been undertaken.

## Care Quality Commission

Many thanks for the opportunity to respond to the DH consultation. Also thank you for the support provided by the DH EU policy team in providing briefing at a meeting on 9th February for CQC and for organising the workshop with other Arms Length Bodies on 12 February to discuss the issues that might inform the response.

In terms of background on the activities of the Care Quality Commission we are the single regulator across health and adult social care created in April 2009, following the passage of the Health and Social Care Act 2008. We operate a single system

of regulation and a common set of standards that all organisations providing care have a legal duty to meet. In addition we have duties to protect detained and compulsory patient under the Mental Health Act. In implementing those changes over the past three years we have brought more than 40,000 hospitals, care homes, providers of care at home and dentists into the new regulatory system by

registering them against the new standards. Around 10,000 GP practices and other primary medical services will join them from April 2013

We have consulted widely with colleagues across CQC about how to respond to this consultation. However we have concluded that in general CQC has a limited contribution to make to the consultation because:

1. CQC works in a legal framework determined mainly by UK law rather than EU law
2. CQC does not have direct and frequent contact with EU bodies, and any contact on regulation and other issues with the EU is through either the Department of Health or other bodies such as the Health Protection Agency
3. CQC does not have practices that the EU commission currently wants to spread across Europe, such as those of NICE, so the Commission takes little direct interest in our work
4. We do not currently work through EU groups to share information and expertise, as when we do this we build direct links with other international organisation directly or through being members of other European bodies such as such as EPSO (a group of European regulators who share learning about their practices).

Also there are problems for CQC, which may be shared by other Arms Length Bodies, in identifying evidence. This is because of the problems in separating the impact of the UK from the EU e.g. would the activity have occurred anyway in the UK without the EU? This makes it difficult to answer some of the questions without making major assumptions.

On the first set of consultation questions on the current impact of the EU on UK national interests.

- How does the EU's competence in health affect you/your organisation?
- Our general answer, given the points made above, is that we think the EU competencies have had little impact on CQC. Below are some more detailed responses on the individual competencies.
- Our view on the impact of the EU on CQC's work on human rights and equality is that it is difficult for us to assess any impact. This is because:
- The UK is subject to the UN Convention on Human Rights, whether or not it is a member of the EU, and although there are detailed points of difference between the UN and EU legislation the broad principles are similar. So there are likely to be few main differences in the legislative framework within which CQC works if the UK was not subject to EU law.
- The European Convention on Human Rights is given effect in UK law in the 1998 Human Rights Act. This UK Act is what CQC uses to test that providers are compliant with standards of care relating to issues such as respect and dignity of people receiving care. So CQC does not directly use EU legislation.

Our views on the specific capabilities are below:

1. NHS and patient services - implications for employment policy including the Working Time Directive.

On the European Working Time Directive (EWTD) the motive for limiting hours was to ensure patients were not being treated by tired doctors. The directive should have had this effect but we know that many doctors still work long hours as the timings are averaged over 26 weeks! This flexibility is used to overcome short rotas where doctors are off sick or on leave. The major concern is that doctors

working reduced hours are not receiving sufficient training and experience. This is especially so during night shifts when seniors are not present.

Cover by several trainees over several shifts leads to the need for frequent handovers. These are a hazard to good communication and if not handled well, may lead to errors of omission and confusion. Good practice guidance for handover does exist but is variably implemented.

In summary CQC's position is that in spite of the EWTD, doctors may continue to work long hours without sufficient breaks. Second, the doctors of the future may be insufficiently trained in some specialties where 'being there' is vital to experience and teaching. There are of course no easy answers to this, though in some EU countries they 'bypass' the regulations by treating service delivery and education via separate contracts that are merged and worked flexibly. So 48 hrs service+ 12 hours education = a 60 hour week.

2. Radiation -an EU Recommendation provides that Member States should keep public exposure to non-ionising radiation below international guidelines.

There appears to be confusion in the consultation document between non-ionising radiation - perhaps it is a typo error. The information in the box relates however to radiation workers or members of the public (i.e. not patients). The radiation regulations for workers and the public are enforced by the HSE (they enforce the IRR'99 regulations); IRMER regulations cover patients -and CQC is the current enforcement authority in England for IRMER. DH themselves are the policy holders for the IRMER regulations. The IRMER regulations are derived from a European Directive 97/43EEC which is itself derived from recommendations made by the International Commission on Radiological Protection, ICRP.

Given that your request was based on public exposure (which we do not enforce) we will not attempt at a reply as this is the Health and Safety Executive's responsibility.

Therefore for its IRMER inspections CQC does work in a legal framework which is strongly determined by the EU that has direct impact on the work of CQC. However CQC has no direct and infrequent contact with EU bodies, as the Health Protection Agency manages the direct relationship with the EU. CQC has a desire to participate in European conference and training events to share methodologies, for instance on investigating errors in radiology departments, but we have not been able to achieve this so far as the Health Protection Agency tends to lead on negotiations in Europe on behalf of the Department of Health and CQC.

3. Public health programmes including Joint Action on Mental Health and Wellbeing and Drug Misuse.

On Drug and Substance Misuse CQC's legal framework is driven by UK not EU law and this also applies to policy issues around substance misuse. The

UK government published the Drug Strategy in 2011 and the Alcohol Strategy in 2012 and this is what providers take into account and what we, CQC, consider as part of our work.

#### 4. Organs, blood, tissues and cells.

We do not believe that any EU Policy in respect of organs, blood and tissue directly (or indirectly) affects CQC.

The standards being referred to in the document (section 4) are covered by Human Tissue Authority (HTA) requirements and we know that NHS Blood Transplant Authority and providers involved in organ donation/ transplantation have to comply with these HTA requirements- including appropriate testing to make sure donated products are safe and to make sure people donating are fit to do so. At the moment the regulation of the management of the supply of blood and blood derived

products is regulated by both HTA and CQC. As part of the review of regulation we know that DH are almost certain to propose that this dual regulation ceases and as such its likely that CQC will not have the responsibility of regulation management and supply of blood and blood products and tissue after Autumn 2014.

In addition any testing to make sure organs, blood or tissue is free from disease and safe for donation is considered part of the regulated activity of management of supply of blood and blood derived products etc. This is because the testing is an activity that is ancillary, or subordinate, to the activity of the management of supply of blood and blood derived products etc. In any case its right that we currently inspect laboratories; however this may change in future because as part of the review of regulations we know that DH are almost certain to propose

that laboratory type procedures are not a regulated activity in their own right- but rather ancillary to a persons treatment.

#### 5. Free movement of persons within the EU- mobility of healthcare professionals.

This notoriously allowed Dr Ubani to arrive in England from Germany as a iocum GP and administer morphine (with which he was unfamiliar) at many times the maximum dose leading to a patient's death. Pre-employment checks were inadequate and his knowledge of English was poor. At the time the General Medical Council (GMC) was powerless to restrict the registration of EEA registered doctors and were not allowed to test their language skills. Doctors

applying for GMC registration from outside the EEA & Switzerland, are required to take a language test (as part of PLAB, the Professional and Linguistic Assessment Board). This includes graduates from Australia and NZ whose first language is English.

However on 23 January 2013, the European Parliament voted on the Recognition of Professional Qualifications Directive. This included three issues which have a major impact on the regulation of doctors in the UK. The outcome was positive in each case:

1. Maintaining the proposed length of basic medical training at five years (all UK programmes will be compliant).
2. Giving clear powers to the GMC and other regulators to test the language skills of EU health professionals after recognising their qualifications, but before giving them access to the profession.
3. Requiring regulators to circulate information about fitness to practise cases, including where they have erased professionals or put conditions on their practice.

The European Council of Ministers will consider the proposed Directive in the next few months and, thereafter, member states will have two years to bring the changes into national law.

Of course employers remain responsible for ensuring that their staff are competent and fit to practise and CQC has a role in ensuring that they are compliant in this.

#### 6. eHealth e.g. telemedicine.

On telemedicine CQC has been in lengthy discussion with a number of bodies in relation to this, including the Royal College of Radiologists, Academy of Medical Royal Colleges and the British Medical Association. Professional bodies are anxious to ensure that doctors providing services from abroad using telemedicine are of equal competence to those who are licensed to provide them in UK. The law

largely prevents GMC and CQC from ensuring this. CQC has stated that it expects any secondary commissioning of care by a CQC-registered provider to be provided by similarly competent staff. Those services offered directly via the internet will fall outside of this scope and so patients who choose to use them risk poor quality. Many such services are provided from outside the EEA especially in relation to provision of drugs.

CQC has no specific comments on the following questions:

- What evidence is there that EU action in health advantages or disadvantages:
  - o The UK national interest?
  - o Business and industry?
  - o Patients and citizens?
- How might the UK benefit from the EU taking more action in health?
  
- How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?
  
- How could action in this area be undertaken differently in your area of interest?

We hope that the Department of Health find these comments helpful in their analysis of the evidence for the impact of the EU on the UK health and adult social care.

## **Foreword**

The NHS is rightly a treasured national institution in our Country.

Unfortunately, it is being damaged by the unforeseen consequences of EU legislation.

The Working Time Regulation, and in particular the SiMAP and Jaeger rulings of the European Court of Justice, are having a negative effect on junior doctor training, the continuity of patient care, waiting lists, NHS finances, acute specialties and doctors themselves, who report a negative impact on their working practices and fatigue.

Although valuable in promoting the exchange of healthcare professionals across the Union, the EU's directive on professional qualifications has led on occasion to doctors with insufficient language skills being able to practice in the UK, which has led to a number of serious incidents. This paper presents a robust analysis of these issues, and proposes a number of practical solutions that the UK could deploy. It draws on the contributions of the Royal College of Surgeons, the Royal College of Physicians, the Association of Surgeons in Training, the British Medical Association, the General Medical Council and other professional bodies during a roundtable in July 2012.

It is the responsibility of all politicians to ensure our healthcare system puts patient safety as its principal objective. EU regulation is failing to do that. The irony that a piece of health and safety regulation, the Working Time Directive, is now endangering patients should not be lost. And these impacts are all unintended. The EU has no competence over healthcare.

Whether europhile or europhobe we must object to the unintended consequences of legislation that puts patients at risk.

Andrea Leadsom MP Charlotte Leslie MP

## **Executive summary**

Despite the fact that the EU treaties establish that it is the member states that have the responsibility for "the management of health services and medical care",<sup>1</sup> EU law still has a profound impact on the NHS.

EU legislation has had unintended negative consequences for the NHS, in part due to the particular structure of the NHS, which often differs to continental models of healthcare provision. The EU's impact on the NHS is particularly significant in the areas of staff qualifications, training and continuity of care, and has been shown to impinge on patient safety.

Although the NHS, like any large organisation, is affected by a broad range of EU regulations, this briefing will focus on two areas – the Working Time Directive and language testing of foreign doctors - and look at potential solutions to the problems faced.

## **The Working Time Directive (WTD)**

The WTD's basic provision, limiting a working week to 48 hours, was introduced in 1998, following the UK Government's failed attempt to block the proposal in the EU's Council of Ministers. Through subsequent amendments, the Directive now applies to almost all workers in the UK across all UK industry sectors.

As of 2009 the WTD now extends to all doctors and doctors in training except for those senior enough to set their own hours. In addition to the limit to 48 hours, the WTD also provides for mandatory break periods.

Two rulings of the European Court of Justice (SiMAP and Jaeger) have compounded the impact on the NHS by reducing doctors' flexibility as to when they take breaks, and deciding that time spent asleep, while on call within a hospital, should count as 'working time'. These rulings have severely disrupted doctors' working patterns and the ability of hospitals to organise rotas.

The WTD has had a serious and negative effect on the NHS in a way that even those who agreed it did not expect or intend. It has had a negative effect on junior doctor training, the continuity of patient care, waiting lists, NHS finances, acute specialties and the doctors themselves, who report a negative impact on their working practices and fatigue.

The WTD has led to junior doctors finding it hard to complete the hours needed for their training, with 84% saying they have had to come in during their spare time to make up hours and 86% saying it has led their “work-life balance” to deteriorate. Two thirds of surgical trainees reported deterioration in the quality of their surgical training as a result of the WTD.<sup>2</sup>

The Royal College of Surgeons has estimated that the WTD has led to a loss of 400,000 surgical hours per month. Likewise, the BMA has calculated it has led to the equivalent of the loss of up to 9,900 doctors. This adds additional costs to the NHS as new doctors have to be recruited to fill these hours.<sup>3</sup>

The application of the WTD has led to disruption in the continuity of patient care and an over reliance on handover notes. This has led to a number of publicised failings in NHS care including cases where the WTD has been cited by coroners as contributing to patient deaths.<sup>4</sup>

The UK is not alone in suffering the effects of the WTD, receiving support in raising concerns from a number of other member states. The European Commission has also realised that there is a need to remedy the worst aspects of the Directive, but due to the EU decision making process, including the intransigence of the European Parliament in relation to it, it is almost powerless to act.

The WTD’s negative effects on the NHS cannot be ignored. If action is not taken, patient care will continue to suffer, with potentially disastrous effects in terms of insufficiently trained doctors, patient care and cost.

#### *Possible solutions*

It is clear that the UK would benefit from changes to the WTD. A desired outcome could involve a limited change such as a reversal of the two ECJ court cases, a higher limit on hours (c.60 hours), or a full opt-out from EU social legislation. Possible solutions to the problems of the WTD include:

- 1) Continue attempting to seek agreement at an EU level to amend the WTD and/or reverse the two court cases.
- 2) Attempt to avoid the Directive or manage a non-compliance with the rulings.
- 3) Seek a treaty change to opt-out completely from EU social and employment legislation.

#### **Language testing**

The EU’s Directive on professional qualifications has led the NHS to treat doctors from the EU differently to doctors coming to the UK from outside of the EU. Whereas those wishing to practise in the UK from non-EU states have to demonstrate a use of the English language before being placed on the General Medical Council’s (GMC) register, those from the EU do not.

The current system for doctors coming in from the EU, who make up 10% of all UK doctors, is that they can automatically have their medical qualifications recognised regardless of their standard of English and are then placed on the GMC’s register. It is then up to the individual hiring hospital to ensure that the doctors they hire have sufficient English language skills. Systematic language testing is prohibited.

This has led to a number of serious incidents including death resulting from doctors with insufficient language skills slipping through the net. This is particularly the case with regard to

locum doctors put forward by agencies at short notice.<sup>5</sup>

This problem is partly due to the system of registration in England and Wales, which differs to those in other EU member states in that there is no formal separation between registration for medical practice and recognition of qualifications.

There are a number of things that can and in some cases are being done in the UK to boost the GMC's powers and increase accountability for language testing. Negotiations on the Directive are also underway at the EU level and could be used to improve the situation. However, these improvements would still fall short of the tests imposed on non-EU health workers. Therefore, more can and should be done to ensure patient safety.

#### *Possible solutions*

1) The UK Government could use the current renegotiation of the EU Directive on qualifications to allow the UK to impose the same language testing for EU and non-EU health workers.

2) In the absence of EU agreement, the UK could formalise the separation between doctor registration and licensing that now exists, introducing language testing at the point of licensing, and extending this system to both EU and non-EU doctors to avoid discrimination.

3) Lastly, the UK could unilaterally extend its current system of testing non-EU health workers to all health workers and potentially face EU infraction proceedings.<sup>6</sup>

## **The Working Time Directive**

### **1.1. The Background**

The EU Working Time Directive (WTD)<sup>5</sup> came into force in 1998.<sup>6</sup> Its provisions are binding on the UK subsequent to the UK's agreement to the Amsterdam Treaty in 1997, which put an end to the UK's previous opt-out from the 'Social Chapter'. The UK Government was opposed to the WTD's introduction but failed in its attempt to block the proposal in the EU's Council of Ministers. Through subsequent amendments, the Directive now applies to almost all workers in the UK.

The 48-hour working week was extended to doctors in training on 1 August 2009, and after the expiry of a number of initial derogations, the Directive has now been applied in full.<sup>7</sup> The WTD was put into UK law via the Working Time Regulations, which require employers to grant most employees the following:<sup>8</sup>

- A 48 hour week (by an average calculated over a four month reference period).
- Eleven hours of continuous rest in a 24 hour period.
- A 20-minute break when working time exceeds 6 hours.
- 24-hour rest every seven days (or a minimum 48 hours rest every 14 days).
- Four weeks of annual leave.
- Maximum eight hours of work in 24 hours for night workers.

Subsequent European Court of Justice rulings in the *SiMAP* and *Jaeger* cases have had a particular impact on the NHS.

In the 2000 *SiMAP* ruling,<sup>9</sup> it was established that time spent resident on-call in a hospital (or any other workplace) must be fully counted as working time, even if the worker is asleep for some or all of that on-call time.<sup>10</sup>

The 2003 *Jaeger* ruling<sup>11</sup> has also provoked controversy, not least because it was clearly not what was intended by the policy makers who originally agreed to the WTD.<sup>12</sup> On that occasion, the ECJ ruled that the mandatory compensatory rest entailed in the WTD has to be taken immediately every time the minimum rest period is interrupted by an emergency.

This has meant that doctors unexpectedly required to work a longer shift have had to cancel appointments the following day.

In 2000, the British Medical Association estimated that the effect of the ruling would have been tantamount to losing between 4,300 and 9,900 junior doctors by 2009, when the full 48 hour limit for junior doctors was due to come into force (the UK later achieved a two year extension).

#### *Individual opt-out from the Working Time Directive.*

There remains an individual opt-out from the WTD, whereby an individual staff member can give their written consent not to be bound by the 48 hour week. However, no staff member, including junior doctors, can be compelled to opt-out making it impossible to plan on that basis. Senior consultants within the NHS do, however, tend to use the individual opt-out or take advantage of a separate derogation available to senior managers who set their own hours. However, the opt-out only covers the 48 hour week aspect of the WTD and does not cover other equally important aspects such as the enforced rest periods.

#### *Four month reference period for calculating the 48 hour week*

The WTD establishes that, when calculating limits to weekly working time, the hours worked can be averaged over a 'reference period'. In practice, this allows staff to work longer hours during certain weeks, provided that shorter hours are worked in other weeks during the same 'reference period' – so that the average remains below 48 hours per week.

Under the WTD, the 'reference period' cannot normally exceed four months – but national governments can unilaterally raise it to six months for certain activities (e.g. training doctors, dock or airport workers etc.). In theory, a further extension up to twelve months is possible, but only based on collective agreements between employers and employees.

## **1.2. The Problem**

Although the NHS's practices, such as the rigidity of the 'New Deal', have contributed to the problem, it is clear that the impact of the WTD has resulted in a serious and detrimental effect on the NHS, in terms of the continuity of patient care, the training of junior doctors and waiting times.

Although other EU states and the European Commission are aware of the problem and are willing to attempt reform, opposition from the European Parliament, and "social partners", both given power by the EU in this area, has so far made reform impossible.

The resulting issues are addressed in turn below:

- Lower standard of training of junior doctors.
- Disrupted continuity of care.
- End to organised rotas.
- Longer waiting lists – due to doctors enforced rest period leading to cancelled appointments.
- Increased cost to NHS.
- Doctors' welfare in terms of managing their non-working hours.

### **1.2.1 Impact on the training of junior doctors**

A combination of the limiting of trainees' hours, the counting of 'on-call' time as working time and the unpredictability created by enforced rest periods has had a major impact on the provision of training.

Firstly, the limiting of weekly hours has reduced the time trainees have to gain experience. Secondly, disruption to the traditional rotas has made it difficult for management to schedule individual training opportunities when supervisors and trainees are both present, in addition to decreasing the chances of trainees being present when unscheduled opportunities arise in the course of routine care. It is also difficult to schedule training events where a sufficient number of trainees are present. Lastly, due to trainees spending a larger proportion of their working time on 'out of hours' service provision, the value of their remaining time is further reduced.

As one doctor put it:

*“There is simply not enough time in the 48 hour week to get trained, particularly in the craft specialties so we all go in on our days off. If we don't, we don't get trained and it is us and our careers (but ultimately the patients) that suffer. Medicine is a competitive profession with only a limited number of desirable jobs in desirable locations to live so we simply have to get ourselves trained. This used to happen in our official working hours, now we work just as hard but get trained in our time off (unpaid) instead.”<sup>15</sup>*

This can be summed up by the diagram below.

**The effect that reduced hours can have on the time available for training**



Source: A review on the impact of the EUWTD on training by Sir John Temple<sup>16</sup>

This has been borne out in a number of surveys. The Association of Surgeons in Training, for instance, has found that over two-thirds of trainees reported deterioration in their surgical training due to the WTD.<sup>17</sup> 47.6% of Ophthalmologist trainees have found the same with similar results<sup>18</sup> for trainees in Obstetrics and Gynaecology (43%),<sup>19</sup> by the BMA (43%),<sup>20</sup>

The Royal College of Surgeons (66%),<sup>21</sup> and by the Scottish Academy which found that 65% of trainees in England and 81% of consultants felt the WTD's effect on training was negative.<sup>22</sup> Another serious factor resulting from the WTD is the trainee doctors' provision of services out of hours. Whereas time spent at night unsupervised could be supplemented by supervised training opportunities during the day, under the WTD, a larger proportion of a trainee's "training" will now be spent with inadequate supervision.

### **1.2.2. Continuity and quality of patient care**

The overall effect of the WTD on the NHS has been to stretch staff availability to the limit and create more and shorter shifts. This in turn has led to more handovers, less continuity of care and resulting mistakes as staff become unaware of patients' circumstances or they fall between the gaps.

A combination of the WTD (and the financial penalties imposed by the NHS's New Deal) has forced hospitals to move away from traditional resident on-call rotas towards shorter shift working or non-resident on-call rotas.

This has all affected the continuity of patient care. Patients will no longer have the same doctor who initially admitted them seeing them throughout their stay in hospital. This leads to more reliance on handover notes and patient care being broken down into individual procedures. It has also led to an expansion in the number and duration of the use of temporary locums in order to fill in gaps created by the WTD, thus breaking up patient care even further.<sup>23</sup>

The decrease in the continuity of care as a result of the WTD was brought to public attention recently with the sad case of Kane Gorny, who died of dehydration, after having even called the police to be given a glass of water.<sup>24</sup>

In her verdict the coroner at Westminster Coroner's Court put the blame for the deterioration in the quality of care on hospital waiting lists and the WTD which she said had affected Gorny's care. The Court specifically heard that many of the medical staff had not read Gorny's notes and did not even know that he suffered from a rare condition that required daily drugs to control it.<sup>25</sup>

This evidence that continuity of care has suffered as a result of the WTD is again backed up by the Association of Surgeons in Training survey, which found that 17% of trainees were aware of formally reported adverse critical incidents, directly arising from reduced working hours or increased frequency of handovers associated with WTD implementation.<sup>26</sup>

In this regards the *SiMAP* ruling over on call time has had a particularly bad effect, with one doctor writing that "the *SiMAP* ruling has, I think, had a devastating effect on acute care."<sup>27</sup>

### **1.2.3. Waiting lists**

Although difficult to quantify, the rulings in the *Jaeger* case have an impact on NHS waiting lists. This is because enforcing a rest period if a doctor has had to work longer than scheduled will mean that he has no option other than to cancel planned appointments at short notice.

### **1.2.4. Cost**

The combination of the *Jaeger* ruling and the 48 hour working week limit was estimated by the British Medical Association to amount to the equivalent of losing 4,300 to 9,900 junior doctors by 2009. The Royal College of Surgeons research and analysis of NHS workforce came up with an equivalent figure of 400,000 surgical hours lost per month due to the WTD.<sup>28</sup>

In addition to this cost, hospitals, as a result of the WTD, have been forced to hire more temporary locum doctors from agencies at a higher cost. These temporary doctors are not only a duplicate cost but due to demand and notice can end up costing far more. For instance, as a result of the need to be WTD compliant, North Cumbria University Hospitals NHS Trust has reportedly spent £20,000 on hiring a surgeon for one week and £14,000 on four days' cover for a gynaecologist. Mid-Staffordshire NHS Foundation Trust has also reportedly paid £5,667 for a doctor to cover one 24-hour shift in casualty—as the Metro newspaper points out, an equivalent salary of £1.36m a year.<sup>29</sup>

In addition to this is the cost of compliance with the WTD in individual hospitals, which can run into tens of thousands of pounds a year in terms of software and employee time. Responses to requests made under the Freedom of Information Act have shown, for instance, that some hospital trusts have engaged specific personnel to keep track of doctors' hours.

In 2010/11, University Hospital Aintree records having spent over £47,000 on WTD compliance, Rotherham NHS Foundation Trust over £41,000, Taunton and Somerset NHS Foundation Trust again over £36,000, to mention only three examples.

### **1.2.5. Doctors' welfare**

The disruption to the residential on-call rota system and the introduction of shorter full shifts supplemented by enforced rest periods has paradoxically left many junior doctors with a more tiring and unpredictable working week. The Royal College of Surgeons concludes that the "move to working 48 hours a week through full shift rotas is exhausting surgical staff. We know from our members that working in a full shift pattern is more tiring when compared to working using an 'on-call' system, and creates a working environment that is impairing to patient safety."<sup>30</sup>

Likewise the Association of Surgeons in Training found that 67% of surgical trainees are attending work while off-duty to protect their training and gain adequate experience, and that 84% of surgical trainees are working in excess of their rostered hours to maintain the quality of the service provided.

It also reported that 86% of surgical trainees working a WTD-compliant rota have seen their work life balance deteriorate or remain unchanged with the theoretical reduction in working hours. For junior doctors in training, the strictures of the WTD can force trainees to make a difficult choice: comply the WTD and fail to accumulate sufficient training hours, or come in on their days off. Many end up working in their own time off.

### 1.3. Contributing factor: The NHS New Deal

The “New Deal” is essentially an employment contract that stipulates expected hours and pay bands. Despite predating the WTD (the New Deal was agreed in 1991),<sup>31</sup> the relevant parts came into force as a contract in 2000 and 2003. The New Deal awards staff financially for working more than 40 hours per week and sets a limit of 56 hours, which to some extent mirrors the WTD.<sup>32</sup>

Although the WTD is the main factor contributing to the disruption of doctors’ working hours, the NHS’ own New Deal is a contributing factor. Absent the WTD, the New Deal would continue to put cost and time restraints on the NHS.

### 1.4. Is the WTD a problem in other EU states?

It is important to understand that the implementation of the WTD and the ECJ rulings is not solely a UK problem - it has caused problems for healthcare providers across the EU. In addition, the European Commission has recognised this in its review of the Directive. It is therefore interesting to see how other states have coped with the WTD. To take a few examples below:

Belgium only enforced the 48 hour cap for training doctors into national legislation from February 2011.<sup>33</sup> Until then, training doctors were working up to 79 hours per week on average in Belgium.<sup>12</sup>

Despite transposing EU working time rules for training doctors into national law in 2004,<sup>34</sup> Ireland is still failing to apply them, and was last year threatened to be taken to the ECJ.<sup>35</sup> At the beginning of this year, the Irish government laid down a plan to ensure compliance with EU rules over the next three years, meaning that Ireland may not be fully applying the rules before the end of 2014.<sup>36</sup>

The following table outlines the level of compliance in Ireland: **Proportion of each grade of Non-Consultant Hospital Doctors (NCHD) compliant with EWTD provisions (2011) in Ireland**

| <b>Grade</b>               | <b>Daily breaks</b> | <b>Daily rest</b> | <b>Weekly/fortnightly rest</b> | <b>Average 48-hour week</b> |
|----------------------------|---------------------|-------------------|--------------------------------|-----------------------------|
| Intern                     | 79%                 | 77%               | 97%                            | 43%                         |
| Senior House Officer (SHO) | 72%                 | 69%               | 93%                            | 30%                         |
| Registrar                  | 73%                 | 67%               | 92%                            | 31%                         |
| Specialist Registrar       | 73%                 | 65%               | 94%                            | 37%                         |
| <b>TOTAL</b>               | <b>73%</b>          | <b>69%</b>        | <b>93%</b>                     | <b>33%</b>                  |

1 Article 168(7) TFEU

2 Association of Surgeons in Training (ASiT) survey, *Optimising working hours to provide quality in training and patient safety (January 2009)* and British Orthopaedic Trainees Association (BOTA) survey, *BOTA position statement on EQTD and training in trauma & orthopaedic surgery (January 2009)*; <http://www.rcseng.ac.uk/policy/briefings/?searchterm=royal>

3 Royal College of Surgeon's briefing (August 2010); [www.rcseng.ac.uk/policy/documents/RCS%20EWTD%20briefing.pdf](http://www.rcseng.ac.uk/policy/documents/RCS%20EWTD%20briefing.pdf)

4 As in the case of the recent death of Kane Gorny, who attempted to ring the emergency services to receive a glass of water. The subsequent inquest cited the WTD as a factor leading to the lapse in care.

5 Directive 2003/88/EC

6 UK implementing legislation, <http://www.legislation.gov.uk/ukxi/1998/1833/contents/made>

7 The remaining derogation relates to doctors in critical areas or rural hospitals has also lapsed [http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH\\_099150](http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_099150)

8 There are limited exemptions for specific groups either unable to calculate their hours or senior enough to dictate their hours.

9 Case C-303/98 *Sindicato de Medicos de Asistencia Publica (SiMAP) v Conselleria de Sanidad y Consumo de la Generalidad Valenciana*. [2000] ECR I-7963

10 The ECJ rulings cover both periods where the worker is working in response to a call (i.e. 'active' on-call time), and periods where the worker is allowed to rest while waiting for a call (i.e. 'inactive' on-call time), provided that he/she does not leave the workplace. See *European Commission*, 'Report to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on implementation by Member States of Directive 2003/88/EC', 21 December 2010, p5

11 Case C-151/02 *Landeshauptstadt Kiel v Norbert Jaeger*. Judgment of 9 October 2003 <http://www.publications.parliament.uk/pa/ld200304/ldselect/ldcom/67/6706.htm>

12 In oral evidence to the House of Lords EU Select Committee in 2004, the then Health Minister John Hutton said: "To require compensatory rest to be taken immediately would potentially have a massively destructive effect across the NHS and might mean that doctors could not work the following shift or rota that they were required to do and that would have knock-on consequences right across the hospital. At the end of the day, the only people who would be negatively affected would be the patients and that is a ridiculous result. House of Lords European Union Committee, *The Working Time Directive: A Response to the European Commission's Review*, 9th report of Session 2003-04, Volume II, answer to Q259

13 Other relevant ECJ rulings are: *Pfeiffer* (C-398/01) and *Dellas* (C-14/04)

14 See *Open Europe*, 'Time's up! The case against the EU's 48-hour working week', March 2009, p25, <http://www.openeurope.org.uk/Content/Documents/PDFs/wtdoptout2.pdf>

15 Mr Tom Palser MRSC, Surgical Trainee, email to Charlotte Leslie MP, 25 April 2012

16 [www.mee.nhs.uk/PDF/14274%20Bookmark%20Web%20Version.pdf](http://www.mee.nhs.uk/PDF/14274%20Bookmark%20Web%20Version.pdf)

17 Association of Surgeons in Training survey, of over 1,600 surgeons-in-training from all specialties ; [http://www.asit.org/news/wtd\\_implementation](http://www.asit.org/news/wtd_implementation)

18 Royal College of Ophthalmologists survey of 189 trainees in October 2009.

19 A review on the impact of the EUWTD on training by Sir John Temple

20 Ibid.

21 RCS survey of 980 doctors in 2010; <http://www.rcseng.ac.uk/news/impact-of-doctor-working-time-cap-on-patient-safety-and-training-getting-worse-says-new-survey> ; <http://www.rcseng.ac.uk/news/impact-of-doctor-working-time-cap-on-patient-safety-and-training-getting-worse-says-new-survey>

22 A review on the impact of the EUWTD on training by Sir John Temple.

23 Goddard A, Pounder R, McIntyre A, Newbery N. Implementation of the European Working Time Directive in 2009 – implications for UK clinical service provision and training for the medical specialties [http://old.rcplondon.ac.uk/professional-Issues/workforce/Workforce-issues/Documents/EWTDRCP\\_2009\\_surveys.doc](http://old.rcplondon.ac.uk/professional-Issues/workforce/Workforce-issues/Documents/EWTDRCP_2009_surveys.doc). London.: Medical Workforce Unit, Royal College of Physicians, 2009.

24 [http://www.publicservice.co.uk/news\\_story.asp?id=20312](http://www.publicservice.co.uk/news_story.asp?id=20312)

25 *Telegraph*, 11 July 2012; <http://www.telegraph.co.uk/health/healthnews/9391899/Kane-Gorny-inquest-medics-did-not-check-pulse-for-24-hours.html>

26 Association of Surgeons in Training (ASiT) and British Orthopaedic Trainees Association survey; [http://www.rcseng.ac.uk/news/docs/ASiT\\_BOTA%20EWTD%20Survey%20results.pdf/view](http://www.rcseng.ac.uk/news/docs/ASiT_BOTA%20EWTD%20Survey%20results.pdf/view)

27 Ibid

28 Royal College of Surgeon's briefing (August 2010); [www.rcseng.ac.uk/policy/documents/RCS%20EWTD%20briefing.pdf](http://www.rcseng.ac.uk/policy/documents/RCS%20EWTD%20briefing.pdf)

29 *Metro*, 18 March 2012; <http://www.metro.co.uk/news/893504-20-000-spent-to-cover-doctor-for-just-1-week>

30 Association of Surgeons in Training (ASiT) survey, *Optimising working hours to provide quality in training and patient safety (January 2009)* and British Orthopaedic Trainees Association (BOTA) survey, *BOTA position statement on EQTD and training in trauma & orthopaedic surgery (January 2009)*; <http://www.rcseng.ac.uk/policy/briefings/?searchterm=royal>

31 The New Deal: <http://www.dhsspsni.gov.uk/scujuniordoc-2>

32 Guide for Medical Students and Newly Qualified Doctors to the New Deal and European Working Time Directive; [http://www.healthcareworkforce.nhs.uk/working\\_time\\_directive/pilot\\_projects/new\\_deal\\_and\\_wtd\\_booklets/](http://www.healthcareworkforce.nhs.uk/working_time_directive/pilot_projects/new_deal_and_wtd_booklets/)

33 Loi du 12 décembre 2010 fixant la durée du travail des médecins, dentistes, vétérinaires, candidats médecins en formation, candidats dentistes en formation et étudiants stagiaires se préparant à ces professions, see <http://www.emploi.belgique.be/defaultTab.aspx?id=33092>

34 European Communities (Organisation of Working Time) (Activities of Doctors in Training) Regulations 2004, S.I. No 494/2004, <http://www.irishstatutebook.ie/2004/en/si/0494.html>

35 See *European Commission* press release, 'Commission requests Ireland and Greece to comply with the EU rules on limits to working time in public health services', 29 September 2011, <http://ec.europa.eu/social/main.jsp?langId=en&catId=157&newsId=1083&furtherNews=yes>

36 See *Irish government, Department of Health*, 'Plan for implementation of EWTD in Ireland – Doctors in training', 17 January 2012, <http://www.dohc.ie/press/releases/2012/20120117.html>

37 *Irish government, Department for Health*, 'Plan to progress measures required to ensure EWTD compliance', January 2012, p6, [http://www.dohc.ie/press/releases/pdfs/Plan\\_to\\_progress\\_measures\\_EWTD.pdf?direct=1](http://www.dohc.ie/press/releases/pdfs/Plan_to_progress_measures_EWTD.pdf?direct=1)

38 See Article R6153-2 of the French 'Code de la santé publique', [http://www.legifrance.gouv.fr/affichCodeArticle.do;jsessionid=8F04D356722BC1D93E769BDB4C952FB5.tpdjo02v\\_2?cidTexte=LEGITEXT000006072665&idArticle=LEGIARTI000022911373&dateTexte=20120807&categorieLien=id#LEGIARTI000022911373](http://www.legifrance.gouv.fr/affichCodeArticle.do;jsessionid=8F04D356722BC1D93E769BDB4C952FB5.tpdjo02v_2?cidTexte=LEGITEXT000006072665&idArticle=LEGIARTI000022911373&dateTexte=20120807&categorieLien=id#LEGIARTI000022911373)

39 In principle, there is no law which would prevent French junior doctors being asked to work longer than the eleven half-days. For further details, see *European Commission* staff working paper, 'Detailed report on the implementation by Member States of Directive 2003/88/EC concerning certain aspects of the organisation of working time', 21 December 2010, p33-34

40 *NHS*, Medical Education England, the impact of the EU WTD; <http://www.mee.nhs.uk/pdf/LiteratureReviewFINAL.pdf> p.26

## Consumers for Health Choice

*What evidence is there that EU action to create the single market for food has been advantageous or disadvantageous for the UK?*

The EU provides a good coordinating role and ensures that the same food standards are applied consistently and across the board throughout the EU Member States. As a consumer organisation, CHC welcome this. However, Regulations that are agreed upon at a European level are often difficult for manufacturers and businesses to adhere to and consumers to understand. The sheer volume of legislation produced at the European level can obstruct innovation, hinder development and confuse consumers.

In addition, in an effort to harmonise rules, the EU legislation does not always take into account the different dietary patterns across the EU. An example could be the Food Supplements Directive of 2002 which seeks to set harmonised maximum permitted levels in vitamins and minerals in food supplements.

Intelligence has long suggested that these levels would be set much lower than are currently seen in the UK. In the name of harmonisation this would end consumer access to safe, higher-potency food supplements that have been available on the market for many years.

Therefore, EU legislation occasionally has the perverse impact of actually limiting the choices of safe products available to consumers.

*What evidence is there that the national interest in terms of trade is best served by action at the EU level, national level or by action being taken at a different level, e.g. in Codex Alimentarius?*

Actions at the EU or international level are only appropriate in specific areas where cross-border co-operation is identified as the most efficient and cost efficient solution to deal with particular problems. Such actions should therefore always be based upon thorough impact assessments. As an example, while it is beneficial for both consumers and businesses that the same food safety standards apply across the EU, it is also essential that food legislation takes into account the particularities and different consumer needs across the continent.

*Has EU action in food law provided the right balance between protecting the consumer and protecting the interests and reputation of UK businesses?*

EU action on food law has often been too blunt, legislating for all 27 Member States and refusing to take into account the nuances that exist between different Member States: the dietary needs of the average person in Southern Spain are very different to those in Scotland, for example.

This has meant that well-intentioned legislation has often, as noted above, restricted consumer access to information about products (as with the Nutrition and Health Claims Regulation) or even safe products that have been used for many years with no harmful effects (as the Food Supplements Directive threatens to do so).

*Is there evidence that legislating for consumer protection at the European level has been advantageous or disadvantageous to the UK national interest?*

In theory, legislating at an EU level has proven advantageous to UK consumers, who are now secure in the knowledge that they can access safe products, well labelled, across all Member States.

As noted above, however, legislating for consumer protection at an EU level has often proven disadvantageous to the UK national interest, failing to take into account the particularities of our market and consumer needs, all in the name of harmonisation. As result, many safe products that have been used for many years with no harmful effects are currently at threat.

*What evidence is there that the principle of science based food legislation at the European level has served the national interest well? Are there any concerns about the principle and its application? Are there any examples of where it was not followed?*

Although theoretically at the heart of food legislation, CHC has observed that too much legislation is not based on scientific principles.

The proposed setting of maximum permitted levels for vitamins and minerals in food supplements under Article 5 of the Food Supplements Directive 2002 is, for example, not based on science: higher potency supplements have long been available in the UK and other Member States with no negative impact on safety.

Similarly, the authorisation of health claims under the Nutrition and Health Claims Regulation has been based on science, but there has been little guidance on what sort of scientific evidence businesses need to submit when applying for claims. This has resulted in a large number of rejected claims and less information available to consumers.

## Electronic Cigarette Industry Trade Association

To whom it may concern

For the avoidance of repetition, we shall try to condense our response to answer all the questions and provide our evidence as succinctly as possible. My name is Katherine Devlin, and I am the President of ECITA (EU) Ltd, the Electronic Cigarette Industry Trade Association. Naturally, this industry, its products and Tobacco Harm Reduction are my specific fields of interest and expertise. Therefore, our submission will be deliberately focussed on these areas. Having said that, where appropriate, it will be possible to comment more widely, based on available evidence.

ECITA is directly involved in assisting the electronic cigarette industry – predominantly, our membership, but with a wide range of advice and assistance offered more broadly – with achieving legal compliance with the regulations which currently apply to electronic cigarette products. Trading Standards described ECITA's Industry Standard of Excellence as "a Code any industry would be proud to have." These are consumer products, not medicines or tobacco products. As such, they are subject to a variety of EU legislative instruments, all of which have been adopted by the UK.

Our business operation is based in South Wales, but we work with partners across the UK – both in the industry, and in co-operation with Trading Standards Officers and the National Measurement Office – and our members are located across England and Wales, as well as on the continental mainland of Europe. Our organisation, and all the SME's which make up our membership, as well as the rest of the industry, are providing employment, paying taxes to the UK government, and achieving significant growth despite the recession – particularly in areas of low employment, such as South Wales, the North East of England, and elsewhere.

Reclassification as a medicinal product would put ALL of us out of business, and assist both the tobacco industry, by making more appealing products less available, and serve to maintain the pharmaceutical industry's monopoly on non-tobacco nicotine products. This is anticompetitive, disproportionate, and illegal. (There have already been 4 cases fought and won concerning this in Europe.i)

The EU's competence, along with that of each Member State, is crucially important, and we have grave concerns that there is an astonishing lack of knowledge about electronic cigarette products and the scientific evidence base concerning them. This is evident at the Commission, with the ill-conceived proposal to include electronic cigarettes in the revisions to the Tobacco Products Directive, despite the Commission's own acknowledgement that these are not tobacco products. Worse still, the European Commission is proposing to include electronic cigarettes in the revised TPD, but as medicinal products unless diluted to the point of utter uselessness. Under Article 288 of the TFEU, this proposal would lead to a regulation "binding in its entirety and ... directly applicable in all Member States". It is probably fair that the Tobacco Products Directive should be such an instrument, but the inclusion of electronic cigarettes in it demonstrates the risks inherent in the EU having such legally-binding competences. There is a worrying tendency to ignore scientific evidence, and not to robustly assess it. This seems to be a disturbingly wide-spread trend, which has significant implications for every area of society, and must be addressed by policy-makers; it is simply not good enough to skim read conclusions from a study, or assess the methodology of a research protocol from the associated press release. We have no desire to 'cherry-pick' the evidence, but ask that all the scientific research studies relating to electronic cigarettes, tobacco harm reduction, etc., be allowed to stand on

their own merits, but this is only possible if policy-makers will pay them the proper attention and take the time to properly assess them. We have collated all the studies we could find ('good' and 'bad', in terms of scientific rigour) on our website at [www.ecita.org.uk](http://www.ecita.org.uk).

The UK national interest is currently enjoying health advantages in having the robust and stringent EU legislation on consumer products (e.g. the General Products Safety Directive, and attendant regulatory statutes) ensuring that the standards of electronic cigarette products are necessarily high. The fact that these standards are codified centrally by the EU for all Member States is actually enormously beneficial, particularly with regard to the centralised reporting systems (i.e. RAPEX) which allow for sub-standard products to be swiftly removed from the market. This system is effective, and very beneficial in protecting the UK's 'vapers' as well as those in the other Member States, and ensuring they can have access to properly legally compliant products which are safe for use as intended. (The same cannot, of course, be said for tobacco products, or some medicinal cessation products.iii)

The UK national interest would, however, be severely disadvantaged if the EU were to reclassify electronic cigarettes out of this robust system, and into the inappropriate (and disproportionate) medicinal classification, as they appear to be trying to do. Ultimately, the EU's approach is legally flawed (Article 34 protecting the Internal Market, proportionality requirements, etc.) and is likely to fail on challenge, but nevertheless, I believe it is crucially important for the UK – with its potentially influential role – to remain in the EU, so as to be able to provide that all important influence to ensure that the citizens of all Member States are empowered to achieve the best possible public health outcomes. That said, the UK must be careful not to make counter-productive decisions on this issue for itself anyway. The UK will struggle to have its voice heard at all if we are not a party to the debate, and we have a crucially important role to play, in insisting on robust scientific analysis relating to policy decisions. (To be fair, this is an area which requires some considerable improvement even in the UK, but we are a long way ahead of some of our European colleagues, who will need the UK's common sense approaches in the future.)

It is fair to say that the UK has been instrumental in driving the growth of the electronic cigarette industry in Europe. Many of our colleagues on the continent are also experiencing significant growth, but the UK has been a leader in manufacturing (we were the first Member State to have entirely EU-sourced ingredients being manufactured into eliquid for electronic cigarettes) and marketing UK-manufactured products to the world. The UK was also the first to develop an internationally recognised and highly-respected Trade Association with a focus firmly on improving the standards and legal compliance for this industry. These are both businesses that I am personally involved with: my brother owns and operates Decadent Vapours Ltd (of which I am a Director), which was the first company in Europe to produce eliquid manufactured with every ingredient being sourced from within the EU; and ECITA (EU) Ltd is the Electronic Cigarette Industry Trade Association, of which I am President.

Now, I am delighted to see that there are many other well-organised and effective Trade Associations acting for the best interests of public health at a population level, as well as representing the businesses within the industry across other Member States. Also, there is an increasing number of manufacturers sourcing ingredients from within the EU for eliquid. This increases the range of choices available to consumers, thus increasing the likelihood that more smokers will be able to successfully make the 'switch'. Naturally, however, it is inappropriate to talk in terms of 'efficacy' as a 'quitting tool', since those are medicinal concepts and this is a consumer-driven behavioural change which has already proven to be more effective than the medical approaches. (The electronic cigarette industry is now estimated to be worth

approximately €500m, and has already overtaken the NRT market share, in the space of a few short years.iv)

It is perhaps worth pointing out that the impact on the pharmaceutical industry, and the tobacco industry, of this 'shift' to the electronic cigarette industry is little more than a 'fly in the ointment'. Both the pharmaceutical and tobacco industries are now 'buying in' to electronic cigarettes, but it is important to remember that the electronic cigarette industry was created and developed entirely separately from both these big players. Furthermore, it is the substantial growth of small to medium enterprises, with their significant contribution to the economic health of the nation, which makes this fledgling industry so desperately important – not just for the health of UK citizens, but also for our economic growth, so desperately needed during these austere times. It is important to recognise the distinction between 'patients' and 'citizens' (or 'consumers', in a non-medicinal context). The reclassification of electronic cigarettes as medicinal products would be a tragedy of significant proportions, if the focus is truly about improving public health outcomes. As Professor John Britton said recently:

"If all the smokers in Britain stopped smoking cigarettes and started smoking ecigarettes we would save 5 million deaths in people who are alive today. It's a massive potential public health prize."

Unfortunately, if electronic cigarettes are reclassified as medicinal products, they will have to fundamentally change, in terms of form factor, flexibility of performance, the range of models, flavours, and strengths available, not to mention the impact this would have on price. At the moment, smokers are not switching to using electronic cigarettes to replace their NRT habit; they are using electronic cigarettes to replace some or all of their tobacco cigarettes.

Smokers are individuals, with individual needs and preferences which are many, varied and constantly variable: one smoker may smoke 3 tobacco cigarettes in quick succession first thing in the morning one day, then hardly smoke at all until the evening; on a different day, this same smoker may not smoke at all until lunch time, and then have occasional cigarettes throughout the afternoon. Each cigarette smoked by this one smoker may be smoked differently at different times – sometimes smoking every possible puff, other times, allowing the cigarette to burn away for much of the time without puffing. It remains a stubbornly tenacious fact that approximately 20% of UK smokers are unable or unwilling to 'quit', and the medicalised interventions are simply not working to reduce that number.v This is the habit which millions of EU smokers are replacing with 'vaping'. And it has nothing whatsoever to do with 'medicine' or 'treatment'. It is crucially important that the 'massive potential public health prize' Professor Britton spoke of is not thrown away due to dogmatic ideology (the 'quit or die' mentality, espoused by the WHO, and widely disseminated with the almost global adoption of the distinctly unpleasant connotations arising from 'denormalising' smokers).

There are already reputational benefits for the UK as being seen to 'lead the way', with the Behavioural Insight Team's acute analysis of the issue, published in September 2011vi, and the Royal College of Physician's frequent calls for an overhaul of the approach to nicotine in all its forms (dating back to 2007)vii. Indeed, quite recently, Professor Ron Borland, Nigel Gray Distinguished Fellow in Cancer Prevention at Cancer Council Victoria, based in Australia, said: "The death and disability toll from cigarette smoking is far too high not to be doing all that we can. The rise of a consumer movement, as I understand almost entirely consisting of ex-smokers, supporting the use of e-cigarettes is the first social-level evidence that there might now be substitutes for cigarettes that will be readily taken up by smokers. These and other strategies should be actively considered. The UK should be congratulated in their apparent leadership in this regard (if the current draft NICE proposal is adopted). More countries should follow.

If tobacco control is important enough to have the FCTC, it is important enough to be taking bold steps to eliminate. We must be doing more.”<sup>viii</sup> Whilst we recognise that this might appear to be an issue of minuscule importance in the grand scheme of public health issues, for individuals such as myself, and the million other vapers in the UK, and the many millions across the EU, it is very significant and literally a matter of life or death. I speak from bitter personal experience having lost my husband to tobacco-related cancer at the age of just 31. The “extent to which the EU’s role in public health supports member state actions effectively and efficiently” is not an area I have studied extensively, but my view is that the EU needs to calm down a bit, and perhaps step away from making centralised rules, but rather seek out best practices from across the Member States and then put these forward for harmonised adoption. Once again, the UK should be a leading voice in such activities, since we have some demonstrably excellent practices, particularly compared to some of our fellow Member States. We cannot influence the EU if we are not part of it, and I believe we have a duty to our fellow citizens on the mainland to offer them the benefit of our considerable expertise and best practices in a range of areas.

There is also the fact that the UK can benefit from the best practices of other Member States in areas where we are not doing so well by ourselves. Certainly, the European Union has many, many flaws and failings. It is almost inevitable that such a huge project would make a great many mistakes – as is true of any political body, or any other large gathering of flawed humans (‘to err is human’, after all). But surely the UK has a duty, along with all the other Member States, to continue to fight for the best that can be achieved, particularly with regard to public health outcomes for the millions of EU citizens.

In terms of public health, it is crucially important to remember that the ‘delivery of health and social care’ is not just about health care service providers; the single market is an enormously beneficial tool for ensuring that health-improving lifestyle choices can be promoted. If policy makers care about public health, surely this should not be in a blinkered, localised manner, but should spread to our neighbours on the continent too? We benefit from having the free movement of workers, since we can welcome skilled workers from outside the UK, and our own citizens can choose to work elsewhere in the EU. This sort of choice is beneficial in the broader sense of ‘well-being’ promotion, in the sense that EU citizens have some freedom in choosing where they want to live and work.

We believe the UK government is right to insist on a reduction in the budget for the proposed ‘Health for Growth’ campaign. It is all too easy to see examples of wastefulness in a range of health projects and other areas of government – in the UK and EU. In terms of cost-effectiveness, government investment in NRT and Smoking Cessation Services through the NHS has been criticised by the Behavioural Insights Team and others, but what we are seeing with the significant uptake of electronic cigarettes is costing the UK and EU governments nothing; citizens are willingly funding this behavioural change for themselves, independently. This is not a health project requiring government funding, and so would seem to be an ideal ‘fit’ for the ‘Health for Growth’ campaign, as well as providing support for a reduction in the Budget.

The UK electronic cigarette industry has significant ‘home-grown’ sales in the UK, but is also heavily reliant upon exports to our European partners in particular, as well as to partners in the rest of the world. It is difficult to see how this would not suffer a negative impact if the UK were to leave the EU, even if some attempt were made to remain part of the single market; inevitably, the UK would be perceived as being ‘cut off’ from continental Europe.

A fundamental misunderstanding has occurred at the EU level about the significant differences between smoking tobacco cigarettes and using an electronic cigarette: a smoker may smoke 20 cigarettes over the course of a day (and many do, hence the problem!) but if that smoker switches to using an electronic cigarette, they are likely to use 2-3ml of e-liquid of 2.4% nicotine concentration over the same period. The level proposed as a 'cut-off', above which a Marketing Authorisation would be required from an MS Medicines Regulator, is 0.4%. Clearly, this is not a proportionate or effective level to propose.

It seems quite likely that the UK has a marginally better grip on this point, and yet there is still a push to reclassify them as medicinal products, with the MHRA due to report back this spring (2013). The MHRA was unable to make a compelling case for burdensome and unnecessary over-regulation back in 2010, and is no closer to being able to do so now. (The Regulatory Policy Committee recently confirmed that the MHRA has not submitted any further policy proposals for consideration, so this is not a viable option and will be legally challenged if an attempt is made to force it through.)

Fortunately, we are confident that the UK will take a strong leadership position with regard to the classification of electronic cigarette products, once the evidence is properly evaluated, particularly since there are considerable concerns (which I have heard from UK public health experts, such as Clive Bates, former Director of ASH UK, as well as UK policy-makers) that although the UK's medicines regulators might – and I must stress, might – be able to take a pragmatic 'light touch' approach, there is so much disparity across the other Member States that it is likely that harmonisation would be enormously difficult. This is similar to the situation regarding the proposed Directive 2009/39/EC (Foods for particular nutritional uses), which was "precipitated partly by perceived difficulties in achieving market harmonisation and consistent enforcement across the EU."

Fortunately, there is already a robust and extremely well-harmonised regulatory framework under the GPSD et al which is already in place and being enforced successfully. We would like to see more rigorous enforcement of the existing legislation, in order to continue to drive standards up for our industry, but we believe that this is being hampered by long, drawn-out uncertainty about the classification. The UK needs to take the lead, and help to influence EU policy on this issue (and others).

I believe the EU could and should act as an 'overview position' provider to the Member States, and can see little benefit for the UK in the EU taking more specific actions in regard to public health. The UK is notably better-placed than some other Member States to make independent decisions, and yet surely the EU could provide a centralised resource for the collation of best practices from across the Member States, and robust scientific evaluation to the benefit of all the Member States. The European Commission has exhibited a tendency to become too embroiled in the details. Certainly, their proposed interference with the electronic cigarette industry is decidedly counter-productive for the health of UK citizens (along with the rest of the EU) and I would hope that the UK (and other MS) would be strongly critical of this being allowed to pass into mandatory legislation for Europe-wide adoption. Furthermore, it would be an absolute tragedy if the better parts of the revisions to the Tobacco Products Directive (i.e. those concerning tobacco products, which ought to be the focus of this Directive) were delayed because of the inappropriate and disproportionate inclusion of electronic cigarettes which are neither tobacco products nor medicines. We trust that the UK government will act swiftly and strongly to guide this significant Directive through to completion in the most expeditious manner

– which must include the removal of recommendations about electronic cigarettes from the proposals.

Proportionality and subsidiarity are particularly key issues. We believe it is essential that, for future proposals, the UK and all the Member States insist on robust academic analysis of the scientific evidence for the development of policy proposals. It is simply not appropriate to disregard some ‘good’ research because it is industry-funded. After all, 90% of all clinical trials are funded by the pharmaceutical industry and there are serious questions about their quality.<sup>ix</sup> Nevertheless, these should not be written off, any more than the research from the tobacco industry, the electronic cigarette industry, the food industry, the alcohol industry, etc., etc. What is absolutely essential is proper academic evaluation of all the evidence on any given proposal, by systematic review undertaken by people properly qualified to undertake such analyses. Without this, we can never have properly evidence-based decision making, despite the fact that the EU and most Member State governments frequently talk about evidence-based decisions.

Greater adherence to the principle of proportionality is equally essential, both at Member State level, but also at EU level. As indicated above, we believe the binding principle of proportionality provides a mechanism for ensuring that “the content and form of EU action must not exceed what is necessary to achieve the objectives of the EU treaties”, but only if this is robustly enforced. There may be benefits overall if the EU views its obligations with regard to proportionality as an obligation to step away from interfering with the details for individual citizens, but rather to focus its attentions on the details of the specific systematic reviews of evidence, including monitoring and analysis of best practices from across the EU, and then presenting these as centralised suggestions for harmonised adoption. The UK could and should have a key role to play in making this happen. Subsidiarity is likely to be of concern for the UK coalition government, since it is currently focussed on the move to ‘localism’. It remains to be seen how effective this will be in reality, but at least in principle, it seems like a good idea. (How seldom the theory translates into reality, though!) As far as the EU is concerned, subsidiarity can provide effective protection for less democratic or capable Member States, but again, only if this is robustly enforced. This is yet another question which leads me to the conclusion that the UK must remain part of the process, offering the benefit of its experience where appropriate.

Clearly, there are “common safety concerns in public health matters”, particularly with regard to the harms caused by tobacco smoking, and there is a common need for “incentive measures to protect human health”. As indicated above, the EU is in a unique position to be able to engage in systematic reviews of evidence relating to every possible area of policy decision making. However, the EU must stop meddling with the details, and act more to provide advice and suggestions for harmonised adoption, always with the strongest possible evidence-base in support. Furthermore, the systematic reviews of evidence in all areas must be published for scrutiny by the wider academic community, for the widest possible peer review.

The World Health Organisation is more problematic than any individual Member State government, and has greater potential to do harm than the European Parliament and Commission. The Member State governments, together with the European Parliament and Commission have very clear guidelines to follow, and are accountable for their actions. The WHO appears to be acting directly against the best interests of public health with regard to electronic cigarettes, as well as being utterly undemocratic and unaccountable, with concerns having been raised in the BMJ and elsewhere:

‘A joint investigation by the BMJ and the Bureau of Investigative Journalism has uncovered evidence that raises troubling questions about how WHO managed conflicts of interest among the scientists who advised its pandemic planning, and about the transparency of the science

underlying its advice to governments. Was it appropriate for WHO to take advice from experts who had declarable financial and research ties with pharmaceutical companies producing antivirals and influenza vaccines? Why was key WHO guidance authored by an influenza expert who had received payment for other work from Roche, manufacturers of oseltamivir, and GlaxoSmithKline, manufacturers of zanamivir? And why does the composition of the emergency committee from which Chan sought guidance remain a secret known only to those within WHO? We are left wondering whether major public health organisations are able to effectively manage the conflicts of interest that are inherent in medical science.’x

This is completely unacceptable if elected governments in individual Member States, together with the European Union are going to effectively take on ‘blind trust’ the advice of the WHO. Rather, as signatories to the FCTC, the UK and the EU (together with all other signatories) must challenge the WHO on the robust scrutiny of the scientific evidence. This issue was discussed recently in an Open Letter to delegates to COP-5, by Clive Bates, former Director of ASH UKxi: “I have been prompted to write to you because during COP-5 you will be considering two papers prepared by the Secretariat:

1. [FCTC/COP/5/12: Control and prevention of smokeless tobacco products](#)
2. [FCTC/COP/5/13: Electronic nicotine delivery systems, including electronic cigarettes](#)

These papers share a serious weakness: they do not properly consider the role of smokeless tobacco or electronic nicotine delivery systems as credible alternatives to smoking. Therefore their potential positive health value in reducing the burden of disease associated with smoking is ignored or marginalised.”

For my specific field of knowledge, the relative merits of legislative and nonlegislative measures are very clear: the legislative measures in place at the EU level, and well-harmonised and adopted across the Member States concerning consumer products, are currently having a very positive impact on public health in the area of tobacco harm reduction. Non-legislative measures could include a centralised systematic review of all the available evidence on electronic cigarettes and Tobacco Harm Reduction more broadly, with the EU drawing on all the resources available to it from across the Member States, and then providing recommendations on how individual Member States might like to introduce non-legislative measures (to support the central and harmonised consumer legislation) within their own countries. These might include advising health-care providers – from within and without the medical community – to provide accurate, evidentially-sound information to smokers about the range of options available to them. The vast public health benefits currently being enjoyed would be tragically reduced if legislation is introduced at a national or EU level to reclassify electronic cigarettes as medicinal products.

The UK is capable of making good decisions for and by itself. Clearly, there are some areas where the UK is not strong, or setting a good example, but in many areas of policy making, the UK is a recognised leader. Presumably, as a current Member State of the European Union, the UK has some current obligations to offer its best practices to its EU partners? If not, surely it should have. However, if the EU is getting things wrong – always with a focus on systematic reviews by qualified academics of the entirety of the evidence base – then the UK must, by default, have an obligation to do the right thing for its own citizens. Clearly, this is often a source of conflict between the UK and Europe, but this ought not to be resolved by taking our football and going home.

The EU must be held accountable for its behaviour, and the UK (along with all the other Member State governments) must ensure that this happens. This will always be challenging, but

is essential nevertheless. The UK national interest could be very well served by increasing its reputation for best practices, and by engaging more with policy-making processes at the EU level. Ultimately, however, in the policy area of public health, it is too important that citizens are protected; if the EU is getting it wrong, the UK must robustly challenge this, and go its own way if necessary. That said, I do feel it would be a shame to leave our partners on the mainland to suffer the consequences of bad EU public health policy, such as is currently proposed with the inclusion of electronic cigarette products in the revisions to the Tobacco Products Directive – an important instrument which must not be delayed due to the trivial error of having inappropriately included electronic cigarettes.

In the grand scheme of things, this is a 'trivial error', but for individuals across the EU, it is literally a matter of life and death. For the whole revisions to the TPD to be derailed because we have no choice but to protect our right to 'vape', would be an egregious tragedy. Future enlargement of the EU would seem to be unwise until the existing Union gets its house in order, hopefully with help from the UK. There are growing concerns in some quarters about the European Commission 'interfering' with the operation of the European Medicine Agency (EMA) regarding 'Orphacol', a medicine for treating orphan liver disease. French kidney/liver drug –vs- American pharma product. This was reported by Gilles Pargneaux, MEP: "This medicine is a product of academic clinical research of a hospital in Paris. A marketing authorization was requested to make it available not only in France but all over Europe.

Despite more than 20 years of use in France, despite the unanimously positive opinion of the European Medicine Agency's (EMA), despite a qualification of the medicine as having a "notable public health interest," despite the repeated expression of a favorable opinion from Member States, the marketing authorization was refused by the European Commission. The European Commission has no scientific expertise whatsoever. It systematically follows the opinions of European Agencies and expert committees of the Member States. In the history of centralized marketing authorization of medicines, it is the first time that a series of scientific opinions are not followed suit by the European Commission.

This unprecedented case must lead to the question: Why? What are the motives of the European Commission and who stands to benefit from these protracted procedures and refusals? As I have raised at the European Parliament during several committee meetings, everything leads to the conclusion that the aim is to favor an (American) pharmaceutical company that has belatedly requested a marketing authorization for a similar medicine. When an institution in charge of health and consumer protection overturns a scientific decision, faces the indignation of Member States concerning its tactics and does not meet the demands for transparency from the European Parliament, such suspicions are legitimate.

This case sheds a new light on the arbitrariness that can overtake an institutional machinery when it ignores democratic alerts, in particular coming from the European Parliament. Confident in its rights, its legal and technical know-how, the European Commission has shown its arbitrariness, thinking that an injustice committed to a small pharmaceutical company would go unnoticed.

More than a year before the next European elections and while European citizens are expressing a growing defiance toward Europe, the European Commission shares her fair share of responsibility. On this case, the image of Europe as a whole is tarnished. The European Commission has to acknowledge its error and approve this medicine which is supported by everyone. Most importantly, in order not to have other cases that may raise legitimate or imaginary suspicion, more than ever we have to implement mechanisms that enable the

European Parliament to make itself heard and respected. The interest, the credibility and the legitimacy of Europe are at stake.”<sup>xii</sup>

Other concerns have been raised about conflicts of interest, including a Report from the European Parliament<sup>xiii</sup> published in 2012:

“...the European Ombudsman criticised EFSA for the way it assesses potential conflicts of interest and ‘revolving door’ cases; calls on other Agencies to employ efficient procedures to detect and prevent any conflict of interest situations: takes the view that the ‘cooling off’ period of anyone who has served as director of an agency or has discharged major responsibilities within an agency needs to be clarified” and “conflicts of interest are a cause of corruption, fraud, mismanagement of funds and human resources, favouritism and have a negative impact on the impartiality of the decisions and quality of work and undermines Union citizens’ trust in the Union institutions, including the Agencies”.

Closer to home, the UK MHRA is also an agency of considerable and widespread concern. Richard Brook published the following, after resigning from his position as an adviser to one of the MHRA’s ‘expert’ groups<sup>xiv</sup>:

“I resigned. If a regulator will not own up to its mistakes, who knows if data about other drugs has not also been overlooked, with potentially fatal results. Regulators are supposed to be a stop-check for safety issues. But at the MHRA, many of the people who work there or advise it have ties to drugs firms. Some have shares in the companies, research departments funded by them or receive fees for advice. The only protection is a musical chairs system where you leave the room if you have an interest in the drug being discussed or its manufacturer, or you can stay but not vote. [...]

There is an urgent need for an independent inquiry into the MHRA. The Government must also change its culture of secrecy.”

I am not one to subscribe to populist ‘conspiracy theories’ about corruptive influences of commercial interests. However, it is not a conspiracy ‘theory’ when it is really happening. The UK must get its own house in order by, for example, engaging in particular scrutiny of the operations of the MHRA, and must then assist the EU in combatting its own corruption issues. My own conflicts of interest have been fully declared herein, and I urge you to look to the evidence, rather than to any individual’s claims about any products relative merits – including my own. Please, do not take my word for it; but in disregarding my statements as ‘conflicted’, please ensure that you do take the time to academically analyse the evidence, which is easily accessible. Much of it is linked from this submission, but I would urge you to look wider, to ensure the UK government is able to take the most informed position possible, and then pass on the benefits of this knowledge to the EU.

Thank you for taking the time to consider our submission to your programme, and for engaging in this call for evidence.

Katherine Devlin  
President

ECITA (EU) Ltd for and on behalf of the members of ECITA, the wider European industry, and all of Europe’s vapers, smokers, and their families and friends, who have supported our organisation

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## Embassy of Japan

### Question Comment

The Embassy of Japan in the United Kingdom of Great Britain and Northern Ireland presents its compliments to the Foreign and Commonwealth Office and has the honour to submit comment of the Government of Japan to the Review of the Balance of Competences between the United Kingdom and the European Union (hereinafter referred to as the Review) as follows.

The Government of Japan understands that this issue should be primarily reviewed and studied by the Government of the United Kingdom of Great Britain and Northern Ireland (hereinafter referred to as the UK) and its people with a long-term perspective.

At the same time, the Government of Japan hopes that the Review will be a constructive contribution for both the UK as a Member State of the European Union (hereinafter referred to as the "EU.") and the entire EU .

Japan shares with the UK fundamental values, as well as interests and responsibilities regarding the challenges which the international community is facing. Japan and the UK have been working closely not only in a bilateral context, but also in the context of Japan-EU relations. The Government of Japan appreciates the role that the UK has played in activities of the EU in various fields such as politics, economy and security.

The Government of Japan recognises that the EU has a large presence and influence in the international community. The Government is committed to strengthening the relationship with the EU more than ever before.

In the context mentioned above, the Government expects that the UK will maintain a strong voice and continue to play a major role in the EU.

The UK, as a champion of free trade, is a reliable partner for Japan. More than 1,300 Japanese companies have invested in the UK, as part of the Single Market of the EU, and created 130,000 jobs, the largest employment in Europe. This fact demonstrates that the advantage of the UK as a gateway to the European market has attracted Japanese investment. The Government of Japan expects that such UK's advantage should always be maintained.

In addition, the Government appreciates that the UK has been leading the deregulation or rationalisation of regulations within the EU and making significant contributions in order to make the EU market more attractive for foreign companies. In this context, Japanese companies operating in the UK express their expectations that deregulation or rationalisation of regulations through the EU mechanism will be further promoted. The Government of Japan expects the determination and efforts of the Government of the UK towards completion of the Single Market of the EU.

The Government of Japan further expects that certain aspects of the EU's external relations such as the speed of decision-making or clarity of the channel of communication, would be further improved through the Review.

The Embassy of Japan avails itself of this opportunity to renew to the Foreign and Commonwealth Office the assurances of its highest consideration.

## Europe Economics

I am an experienced economic consultant who has worked on a number of studies in the area of healthcare and pharmaceuticals. Clients have included the Department of Health, the European Commission, and the pharmaceutical industry.

These studies have been carried out by my employers (NERA from 1985 to 1998 and Europe Economics<sup>16</sup> since 1998) but this note is my personal responsibility and does not necessarily reflect the views of my employers or of the clients for the studies mentioned.

The points made follow the questions in the call for evidence, copied in red.

### **Copy of questions in Call for Evidence**

#### **Impact on the national interest**

- How does the EU's competence in health affect you/your organisation?
- What evidence is there that EU action in health advantages or disadvantages:
  - o The UK national interest
  - o Business and industry
  - o Patients and citizens

EU Single Market policies act to the substantial disadvantage of patients in the UK and in all other Member States by reducing affordable access to patented medicines, increasing the risk of counterfeits and reducing incentives for discovering new patented medicines.

This is because the Commission (particularly DG Competition) and the ECJ have given priority to encouraging free trade within the Single Market and have not understood or accepted that in some circumstances, such as those applying to patented medicines, it would be more efficient and more equitable if prices were set according to ability to pay and subsequent arbitrage were prevented.

Due to these EU policies companies owning a patent for an important new medicine are obliged either:

- To supply it at similar prices throughout the EU, or
- To defer launch in low income countries, so that higher prices can be agreed first in high income countries, and then
- To accept the loss of income when sales or prices are reduced in high income countries by parallel trade, External Reference Pricing, or both.

The effects on patients and on those funding healthcare on their behalf that result from these incentives are:

- Patients in lower income countries do not receive new medicines until a long time after they are launched elsewhere in the EU
- Those funding healthcare in Member States with lower incomes per capita have to pay higher prices than would otherwise be available or refuse to supply the medicines to their patients.

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<sup>16</sup> [www.europe-economics.com](http://www.europe-economics.com)

- In the long term, fewer new medicines will be discovered.
- The risk of counterfeit medicines entering the supply chain is increased, since the supply chain is deliberately made obscure and hence becomes more difficult to police.
- There is an increased risk of medicines being damaged when they are re-packaged, or of erroneous patient information leaflets being inserted.

Parallel trade brings no offsetting benefits for patients or taxpayers. Those funding healthcare in higher income countries, including the UK, save very little since most of the gap between prices at which parallel trader buy and sell is taken by the traders.

The only significant beneficiaries are the parallel traders.

Publicly available evidence for the above includes:

- a) Studies by Europe Economics for clients in the pharmaceutical industry showed that there have been different delays to launch dates in different countries, with lower income countries having to wait longest. These findings have been confirmed in subsequent studies by (among others) Patricia Danzon.
- b) Trade theory predicts that in a single market, prices will tend to converge. There is empirical evidence of price convergence in practice in medicines, implying higher prices than would otherwise have been available in the low income countries.
- c) Economic theory shows that where there are significant fixed costs to be recovered, efficient pricing depends on willingness to pay ('Ramsey pricing').
- d) The conclusion that there is very little saving for purchasers in high income countries was found from LSE research, published in a recent report to the European Parliament by Kanavos and others.<sup>17</sup>
- e) The conclusion that banning repackaging of medicines would reduce the risk of erroneous patient information leaflets and of damage to medicines repackaged was reached in a report by Europe Economics for the European Commission (DG Enterprise).
- f) The conclusion that fewer new medicines will be resulted rests on the fact that the profitability of patents is reduced by EU policy, and the economic argument that prospective returns influence investment.

• Please consider what evidence there is to demonstrate;

o the extent to which the EU's role in public health supports member state actions effectively and efficiently

o the opportunities and costs for the delivery of health and social care in the UK that flow from wider EU competences and policies such as the free movement of workers or the single market generally

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<sup>17</sup> IP/A/ENVI/ST/2010-12 2010 PE 451.481 "This practice, which has been reviewed and upheld by the European Court of Justice, has been cited as a mechanism that can reduce prices in the sales markets. Overall, however, it appears that the final sale prices of pharmaceuticals have not been significantly reduced by parallel trade. In other words, most of the difference in price accrues to the intermediaries (Kanavos and Costa Font, 2005; Kanavos and Vandoros, 2010).

o the extent to which EU competence and policies intended to allow EU citizens to access healthcare across the EU are effective and proportionate

o the extent to which health objectives are effectively and proportionately taken into account in wider EU policies

See above. Healthcare is given a lower priority than parallel trade, despite clear evidence that this trade is damaging to healthcare.

Another example is the intervention into working hours in hospitals, for which there was no real justification under the Treaty or on any grounds of good policy-making. Whatever the merits of particular rules on working and resting hours, this was a matter that could and should have been left to national policy.

### **Future options and challenges**

- How might the UK benefit from the EU taking more action in health?
- How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?

See above. The EC should

- a) Make it clear it will take no further steps to promote parallel trade
- b) Put forward new legislation overturning the previous decisions by the ECJ, starting with *Merck v Stephar*, and thus removing the risk of successful litigation against patent-holders charging different prices to different customers or taking other action likely to have similar result.
- c) Put forward legislation to ban repackaging, or alternatively to allow any Member State that wishes to do so to ban the importation of repackaged medicines.

- How could action in this area be undertaken differently e.g.

o Are there ways of improving EU legislation in health, e.g. revision of existing legislation, better ways of developing future proposals, or greater adherence to the principle of subsidiarity and proportionality?

See above

o Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest?

Could action be taken at any other international level i.e. by the WHO?

o What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?

- How else could the UK implement its current obligations?
- What future challenge/opportunities might we face in EU health competence and what impact might these have on the national interest?
- What impact would any future enlargement of the EU have on health competence?

### **General**

- Is there evidence of any other impacts resulting from EU action in health that should be noted?
- Are there any general points you wish to make which are not captured above?

- Are there any published sources of information to which you would like to draw our attention for the purposes of this review?

More detail can be provided if that would be helpful.

## European Commission

### IV) Health

#### 1. Overview of Health Policy

- Commission White Paper of 23 October 2007 'Together for Health: A Strategic Approach for the EU

2008-2013' - [http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0630:FIN:EN:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0630:FIN:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0630:FIN:EN:PDF)

- Multi-annual programme of action for health (2014-2020) (Proposal) - [http://eurlex.](http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0709:FIN:EN:PDF)

[europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0709:FIN:EN:PDF](http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0709:FIN:EN:PDF)

- Report on the mid-term evaluation of the EU Health Strategy 2008-2013 -

[http://ec.europa.eu/health/strategy/docs/midtermevaluation\\_euhealthstrategy\\_2011\\_report\\_en.pdf](http://ec.europa.eu/health/strategy/docs/midtermevaluation_euhealthstrategy_2011_report_en.pdf)

- Publication: Health in the EU – What is there for you? -

[http://ec.europa.eu/health/strategy/docs/recent\\_achievements\\_2012\\_en.pdf](http://ec.europa.eu/health/strategy/docs/recent_achievements_2012_en.pdf)

#### 2. Recent proposals, Directives and Regulations, including their impact assessments

- Proposal for a Directive of the European Parliament and of the Council on the approximation of the

laws, regulations and administrative provisions of the Member States concerning the manufacture,

presentation and sale of tobacco and related products

[http://ec.europa.eu/health/tobacco/docs/com\\_2012\\_788\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/com_2012_788_en.pdf)

- Directive on standards of quality and safety of human organs intended for transplantation (2010) +

Implementing regulations (2Q 2012) - [http://eurlex.](http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:207:0014:0029:EN:PDF)

[europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:207:0014:0029:EN:PDF](http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:207:0014:0029:EN:PDF)

- Proposal for a decision of the European Parliament and of the Council on serious cross-border threats

to health (2011) - [http://ec.europa.eu/health/preparedness\\_response/docs/hsi\\_proposal\\_en.pdf](http://ec.europa.eu/health/preparedness_response/docs/hsi_proposal_en.pdf)

- Directive 2011/24 on patients' rights in cross-border healthcare (2011) - [http://eurlex.](http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF)

[europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF](http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF)

- Regulations on advanced therapy medical products (2007) - [http://eurlex.](http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:324:0121:0137:en:PDF)

[europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:324:0121:0137:en:PDF](http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:324:0121:0137:en:PDF)

- Pharmacovigilance Directive - [http://ec.europa.eu/health/files/eudralex/vol-](http://ec.europa.eu/health/files/eudralex/vol-1/dir_2010_84/dir_2010_84_en.pdf)

[1/dir\\_2010\\_84/dir\\_2010\\_84\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-1/dir_2010_84/dir_2010_84_en.pdf) and Regulation (2010) -

[http://ec.europa.eu/health/files/eudralex/vol-1/reg\\_2010\\_1235/reg\\_2010\\_1235\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-1/reg_2010_1235/reg_2010_1235_en.pdf)

- Directive regarding the prevention of the entry into the legal supply chain of falsified medicinal products (2011) - [http://ec.europa.eu/health/files/eudralex/vol-](http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf)

[1/dir\\_2011\\_62/dir\\_2011\\_62\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf)

- Proposal for Revision of Clinical Trials Directive (Regulation) (2012) -

[http://ec.europa.eu/health/files/clinicaltrials/2012\\_07/proposal/2012\\_07\\_proposal\\_en.pdf](http://ec.europa.eu/health/files/clinicaltrials/2012_07/proposal/2012_07_proposal_en.pdf)

- Proposal for a Regulation of the European Parliament and of the Council on medical devices, and

amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 -

[http://ec.europa.eu/health/medical-devices/files/revision\\_docs/proposal\\_2012\\_542\\_en.pdf](http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf)

Ref. Ares(2013)275954 - 01/03/2013

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- Commission Decision 2010/453/EU establishing guidelines concerning the conditions of inspections and control measures, and on the training and qualification of officials, in the field of human tissues and cells provided for in Directive 2004/23/EC of the European Parliament and of the Council - <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:213:0048:0050:EN:PDF>

- Commission Directive 2006/86/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells - [http://eurlex.europa.eu/LexUriServ/site/en/oj/2006/l\\_294/l\\_29420061025en00320050.pdf](http://eurlex.europa.eu/LexUriServ/site/en/oj/2006/l_294/l_29420061025en00320050.pdf)

- Commission Directive 2006/17/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells - <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:038:0040:01:EN:HTML>

- Commission Implementing Directive 2011/38/EU of 11 April 2011 amending Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf life - <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:097:0028:0029:EN:PDF>

- Commission Directive 2009/135/EC allowing temporary derogations to certain eligibility criteria for whole blood and blood components donors laid down in Annex III to Directive 2004/33/EC in the context of a risk of shortage caused by the Influenza A(H1N1) pandemic. - <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:288:0007:0009:EN:PDF>

### **3. Council Recommendations (selection)**

- Prevention of drinking of alcohol by young people (2001) – <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:161:0038:0041:EN:PDF>

- Prevention of health-related harm associated with drug dependence (2003) - <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:165:0031:0033:en:PDF>

- Cancer screening (2003) - <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:327:0034:0038:EN:PDF>

- Prevention of injury and the promotion of safety (2007) - <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2007:164:0001:0002:EN:PDF>

- Patient safety and the prevention of healthcare associated infections - <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:151:0001:0006:EN:PDF>

- Action in the field of rare diseases (2009) - <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:151:0007:0010:EN:PDF>

- Smoke-free environments (2009) - <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:296:0004:0014:EN:PDF>

- Seasonal influenza vaccination (2009) - <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:348:0071:0072:EN:PDF>

### **4. Policy documents**

#### **4.1 Health in society**

##### **• Social determinants and health**

- Commission Communication - Solidarity in Health: Reducing Health Inequalities in the EU (2009) - <http://eur3>

lex.europa.eu/Notice.do?checktexts=checkbox&checktexte=checkbox&val=502712%3Acs&pos=1&pag

e=1&lang=en&pgs=10&nbl=1&list=502712%3Acs&hwords=&action=GO&visu=%23texte

- **Ageing**

- Communication on the EIP on AHA: putting forward the Strategic Implementation Plan (2012) - <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0083:FIN:EN:PDF>

#### **4.2 Ensuring health security**

- **Preparedness and response**

- Strategy for Generic Preparedness Planning: Technical guidance on generic preparedness planning for public health emergencies (2009) -

- [http://ec.europa.eu/health/preparedness\\_response/docs/gpp\\_technical\\_guidance\\_document\\_1\\_december\\_2009.pdf](http://ec.europa.eu/health/preparedness_response/docs/gpp_technical_guidance_document_1_december_2009.pdf)

- **Blood tissues and organs**

- Action plan on Organ Donation and Transplantation (2009-2015) -

- [http://ec.europa.eu/health/ph\\_threats/human\\_substance/oc\\_organs/docs/organs\\_action\\_en.pdf](http://ec.europa.eu/health/ph_threats/human_substance/oc_organs/docs/organs_action_en.pdf)

#### **4.3 Taking actions against diseases**

- **Vaccination**

- Council Conclusions on childhood immunisation (2011) -

- [http://www.consilium.europa.eu/uedocs/cms\\_Data/docs/pressdata/en/lisa/122391.pdf](http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/en/lisa/122391.pdf)

- Staff working document on Joint procurement of vaccine against influenza (2009) -

- [http://ec.europa.eu/health/archive/ph\\_threats/com/influenza/docs/flu\\_staff1\\_en.pdf](http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/flu_staff1_en.pdf)

- **Major and chronic diseases**

- Communication on European Partnership for Action Against Cancer 2009-2013 -

- [http://ec.europa.eu/health/archive/ph\\_information/dissemination/diseases/docs/com\\_2009\\_291\\_en.pdf](http://ec.europa.eu/health/archive/ph_information/dissemination/diseases/docs/com_2009_291_en.pdf)

- **Rare diseases**

- Communication on rare diseases: Europe's challenges (2008) + review 2013 -

- [http://ec.europa.eu/health/ph\\_threats/non\\_com/docs/rare\\_com\\_en.pdf](http://ec.europa.eu/health/ph_threats/non_com/docs/rare_com_en.pdf)

#### **4.4 Fostering good health**

- **Nutrition and physical activity**

- White Paper on a strategy on nutrition, overweight, and obesity-related health issues (2007) -

- [http://ec.europa.eu/health/archive/ph\\_determinants/life\\_style/nutrition/documents/nutrition\\_wp\\_en.pdf](http://ec.europa.eu/health/archive/ph_determinants/life_style/nutrition/documents/nutrition_wp_en.pdf)

- Council conclusions on action to reduce population salt intake for better health -

- [http://www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/lisa/114998.pdf](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lisa/114998.pdf)

- **Alcohol**

- EU alcohol strategy (2009) - [http://eurlex.europa.eu/LexUriServ/site/en/com/2006/com2006\\_0625en01.pdf](http://eurlex.europa.eu/LexUriServ/site/en/com/2006/com2006_0625en01.pdf)

- [http://eurlex.europa.eu/LexUriServ/site/en/com/2006/com2006\\_0625en01.pdf](http://eurlex.europa.eu/LexUriServ/site/en/com/2006/com2006_0625en01.pdf)

- **Mental health**

- European pact for mental health and well-being / EU compass -

- [http://ec.europa.eu/health/mental\\_health/docs/mhpact\\_en.pdf](http://ec.europa.eu/health/mental_health/docs/mhpact_en.pdf)

- **Sexual transmitted diseases**

- Action Plan on combating HIV/AIDS (2009) -

- [http://ec.europa.eu/health/sti\\_prevention/docs/eu\\_communication\\_2009\\_action\\_en.pdf](http://ec.europa.eu/health/sti_prevention/docs/eu_communication_2009_action_en.pdf)

#### **4.5 Improving healthcare**

- **Health workforce**

- Action Plan for the EU health workforce adopted as part of the Commission Communication for a job

rich recovery in Europe -

[http://ec.europa.eu/dgs/health\\_consumer/docs/swd\\_ap\\_eu\\_healthcare\\_workforce\\_en.pdf](http://ec.europa.eu/dgs/health_consumer/docs/swd_ap_eu_healthcare_workforce_en.pdf)

- **Patient safety**

- Report from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation (2009/C 151/01) on patient safety, including the

prevention and control of healthcare associated infections -

[http://ec.europa.eu/health/patient\\_safety/docs/council\\_2009\\_report\\_en.pdf](http://ec.europa.eu/health/patient_safety/docs/council_2009_report_en.pdf)

- **Healthcare and cross-border healthcare**

- Council conclusions: towards modern, responsive and sustainable health systems (2011) - <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:202:0010:0012:EN:PDF>

- Cross-border Healthcare Directive – (see Section 2)

- **eHealth**

- eHealth Action plan for 2004-2010 -

[http://ec.europa.eu/information\\_society/activities/health/docs/policy/ehap\\_assess082011.pdf](http://ec.europa.eu/information_society/activities/health/docs/policy/ehap_assess082011.pdf)  
and

preparation of new eHealth action plan 2012-2020 -

[http://ec.europa.eu/information\\_society/activities/health/ehealth\\_ap\\_consultation/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/ehealth_ap_consultation/index_en.htm)

- Permanent voluntary HTA network to be created by directive on patients' rights in cross-border health

care - [http://eur-](http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF](http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF)

#### **4.6 Pharmaceuticals**

- Communications and guidelines on established pharmaceutical legislation, including legislation on rare

diseases and paediatrics - [http://ec.europa.eu/health/documents/eudralex/index\\_en.htm](http://ec.europa.eu/health/documents/eudralex/index_en.htm)

- Communication: Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical

Sector (2008) - [http://eur-](http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0666:FIN:en:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0666:FIN:en:PDF](http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0666:FIN:en:PDF)

- Adapting the assessment of medicinal products to scientific progress (2009) - <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:242:0003:0012:EN:PDF>

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- Commission Implementing Decision of 23 January 2013 on the assessment of a third country's regulatory framework applicable to active substances of medicinal products for human use and of the

respective control and enforcement activities pursuant to Article 111b of Directive 2001/83/EC of the

European Parliament and of the Council - [http://ec.europa.eu/health/files/eudralex/vol-1/dec\\_2013\\_51/dec\\_2013\\_51\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-1/dec_2013_51/dec_2013_51_en.pdf)

#### **4.7 Medical devices**

- Council Conclusions on innovation in the medical device sector - <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:202:0007:0009:EN:PDF>

- Revision of Medical devices directive (see Section 2)

#### **4.8 Global health**

- Communication from the Commission: The EU Role in Global Health (2010) -

[http://ec.europa.eu/development/icenter/repository/COMM\\_PDF\\_COM\\_2010\\_0128\\_EN.PDF](http://ec.europa.eu/development/icenter/repository/COMM_PDF_COM_2010_0128_EN.PDF)

### **5. Working time rules and healthcare services**

- Overview of the replies received from the social partners at European Level to the first-phase consultation on Reviewing the Working Time Directive, SEC (2010) 1610 (includes views expressed by

UK and other social partners about working time in public health services)

SEC (2010) 1610

- Independent expert study to support an impact assessment of Working Time Directive (Deloitte,

2010): see particularly chapters 4, 6 and 7 on impact of WTD rules in public health services, including

in UK, and Annex 1 (expert review of occupational health and safety studies on working time rules,

Working time rules and healthcare services

Deloitte Study (December 2010), Annex 1: Study on health and safety aspects of working time

### **6. Bodies for Cooperation between Member States**

- Senior Level Working Party on Public Health (SLWP) created in 2008 -

<http://register.consilium.europa.eu/pdf/en/08/st16/st16139.en08.pdf>

- Chronic Disease reflection process: "Innovative approaches for chronic diseases in public health and

healthcare systems" (2010) -

[http://www.consilium.europa.eu/uedocs/cms\\_Data/docs/pressdata/en/lsa/118282.pdf](http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/en/lsa/118282.pdf)

- Reflection Process on Health Systems as follow-up to the Council Conclusion 2011 (organised by SLWP,

see council conclusions: towards modern, responsive and sustainable health systems)

### **7. Financial Instruments**

- EU health programme - [http://ec.europa.eu/health/programme/policy/index\\_en.htm](http://ec.europa.eu/health/programme/policy/index_en.htm)

- Research and Innovation - [http://ec.europa.eu/research/health/public-health/public-health-andhealth-](http://ec.europa.eu/research/health/public-health/public-health-andhealth-systems/projects_en.html)

[systems/projects\\_en.html](http://ec.europa.eu/research/health/public-health/public-health-andhealth-systems/projects_en.html)

- Cohesion policy and Structural funds - [http://ec.europa.eu/regional\\_policy/videos/videodetails.cfm?vid=862&LAN=EN](http://ec.europa.eu/regional_policy/videos/videodetails.cfm?vid=862&LAN=EN)

### **8. EU data, information and scientific advice**

- Health at a Glance: Europe (publication - presents the most recent key indicators of health and health

systems across 35 countries)

[http://ec.europa.eu/health/reports/docs/health\\_glance\\_2012\\_en.pdf](http://ec.europa.eu/health/reports/docs/health_glance_2012_en.pdf)

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- European Observatory on Health Systems and Policies - [http://www.euro.who.int/en/who-](http://www.euro.who.int/en/who-weare/)

[weare/](http://www.euro.who.int/en/who-weare/)  
partners/observatory

- European Community health indicators (ECHI) -

[http://ec.europa.eu/health/indicators/echi/list/index\\_en.htm](http://ec.europa.eu/health/indicators/echi/list/index_en.htm)

- Scientific Committees - [http://ec.europa.eu/health/scientific\\_committees/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/index_en.htm)

- Expert Panel to provide advice on effective ways of investing in health -

[http://ec.europa.eu/health/healthcare/consultations/call\\_expertpanel\\_long\\_en.htm](http://ec.europa.eu/health/healthcare/consultations/call_expertpanel_long_en.htm)

## European Scrutiny Committee

### Medicines and Medical Devices

11<sup>th</sup> Report, 2012-13, 86-xi, Chapter 9, *Regulating clinical trials* (12751/12)

The Committee queried the legal basis for the provision in a draft Directive for the Commission to carry out Member State inspections to check whether the States were able to comply with the regime for clinical trials for medicines for human use. (The Government replied that it felt the inspection regime would be otiose and would seek amendments to reflect this.)

53<sup>rd</sup> Report, 2010-12, 428-xlviii, Chapter 14; 5<sup>th</sup> Report, 2012-13, 86-v, Chapter 8; 11<sup>th</sup> Report, 2012-13, 86-xi, Chapter 10; 20<sup>th</sup> Report, 2012-13, 86-xx, Chapter 23, *Responding to serious cross-border health threats* (18509/11)

The Commission put forward a draft Decision on serious cross-border threats to health. The Government and Committee were concerned about competency creep in relation to a requirement to 'consult', rather than 'inform', the EU on preparedness and response planning. This was later amended. Article 12 of the Decision, which delegated the Commission to put into place 'common temporary public health measures' in a situation where national measures were insufficient and/or a major outbreak of hospitalisation or death occurred across the EU was also a concern. The Government considered that this did not comply with the subsidiarity principle and had asked for it to be deleted, which it eventually was.

## European Society of Radiology

### General comment

Health systems vary considerably between different member states and therefore it is only where there is cross-border health issues where EU competence is relevant.

It is also paramount that the focus is on the patient and citizen while recognizing that national and business interests also have a role

As identified in the consultation document there are a number of areas of EU legislation that are not specifically related to health care which nevertheless have a significant effect on the quality of care of the UK patient.

I wish only to comment on the following:

### 9. Radiation.

The EU has produced the very valuable euratom directive on the use of ionizing radiation in patients which has increased the safety of patients throughout Europe including the UK.

The UK had a commendable history through the work of the Royal College of Radiologists, the radiation protection agency and the department of Health in reducing and managing patient radiation burden over many years and played a very significant part in the development of the Euratom (97) directive.

Unfortunately due to the fact that radiation comes under the environment DG and the European atomic energy community there is very little input from doctors into their deliberations.

Recently there has been a major issue on Magnetic Resonance Imaging resulting from a directive on electromagnetic exposure to workers which emanated from a DG with no health input which has resulted in the temporary withdrawal of the directive and expensive and tortuous renegotiation

It is therefore time that the health care sector was better represented in this area.

### Implications of employment policy

12.2 Working time directive. I comment briefly as there are many competent authorities who will be making submissions and also this issue has been widely discussed. As a previous trainer and also a medical director of a foundation trust the strictures caused by the working time directive have negatively impacted on training of doctors and has reduced the continuity of care of patients in hospitals.

While not wishing to extend the hours worked of doctors significantly the healthcare sector should be reviewed separately to find an appropriate format which provides quality of care for patients and appropriate working times for doctors.

### Implications of free movement of persons: health care professionals

The coordination of specialty training requirements for doctors throughout has improved significantly over the last decade and many specialties now have European qualifications to

supplement those achieved at national level. There is however still considerable diversity of training quality and standards through the 27 countries of the EU.

However there is increased diversity in the continuous medical education and professional development requirements between member states and especially in the UK with the requirement for revalidation.

While this is not so important for patients receiving treatment in their own member state it is of considerable importance for cross-border health care. In particular it is a considerable risk for patients who have are partaking of telemedicine and often unknowingly having their radiological examinations reported through a cross-border tele-radiology service.

As far as I am aware there is still no EU wide legal requirement for member state regulatory bodies to share information on all doctor's registration status although progress on this was made in the cross border directive. Again this is particularly relevant for patients having cross-border tele-radiology.

## 16.E-Health

The EU promotion of E-Health is to be welcomed. However this term covers a wide variation in services including electronic monitoring of patients, e-prescribing and EPR. Unfortunately telemedicine and particularly tele-radiology have been included in this overarching term as they are very different involving as they do direct input of a specialist doctor.

The EU have been discussing the issues over a considerable period of time and have received a great deal of input from the European Society of Radiologists. This has resulted in a working paper from the commission on the legal issues involved. Unfortunately this paper has substantially restated the present position without moving the debate forwards. The majority of legislation related to tele-radiology fall into the information technology and cross-border contract directives rather than the cross-border health directive despite considerable efforts to include it in the latter.

The present position is absurd that in some member states the reporting of a tele-radiology examination is not considered a medical act whereas in the UK the radiologist reporting the examination has to be a specialist subject to revalidation.

It is therefore of considerable concern that your consultation document states in 10.3 that the UK seeks assurance that areas such as e-health and HTA would remain matters of voluntary cooperation.

It is essential that patients are fully informed as to where their radiological examinations are being reported and the status of the reporting doctor prior to the examination and that they give consent for a cross-border service. They should also be able to seek redress in their own country of domicile.

#### 19: Further Legislation and case law;

The extensive influence of legislation in many areas outside of health causing problems for delivering high quality and efficient patient care is recognized by the commission. It is therefore fundamental that the implications of any legislation in preparation should consider the impact and be widely discussed with derogation where necessary.

There is a strong case for specific legislation to cover health issues. Particularly a directive on teleradiology and telemedicine separately from other E-health related issues.

## Faculty of Public Health

### About the Faculty of Public Health

The Faculty of Public Health (FPH) is the standard setting body for specialists in public health in the UK. FPH is the professional home for more than 3,300 professionals working in public health. Our members come from a range of professional backgrounds (including clinical, academic and policy) and are employed in a variety of settings, usually working at a strategic or specialist level.

FPH is a joint faculty of the three Royal Colleges of Public Health Physicians of the United Kingdom (London, Edinburgh and Glasgow). In addition, FPH advocates on key public health issues and provides practical information and guidance for public health professionals, aiming to advance the health of the population through three key areas of work: health promotion, health protection and healthcare improvement.

### Overall focus of the review

#### ***How does the EU's competence in health affect you/your organisation?***

FPH sets the standards for education and training in the UK for public health specialists. Legislation and regulations related to the working of public health specialists including trainees, for example the European Working Time Directive, will directly affect our members, and FPH considers the impact of this in our policies and programmes of work.

We also advocate on public health issues including tobacco, alcohol, obesity and other major public health issues across the three public health domains of health improvement, health protection and health services. EU legislation and regulations impact on these issues – for example, food labelling regulations, trade laws on tobacco and alcohol – and these are taken into consideration when FPH develops policies and programmes around public health advocacy.

FPH also works through its International Committee to consider issues of relevance relating to the EU and international policy agenda.

- *What evidence is there that EU action in health advantages or disadvantages:*
  - *The UK national interest*
  - *Business and industry*
  - *Patients and citizens*

FPH works closely with the National Heart Forum and supports their response to the EU Balance of Competences consultation. We would also add, in particular, that public health is a recognised medical specialty across the European Union. FPH supports and embraces the broad and multidisciplinary nature of public health, which incorporates a wide variety of roles

that contribute to the development and delivery of the public health agenda. In the UK public health is regulated by the General Medical Council<sup>18</sup> for those from a medical background and the UK Public Health Register<sup>19</sup> for those from a background other than medicine. The EU would, as the UK has for many years, benefit from embracing the multidisciplinary nature of public health. In the UK, these professionals train to the same rigorous standards, have a duty to undertake continued professional development and are eligible to apply for the same jobs.

FPH support the public health skills and career framework<sup>20</sup> – a framework which helps to articulate the multi-faceted roles which contribute to the public health agenda and has agreement across the four countries of the UK. The framework outlines the public health competences and underpinning knowledge of those working across the various levels in public health:

- The wider workforce
- Public Health Practitioners
- Specialists

***Please consider what evidence there is to demonstrate;***

- *the extent to which the EU's role in public health supports member state actions effectively and efficiently*

FPH would reinforce the following points made by other public health partners in responding to the consultation.

There is consensus among health and consumer organisations and many food retailers that 'traffic light' nutritional labelling on front of pack can help people make better informed food choices and can stimulate healthy reformulation to reduce levels of fat, sugars and salt. In 2008, FPH jointly produced a position statement on the benefits of traffic light food labelling<sup>21</sup> and provided evidence-based and practical recommendations for its support and implementation across Europe. The Food Information to Consumers Regulation (EU FIC) allows Member States to introduce, albeit at on a voluntary basis, '*additional forms of expression and presentation*' – so balancing what can be achieved at EU level with some scope for Member States to 'experiment' with national labelling schemes.

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<sup>18</sup> The General Medical Council - <http://www.gmc-uk.org/>

<sup>19</sup> The UK Public Health Register - <http://www.publichealthregister.org.uk/>

<sup>20</sup> The public health Skills and career framework - [http://www.sph.nhs.uk/sph-files/PHSkills-CareerFramework\\_Launchdoc\\_April08.pdf](http://www.sph.nhs.uk/sph-files/PHSkills-CareerFramework_Launchdoc_April08.pdf)

<sup>21</sup> Position statement – Traffic light food labelling - [http://www.fph.org.uk/uploads/ps\\_food\\_labelling.pdf](http://www.fph.org.uk/uploads/ps_food_labelling.pdf)

EU competence on tobacco issues has been helpful in setting a baseline but has also allowed the UK to go further where appropriate. Over the last decade EU directives on tobacco advertising and promotion, on TV advertising and on packaging and labelling have supported the UK in banning advertising promotion and sponsorship of tobacco products and in requiring larger health warnings on tobacco packs. Flexibility on EU competencies, for example within the TPD allowed the UK to go further and to introduce in addition picture warnings on packs.

UK action on tobacco control has been supported by the WHO Framework Convention on Tobacco Control as the world's first health treaty which sets out a comprehensive set of obligations for tackling the harm caused by tobacco. It is notable that the EU negotiated the FCTC as a bloc.

Other important actions taken by WHO which benefit the UK and other Member States include:

- Surveillance of disease burdens and risk factors.
- Assessing effectiveness and cost-effectiveness of interventions (for low- and middle-income countries).
- Developing recommendations for action - e.g. controls on food and drink marketing to children.<sup>22</sup>

Developing tools to support implementation of policies – e.g framework for implementing controls on marketing to children<sup>23</sup>

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<sup>23</sup> WHO. Set of Recommendations on the Marketing of Foods and Non-alcoholic Beverages to Children. 2010. WHO. Geneva.

## Federation of Surgical Specialist Associations

The Federation of Surgical Specialist Associations (FSSA) would like to contribute evidence as part of your review. The Federation is comprised of all of the presidents of ten recognised specialist surgical associations. As such it represents the views of the vast majority of practising surgeons in the UK and Ireland.

We wish to make comments in relation to 4 aspects of healthcare: surgical training, patient safety, equivalence of qualifications, and health tourism.

1) The restrictions imposed by the combination of effects from the European Working Time Directive, the associated European Court of Justice rulings in Jaeger and SINAP, and the junior doctors contract “The New Deal” have been detrimental to surgical training. This is not only because of the absolute reduction in the available hours for surgical training, but also because the lack of flexibility, means that many surgical trainees are unable to take advantage of training opportunities as and when they arise. Whilst it is important that surgical trainees do not become fatigued by over-work, it is equally important that the pattern of work is sufficiently flexible to optimise surgical training. The effect of shift pattern working has been widely recognised as being detrimental for most trainees, and we have reported evidence to the Minister of Health from surveys conducted amongst surgical trainees which supports this.

2) The reduction in working hours and adoption of shift pattern working has led to a reduction in the safety of patient care, by virtue of a reduction in continuity of care, particularly where shift patterns of working have been adopted. This has been highlighted in a number of reports from the National Confidential Enquiry into Patient Outcome and Death (NCEPOD). A balance needs to be struck between the laudable desire to prevent doctors becoming unduly fatigued, providing optimal training, and providing safe continuity of care. The evidence suggests that the present level of restrictions placed on working hours places too much emphasis on the former and insufficient emphasis on training and safety.

3) The FSSA fully supports the primary Treaty obligation of promoting freedom of movement of labour and services across the EEA, and the principle of the EU Medical Directives and European Qualifications Statutory Instruments, which enable the mutual recognition of basic and specialist medical qualifications. However, that process was supposed to be accompanied by harmonisation of training, so that diplomas issued in any Member State would eventually provide equivalent levels of assurance of the competence of medical practitioners. Regrettably the process of harmonisation has not been effective, with the consequence that diplomas issued in the various Member States do not provide the public or employers with assurance of the equivalence of the competence of specialists trained across the EEA.

4) There is an increasing tendency for patients to be enticed into seeking healthcare in other Member States, particularly for areas of surgery which are aimed at lifestyle, rather than restoration of health, e.g. cosmetic and bariatric surgery. Whilst we fully support the right of patients to choose, this must be based on clear, accurate information,

and safeguards must be put in place to ensure that often vulnerable patients have access to appropriate aftercare, and support, particularly when complications arise. At present the NHS is often left to deal with the consequences of inappropriately performed procedures arising out of “health tourism”.

**We would recommend that the UK government seeks renegotiation of the EWTD in parallel with the junior doctors’ contract, to restore a flexible approach to work and training, particularly in the craft specialties.**

**We would recommend that more effort is put into the process of harmonisation of EEA medical diplomas, and where there is failure of harmonisation the automatic mutual recognition of diplomas should be withdrawn, and replaced with a process of establishing equivalence on an individual basis (the CESR route).**

**We would recommend that regulations be put in place to ensure that patients choosing to seek treatment in Member States other than their place of residence are protected.**

## Food and Drink Federation

### Nutritional Information

FDF members operate across Europe and therefore support a harmonised European approach to nutritional information which provides a level playing field across the Member States and prevents barriers to trade. National legislation increases complexity and costs for companies operating in a single market. Devolution also has the potential to create additional burdens for companies operating across the UK. For example, the current UK-wide salt reformulation targets had a completion date of 2012. DH has already indicated it will be reviewing and revising these targets throughout 2013 as part of the English Public Health Responsibility Deal, giving rise to the possibility there will be different targets set in each administration.

In terms of Front-of-Pack (FoP) nutrition labelling, FDF members have voluntarily provided consistent FoP monochrome Guideline Daily Amounts (GDA) labelling for many years in the UK and, in many, cases companies have adopted consistent FoP nutrition labelling approach across Europe. On 14 November 2012 at a meeting of the EU Platform on Diet Physical Activity and Health, 11 large European food and drink manufacturers and retailers renewed their support for European wide voluntary FoP GDA labelling. We are therefore pleased that **Regulation (EU) 1169/2011 on the provision of food information to consumers (FIR)** recognises the importance of FoP nutrition information and authorises its use. However, whilst remaining committed to working constructively with DH as it develops a national additional voluntary approach, we are concern about the additional label changes, with their associated costs and complexities, that a national additional voluntary focus of expression could impose on businesses in the future.

Another concern it that when legislation is developed at an EU level it should not restrict good practice that has developed in one or more Member State. For example the FIR prevents companies labelling calories on pack without in addition labelling kilojoules which is a term that consumers in the UK are not familiar with and could lead to confusion. Furthermore companies have invested considerably in consumer education and understanding of the term GDAs but will no longer be able to refer to them on pack and will instead have to label Reference Intakes which is a term not widely familiar to consumers.

We support **Regulation (EC) 1924/2006 on nutrition and health claims made on foods** which harmonises the use of scientifically substantiated nutrition and health claims and enables consumers across the EU to make informed and meaningful choices.

We welcome the review of “**Framework**” **Directive 2009/39/EC on Foods for Particular Nutritional Uses** with the aim of achieving market harmonisation and consistent enforcement across the EU. In the area of gluten claims particularly, we view this to be an opportunity to widen the choices available to people intolerant to gluten, whilst maintaining a high degree of safety, firmly based on scientific understanding.

### Non-legislative action on nutrition

FDF members are committed to playing a role in improving public health and have over many years proven the effectiveness of voluntary approaches. By changing product recipes, creating new healthier options, investing in consumer education and providing clear nutritional information to enable healthier choices, manufacturers are playing their part to deliver better long-term public health outcomes.

We are supportive of voluntary EU initiatives to coordinate and encourage action in this area, in particular the recent priority focus of the EU Platform for action on diet, physical activity and health on food reformulation. Its work to look at how existing salt and saturated fat reduction initiatives in Member States can be replicated across the EU to help improve consumers' diets is extremely valuable.

Another example of how companies can work together successfully through the Platform is on responsible marketing. The EU Pledge is a voluntary initiative by leading food and beverage companies to change the way they advertise to children under 12 on TV, print, internet and in primary schools. There are currently 19 signatories, which collectively account for more than 80% of EU food and beverage advertising spend in the EU.

Food and Drink Europe

<http://www.fooddrinkeurope.eu/publication/food-industry-calls-for-an-eu-industrial-policy-for-food/>

## Food Standards Agency

1. The Food Standards Agency (FSA) was established in April 2000 as a non-Ministerial UK Government Department, operating at arm's length from Ministers. FSA is headed by a Chair and Board, who are appointed to act in the public interest. The FSA is an independent national regulator and the central competent authority (CCA) for food and feed legislation. Section 1 of the Food Standards Act 1999 sets out that the main objective of the FSA is 'to protect public health from risks which may arise in connection with the consumption of food ..... and otherwise to protect the interests of consumers in relation to food'. The FSA is guided by a set of core principles:

- Putting the consumer first;
- Openness and transparency;
- Science and evidence based;
- Acting independently;
- Supporting businesses to comply with food law effectively.

2. FSA leads on food safety policy for the UK. In Scotland, Wales and Northern Ireland we also cover food labelling and compositional standards policy. In Scotland and Northern Ireland our remit extends to nutrition policy. FSA represents the UK Government at EU negotiations when the European Commission proposes to exercise competence. This evidence on food law is to the Animal Health, Welfare and Food Safety and Health<sup>24</sup> Calls for Evidence.

3. The FSA Board discussed the Balance of Competence review in relation to food law at its meeting on 5 March 2013. These are the views of the Board.

### **Consumer protection is paramount**

4. Consumer safety is central to FSA's work. It is estimated that each year about 1 million people in the UK suffer a foodborne illness (1 in 60 citizens), of whom 20, 000 receive hospital treatment. In the UK, approximately 500 deaths a year are associated with foodborne illness. None of these figures account for the unquantifiable health impacts from chemical contaminants and biotoxins.

5. The European Union (EU) has extensive food hygiene and food safety law. The legislation firmly places the responsibility to supply safe food on food business operators. Feed hygiene law ensures that animal feed does not introduce contaminants into the human food chain. Other law controls, among other things, the use of additives, irradiation and sets limits for harmful contaminants, such as heavy metals.

6. EU food law also provides other protections to consumers. It requires clear labelling that is not misleading and that enables consumers to make informed choices. It also ensures that unsubstantiated health claims are not made and sets compositional, quality standards for certain foods where inferior standard products have been an issue.

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<sup>24</sup> Our evidence is relevant to the nutrition related aspects of the Health report

7. FSA commissioned a UK wide survey of consumers that was undertaken between 19 February and 24 February 2013.

8. Around three quarters of consumers claim to be interested in who makes food law, but 80% do not know that the EU is responsible. Confidence in the UK Government in regards to food safety was at 42%, but it was only 27% for the EU. Only 42% feel protected by current food law. The horsemeat issue has influenced perceptions greatly, resulting in reduced confidence.

9. Approximately three quarters of consumers preferred food law to be made by the UK Government, with only 11% preferring the EU. This was similar across all four UK nations. Reasons for preferring national law included more direct control, UK Government has better understanding, UK standards are higher and the different cultures across the EU.

10. When given some further information about the benefits of EU level food law the figures changed, with 58% now preferring food law to be made by the UK Government and 23% preferring the EU. The perceived advantages of food law being made in the EU included consistency and common standards.

11. Overall, UK consumers are fairly sceptical about the value of EU level competence for food law, although we note that this view has been influenced by the current horsemeat situation and that when given some further information about EU food law some people's attitudes did change.

12. While recognising the consumer view, the Board's general view is that EU food law provides a comprehensive set of robust controls that protect consumer health and other interests. The question for the Balance or Competences (BoC) review is whether there is any benefit to consumers in the EU having competence rather than it being repatriated to the UK.

13. To answer this we need to consider:

- the international trade in food; and,
- whether the approach taken in EU legislation gives the best protection to UK consumers.

## **Trade**

14. Food is extensively traded, both within the EU and with third countries. The value of UK food and drink exports to the EU in 2011 was £12.3<sup>25</sup> billion, accounting for 63% of all UK food and drink based exports. For the same period the value of UK food and drink imports from the EU was £26.5 billion representing 69% of all food and drink imports in the UK. In 2011, the

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<sup>25</sup> All values are at current prices (Oct 2012)

value of exports and imports to and from third countries was £7.2 billion and £12.1 billion respectively. Consideration of any system of food law and consumer protection has to recognise the importance of trade.

15. UK consumers have the right to expect the same level of protection from food produced in the UK and from that produced in the EU and third countries. This could be achieved through UK legislation, requiring imported food to meet UK legal standards and with extensive checking of imports. But would a national system, which our survey suggests is what consumers would prefer, be in consumers' best interests? While the single European market and the use of harmonised food law across the EU is normally spoken of as a benefit to industry, it also has benefits for consumers. Economic literature contains theoretical arguments postulating that free trade leads to lower prices. Empirical evidence, however, suggests free trade is more advantageous in terms of mitigating the impact of price fluctuations from random supply side shocks. National rules would be likely to create trade barriers, so restricting the range of foods on offer. Having common standards can also give UK consumers confidence when they travel within the EU.

16. One of the most important benefits of an EU wide system for consumers is the protection offered when things go wrong. Europe operates a system where Member States are required to share intelligence on food safety problems and work together to manage risks. This strong network offers important additional protection to consumers when incidents occur, such as the dioxin contamination that occurred in Germany in December 2010/January 2011 when fats and oils intended for use as biofuels got into animal feed. The international network, both within the EU and with third countries, is also important for identifying and evaluating emerging risks.

17. Harmonised EU food law also applies to imports from third countries and the UK benefits from the centralised European system where production facilities in third countries are checked for compliance by European Commission inspectors.

18. Given that food is traded globally it is worth considering whether we should simply rely on standards for food that are set at world level by the Codex Alimentarius Commission. This body develops and harmonises world-wide food standards, guidelines and codes of practice that contribute to the safety, quality and fairness of international food trade. While Codex standards are recommendations for voluntary application by Codex member countries, in many cases they form the basis for national legislation. Codex standards are respected and can impact on EU legislation through World Trade Organisation disputes. But many countries that base their national legislation on Codex standards complain that they remain locked out of lucrative export markets. Also, the pace of deciding Codex standards tends to be very slow and UK influence can be diluted compared with negotiating within the EU. Therefore, we do not recommend the reliance on Codex standards as a viable alternative to EU food law.

### **Risk-based legislation**

19. Most EU food law is risk-based, but there are some areas, such as in relation to meat controls, that are not. We recognise that for meat the direction of travel in the EU is towards risk-based controls. We need to ensure that any developments take full account of the current EU wide incident involving horse meat, once the facts have been fully established and considered.

20. The European Food Safety Authority (EFSA) is an important and respected body offering independent and transparent, scientific risk assessment advice. We strongly support the centralisation of risk assessment within EFSA.

21. Decisions about risk management are never based on scientific evidence and risk alone. Risk perception, acceptability and other societal concerns will also inform the consideration. It is apparent that these issues inform the views of different Member States and EU institutions to different degrees. This can lead to decisions that are not as risk-based as we would like. One example is the control level set for products from Japan following the Fukushima nuclear disaster, when levels were set that were far lower than what was required to protect European consumers. Decisions based too heavily on matters other than science can also inhibit development of and access to new technologies that can be beneficial to consumers.

### **Principle/outcome-based versus prescriptive legislation**

22. Prescriptive legislation can give certainty, although it can stifle innovation. Principle-based (or outcome-based) legislation allows flexibility and puts the onus on business. Businesses should be best placed to know the risks involved, so principles-based legislation can offer strong consumer protection. Each approach has its place and is normally used appropriately in EU food law.

23. It is in consumers' interests that businesses thrive and consumers benefit from innovation. As well as considerations about principle versus prescription, and whether decisions are science based, the pace at which legislation is made can be an important factor. By changing the legislative process, new additives can now be approved more quickly but with no loss of consumer protection. Revised novel foods legislation should have facilitated greater innovation, including enabling traditional foods from outside the EU to be approved more easily, but the proposal failed to reach agreement. We look forward to the EU returning to that issue.

### **Flexibility**

24. Some EU food law has inbuilt flexibility and this can be to the UK's advantage. For example, the new EU food information legislation allows national rules for loose food (ie food that is not pre-packed). There is a requirement that consumers be informed about allergens in loose foods, but Member States are free to decide how this is delivered. This flexibility allows innovative approaches to meeting consumer needs, including the possibility of restaurants etc displaying signs prompting customers to ask staff about allergy information.

### **Official Controls**

25. It is important for consumer protection that appropriate, risk-based official controls are in place. EU legislation provides a framework for official controls, such as inspections or approvals, which Member States carry out to verify businesses' compliance with EU agri-food legislation. The rules are harmonised in order to afford EU citizens a high level of human, animal and plant health and facilitate the functioning of the internal market. The legislation is

expected to be reviewed shortly with the aims of simplifying and clarifying the legal framework and to address issues relating to the financing of official controls. The most controversial aspect is likely to be the intention to significantly increase the number of controls with mandatory charges on industry. There is concern about the direction of travel in relation to charging.

26. The Food and Veterinary Office (FVO) has a role in official controls. They audit Member States' application of official controls. We do not always agree with their interpretation of certain requirements (for instance in relation to desinued meat), but recognise the importance of their role and the positive impact FVO has on both consumer protection and the functioning of the single market.

27. The FVO also has an important role protecting consumers in relation to food imported from third countries. FVO assesses whether the standards required by third country food authorities are equivalent to those in the EU. They have an ongoing programme to visit and audit a sample of suppliers in that country. This allows FVO to assess the level of confidence in the competent food authority in the third country. If this work was not done at the EU level, the UK would need to do it.

### **Future challenges**

28. Enlargement has clear benefits for business in extending the number of potential customers. It also expands the availability of food within the single market. Enlargement candidates have to meet EU food law requirements. Where food processing plants, dairies and abattoirs fail to meet the standards these are normally shut down prior to accession, although derogations can be given to allow continued sale on the local market while they improve standards. This protects consumers in the UK. The European TAIEX programme (Technical, Assistance and Information Exchange) is important to help candidate countries to meet EU requirements.

### **Summary**

29. There are good reasons to believe that the EU having competence in food law is beneficial to UK consumers, even though consumers themselves are yet to be convinced. EU competence recognises that food is widely traded. EU food law is robust and in the main risk-based and proportionate. Were competence to be repatriated to the UK it is unlikely that the national legislation that we would have to put in place would be significantly different to existing EU food law. There would also be significant resource implications as the UK would have to take over the monitoring and audit functions currently delivered by the European Commission and other Member States.

## Fresh Produce Consortium

The Fresh Produce Consortium (FPC) is the UK trade association for the fresh fruit and cut flower industry. FPC represents retailers, importers, processors, packers, distributors, wholesalers, growers and other organisations.

FPC welcomes the opportunity to participate in the UK Government's review of the balance of competencies between the UK and the European Union.

We believe that there is significant scope for the European Commission to do more in terms of non-legislative action on nutrition and its platform for action on diet, physical activity and health. Whilst the Commission looks to encourage voluntary initiative to improve the nutritional quality of food, it appears to ignore the most obvious way of improving the health of the European consumer, by increasing consumption of fresh fruit and vegetables.

Given that the UK consumer eats on average just 2.5 servings of fresh produce a day, well below the recommended **5 A DAY**, the UK Government needs to consider urgently how it promotes fresh fruit and vegetables as part of a healthy diet.

It is critical that the UK Government does not devolve its responsibilities to European initiatives and that it puts a greater focus on promoting fresh fruit and vegetables as part of a healthy diet. The 5 A DAY campaign has been successful in establishing awareness of the minimum number of helpings per day which should be consumed to achieve a healthy diet; however, the campaign is failing to help consumers find ways to achieve this. The 5 A DAY campaign has lost its impetus and has been subsumed by the wider scope of the Change4Life campaign. The insidious inclusion of processed foods as portions contributing to 5 A DAY is a worrying trend, and we believe that the UK Government needs to act more vigorously in maintaining the integrity of 5 A DAY.

## School Fruit and Vegetable Scheme

FPC has been lobbying the UK Government to expand the successful Schools Fruit and Vegetable Scheme which has proved that it can increase consumption of fresh produce and establish healthy eating habits among young children. Many UK fresh produce businesses are involved in the School Fruit and Vegetable Scheme.

We urge the UK Government to build on the success of the School Fruit and Vegetable Scheme. The EU provides funding for Member States to develop such schemes, however, the UK Government has taken the decision not to take advantage of this source of additional funding.

Obesity and poor diet among children are a rising epidemic across Europe, and nearly one in three 10-11 year olds in the UK is overweight. An ambitious national programme is needed to tackle this public health issue; one which recognises the need to establish health eating habits

at an early age, and which avoids placing greater strain on stretched NHS resources required to combat poor health and rising obesity levels.

## General Medical Council

### **GMC response to the Department of Health review of the balance of competences February 2013**

#### **Introduction**

1. The General Medical Council (GMC) is the independent regulator for doctors in the UK. Our purpose is to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine.

2. The law gives the GMC four main functions:

- keeping up-to-date UK registers of qualified doctors
- fostering good medical practice in the UK
- promoting high standards of medical education in the UK
- dealing firmly and fairly

#### **Overall comments**

3. We welcome the opportunity to respond to the Department of Health's call for evidence on the Review of the Balance of competences between the United Kingdom and the European Union (EU). Our response focuses primarily on those sections in the consultation paper that impact on our work as a regulator.

4. The fundamental purpose of medical regulation is to ensure safety and quality of care for patients. In this context, we believe that all European initiatives involving or affecting the health and healthcare of European citizens must, without exception, make the protection of the public and patients their first priority.

5. As highlighted by the call for evidence, EU action in health is of a supporting nature. However legislative and policy initiatives in other areas have implications for health policy and patient safety across Europe. This is complicated by the fact that a number of different European Commission Directorate Generals (DGs) have competence over matters that affect patient safety and may not always work jointly to consider the specific requirements and implications for the health of those living in the EU. For example, DG Internal Market and Services is responsible for freedom of movement initiatives, rather than DG Health and Consumers, despite the fact that the movement of health professionals has significant implications for the health and safety of the public.

#### **Section 12 – Implications of employment policy**

6. The European Working Time Directive (EWTD) has an impact on patient safety and medical education and training in the UK.

7. Under the Working Time Regulations (WTR), which implement the EWTD in the UK, the UK's 55,000 doctors in training should not be working more than 48-hours a week, averaged over 26 weeks. They are also bound by another set of regulations from the UK government (The New Deal regulations) which also limit the hours they can work.

8. The interpretation of the regulations by the Courts has also had an impact. The Sindicato de Médicos de Asistencia Pública (SiMAP) and Jaeger rulings of the European Court of Justice have defined working time and compensatory rest respectively.

9. To help us understand and consider the effects of the WTR, in 2012 we commissioned research<sup>1</sup> into the impact of working time restrictions, and how they were working in practise. We have summarised below the main findings and implications for patient safety and education and training.

10. Following this research, we will write to employers and those responsible for training at local level to review how they manage and monitor working patterns. It is vital that rotas strike the right balance between training opportunities and clinical work. We will also highlight examples of what works well in designing rotas so that others can follow this good practice.

11. We have shared our findings with the European Commission Employment, Social Affairs and Inclusion DG as it reviews the EWTD and prepares for the adoption of a revised proposal

#### *Implications for patient safety and education and training*

12. The restriction of working hours in the last twenty years has brought benefits to many doctors in training and there is now a consensus that the very long working hours of the past were counter-productive, and dangerous.

13. Many (though not all) doctors in training believe that the 48-hour limit is appropriate and that they gain enough training experience within the current limit, although many were also frustrated by what they regard as a lack of flexibility within the current arrangements.

<sup>1</sup> *The Impact of the Working Time Regulations on Medical Education and Training: Final Report on Primary Research. A Report for the General Medical Council*, February 2013.

14. However, many of the problems the WTR were intended to solve persist, and the evidence suggests that some doctors in training are still subject to tiring, and potentially dangerous, working patterns.

15. Educational opportunities vary with time of day, and with specialty. Many Foundation Programme doctors find that out-of-hours work provides them with useful experience, but with the caveat that at those times there is limited availability of consultants and other seniors to teach and supervise. Senior presence was felt to provide the best educational experience.

16. Increasing pressure to deliver service means that more educational activity, including reading and completion of e-portfolio but also attendance at some clinical opportunities (e.g. ward rounds, theatre, and clinics), takes place in the doctors' own time.

17. The WTR and the end of the 'firm' of junior and senior doctors working closely and regularly together have changed the educational relationship between consultant and trainee. This is seen by some as a considerable loss, with consequences for training, assessment and recruitment.

18. Acute fatigue and stress remain a significant concern both in terms of the welfare of these doctors and the patients they treat. There are differences in the issues faced by different

specialties from working hours and patterns. Most medical specialties were reported to be more consistently intense than surgical specialties, even across shorter hours, with the result that more tasks build up during a shift. A shorter, more intense period of work was felt to be as fatiguing as a longer, less intense one. The same issues were present across nations and training grades.

19. The WTR are not, however, the sole cause of ongoing problems of fatigue. Other changes in medical training, and the composition of the medical workforce, have led to strains on medical rotas.

### **Section 13 – Implications of free movement of persons: healthcare professionals**

20. We are responsible for implementing the recognition of professional qualifications Directive (2005/36/EC). The Directive lays down the rules for how we register doctors that have qualified in other parts of the European Economic Area (EEA).

21. There are currently more than 250,000 doctors on the UK Medical Register; 25,000 (10%) of these doctors qualified in other parts of the European Economic Area (EEA). In 2012, we granted registration to more than 3,200 doctors under the provisions of the Directive.

22. The GMC supports the principles of free movement. The UK has significant experience of absorbing doctors both from Europe and internationally. This has contributed to a more diverse medical profession, and sustained our national health system. UK doctors have also benefited from the training and work opportunities available to them outside the UK.

23. However, the Directive has created a number of challenges to patient safety in the UK. While we recognise that the EU institutions are trying to address many of these through the proposal adopted by the European Commission in December 2011, we believe there are further measures that could be taken to improve the current legislative framework.

#### *Administrative simplification and cooperation*

24. Our interaction with competent authorities in other EEA countries have benefited from the introduction and use of the Internal Market Information System (IMI). IMI has helped us to build a network of contacts that is able to assist with more complex recognition queries and has helped to improve our understanding of medical regulation in other countries. We hope the Commission will continue to fund and improve this system in the coming years.

25. In addition, we have benefited from our role in key networks operating in the EU.

- a. We convene the Alliance of UK Health Regulators on Europe (AURE), which brings together 10 of the UK health and social care regulators to work on European issues affecting patient and client safety. The group shares information, agrees positions and responds to relevant European initiatives, particularly the recognition of professional qualifications and data protection Directives.
- b. Over the past three years, we have also built and consolidated relationships with other medical regulators across the EEA through the European Network of Medical Competent Authorities (ENMCA). ENMCA has enabled us to share experiences with the recognition Directive and present a united response to the proposals to reform it. This has led to

increased recognition of ENMCA's role by the EU institutions and the inclusion of many of its suggestions in the Commission's recognition proposal published in December 2011 and the European Parliament first reading report adopted in January 2013.

26. Our involvement in AURE and ENMCA has helped us share best practice with other regulators, and contributed to a number of GMC projects including:

- a. The structure of specialties and progression through training.
- b. The GMC's *State of Medical Education and Training in the UK* reports.
- c. Building an evidence base for an induction for doctors new to UK practice by asking international regulators what the challenges are for new doctors in their countries and whether they have any arrangements in place to support them.
- d. Our review of the way in which we quality assure medical education in the UK.
- e. The review of our Professional and Linguistic Assessments Board test which doctors from other parts of the world are required to pass before gaining entry to the UK register.

#### *Transparency of regulatory structures*

27. Although IMI and our informal networks have significantly improved our communication with other competent authorities, practical difficulties remain. There is wide diversity of regulators and competent authorities with a range of structures, approaches, and emphases. Some are government bodies and some are self-governing, while others are professional associations with a regulatory function.

28. However, we do not believe a harmonised regulatory model would be beneficial or desirable. Each approach, is arguably, appropriate to each individual jurisdiction and is a member state competence. But we do believe that public and patient protection should be at the heart of all regulatory approaches and that more could be done to improve our understanding of these.

29. We would also like to see greater clarity over main contact points, particularly in federal jurisdictions, where there is more than one organisation holding information about a health and social care professional's registration history. Confusion and complex organisational relationships and structures can make sharing fitness to practise information between member states, and even within member states, time consuming and ineffective.

30. We believe that the Commission could encourage greater transparency of regulatory structures which could facilitate the free movement of professionals while supporting competent authorities to share information and communicate in a timely and effective way. Initiatives such as IMI, and ENMCA have already helped our understanding of how medical regulation is defined and organised in other countries and we hope the Commission will continue to encourage and support these activities.

#### *Fitness to practise information sharing*

31. Currently there is no legal obligation on competent authorities to share information immediately about disciplinary findings against doctors and other health professionals. This

means that competent authorities such as the GMC are not routinely informed about doctors who may not be fit to practise in the UK.

32. The flow of information between competent authorities is often hampered by domestic data protection legislation in member states. Given that doctors are one of the most mobile professions in Europe and have powers of life and death over their patients, this is a serious concern.

33. There should be a clear obligation upon competent authorities to disclose details of disciplinary actions they have taken against doctors within their jurisdictions to other competent authorities. This should be done routinely and proactively by issuing the details to all other competent authorities in Europe. This would prevent doctors from avoiding or evading regulatory sanctions and posing a risk to patients by moving across jurisdictions with impunity.

34. We hope that the revised recognition Directive and the review of the data protection Directive will go some way to address these challenges.

#### *Language skills*

35. We strongly believe that the ability of the professional to communicate effectively with patients and colleagues in the language of the host member state lies at the heart of good medical practice and as such should be a prerequisite for access to the profession.

36. The language requirements in the existing Directive are not expressed clearly enough and have led to different interpretations and implementation across the EEA. We therefore welcome the European institutions' intentions to clarify Article 53 to enable competent authorities to assess the language competency of EEA doctors wishing to practise medicine in another member state. This would ensure that patients are fully protected while increasing trust and confidence in the recognition system.

#### *Minimum training requirements*

37. There are some inherent tensions between member states' exclusive competence in education and the minimum training times set out in the Directive under automatic recognition.

38. The mutual recognition of professional qualifications assumes comparability of medical education across the EEA. It is on the basis of medical qualifications that are deemed to have met certain minimum standards, that doctors can exercise their right of free movement within the EEA.

39. However the minimum training requirements in the Directive are so broadly drawn and general that they are of limited practical value in providing assurance about the standards of medical education and training of migrants. At the same time, the focus on time served in training rather than the outcomes of that training has imposed constraints which have impeded the UK sector from developing undergraduate medical education (of a shorter duration, for example).

40. To ensure public protection, competent authorities, employers and patients must have better assurances that the qualifications included in the Directive are genuinely comparable. In this

context the lack of transparency on the nature and content of medical education and training or the skills, knowledge and competencies acquired means that the level of assurance that states can draw from the training obtained by migrants is limited.

41. We believe the criteria for automatic recognition and the minimum training requirements outlined in the Directive should be reviewed to reflect current practice in medical education and training and should over time be developed in terms of learning outcomes rather than inputs (hours and length of study).

### *Competence Assurance*

42. The Directive as it currently stands does not allow competent authorities to assure themselves that the migrant doctors they register have kept their skills and knowledge up to date since the award of their professional qualifications. We do not consider that minimum Continuing Professional Development or revalidation/relicensing requirements of the kind used in relation to medical education and training for the purposes of recognition should be imposed at Union level. However, the inability of member states to obtain assurance of an individual's competence inevitably weakens the level of confidence that competent authorities can have in the doctors seeking establishment in another member state.

43. We believe that there should be a requirement on doctors to maintain and improve their knowledge and skills throughout their careers and that only those doctors who have satisfied the competence assurance requirements in their home member states should be eligible for automatic recognition elsewhere in the EU.

44. Where a professional cannot provide proof of continuous competence, competent authorities should have the discretion to assess applicants under general systems and, if appropriate, apply compensation measures. This process does not need to be burdensome and would increase trust and confidence in the mutual recognition system.

45. In this context, we welcome DG SANCO's intention to publish a study reviewing and mapping national systems, governance and practices in place for the continuous professional development of healthcare professionals.

### *Review of the Directive*

46. Despite the challenges highlighted above, the GMC welcomes the review of the Directive and the EU Institutions' attempts to address many of the public protection gaps we and other organisations have brought to their attention in recent years.

## **Section 16 – eHealth**

47. The GMC recognises the increasing importance of EU initiatives aimed at advancing the implementation of eHealth to address healthcare needs while enabling entirely new modes of care in the context of budget deficits and ageing populations.

48. Any measures to encourage eHealth services must go hand in hand with the right for patients to effective and robust medical regulation. Legal clarity about regulatory responsibility in instances of cross-border provision of telemedicine is therefore essential to avoid ambiguity.

49. However, we do not believe that the current legal framework is a significant barrier to the uptake of eHealth services and would not support a European model for the licensing and

accreditation of professionals carrying out telemedicine services. Any such move would be neither proportionate nor appropriate given the small number of patients and professionals accessing cross-border eHealth services.

50. In this context, a more appropriate solution would be for all member states to provide online registers of healthcare professionals and publish details about fitness to practise actions. That way, patients, employers and those commissioning eHealth services could easily check a doctor's registration and disciplinary status. This would improve regulatory transparency and in turn increase confidence and trust in professionals providing cross-border eHealth services.

## **Section 20 – Non legislative action**

### *Implementation of EU legislation*

51. EU legislation, which is intended to govern action in the member states, is sometimes interpreted and implemented differently across the EEA. These discrepancies have the potential to jeopardise patient safety. We would welcome better coordination and sharing of good practice among member states when they implement Directives and other EU initiatives.

## General Optical Council

The General Optical Council (GOC) welcomes the opportunity to respond to the call for evidence on the Government's review of the balance of competences between the United Kingdom and the European Union. The GOC is the regulator for the optical professions in the UK and our purpose is to protect the public by promoting high standards of education, performance and conduct amongst opticians. We currently register around 25,000 optometrists, dispensing opticians, student optometrists and dispensing opticians, and optical businesses.

The statutory function of the GOC is 'to protect, promote and maintain the health and safety' of members of the public and the EU's competence in health does have an effect on the work of the GOC, the optical sector and UK citizens in relation to eye health and safety.

This paper sets out high level answers to a number of the proposed questions included in the consultation document. Overall the GOC believes that the EU has a valuable role to play in issues concerning public health and healthcare.

### **How does the EU's competence in health affect your organisation?**

As a healthcare regulator in the UK the EU's competence in health has an effect on the work of the GOC. It also has an effect on the optical sector and UK citizens in relation to eye health and safety.

Specifically, the EU's competence in health currently has an impact on the GOC, optical sector and citizens in the following areas:

Medical devices

Free movement of healthcare professionals

In general EU action in health can improve health and safety standards across Europe and bring benefits from the sharing of knowledge, data and best practice.

### **What evidence is there that EU action in health advantages or disadvantages patients/citizens/your organisation?**

#### *Medical devices*

The GOC recently responded to the Medicines and Healthcare products Agency (MHRA) consultation on the revision of European legislation on medical devices<sup>1</sup>. Overall the GOC welcomed the proposals to update and replace the existing EU directive with two new EU regulations on medical devices and in vitro diagnostic devices.

1 <http://www.optical.org/en/get-involved/consultations/our-responses-to-other-consultations.cfm>

The GOC particularly supported the proposal to broaden the scope and definition of 'medical devices' to include non-corrective contact lenses (sometimes described as 'cosmetic contact lenses'). This is an example where action at an EU level advantages citizens and also complements the work of the GOC.

We believe this reclassification should help enhance public protection as non-corrective contact lenses will be required to be produced to the same regulatory standards as corrective contact lenses. This will help address a current inconsistency whereby corrective lenses are regulated as medical devices but non-corrective contact lenses are regulated under general product safety legislation. Although non-corrective contact lenses do not have a medical purpose they can still carry health risks.

The sale of non-corrective contact lenses is governed by section 27 of the Opticians Act 1989. This states that 'non-corrective contact lenses can be sold only by, or under the personal

supervision of, a registered medical practitioner, registered optometrist or registered dispensing optician'. The majority of illegal practice allegations the GOC receive relate to the sale of non-corrective contact lenses and the GOC is pursuing a risk based approach to tackling this issue. The proposed EU action in relation to medical devices complements and strengthens the GOC's activity in this area.

As well as the benefit of enhancing the quality and safety of products placed on the market as a result of greater uniformity and harmonisation across the EU, the proposed changes would also help to bring the EU in line internationally. For example, non-corrective contact lenses have been classified as Class II medical devices in the United States since 2005, Class III medical devices in Japan since 2008, Class II medical devices in Canada and Class III medical devices in China since 2012.

### *Free movement of healthcare professionals*

It is important that regulated medical professionals can move between European Economic Area countries. However ensuring patient safety is critical. We have closely followed the review of the recognition of professional qualifications Directive (2005/36/EC).

The existing Directive, which has applied since 2007, secures the automatic recognition of 7 professions across Europe: doctors, dentists, pharmacists, nurses,

midwives, veterinary surgeons and architects. As optometrists and dispensing opticians are not subject to automatic recognition, this has less impact on the GOC than other regulators.

The GOC supports the Alliance of UK Health Regulators on Europe (AURE) response to the call for evidence which sets out the analysis in this area in more detail. AURE brings together 9 of the health and social care regulators (competent authorities) in the United Kingdom to work collaboratively on European issues affecting patient and client safety.

### **How might the UK benefit from the EU taking more or less action in health?**

The eye health and safety of patients and citizens is regulated at a national level, however the use of the internet as a delivery channel in the optical sector raises new questions about how to assure public and patient safety.

Section 25 of the Opticians Act states that contact lenses can be fitted only by a registered medical practitioner, registered optometrist or registered dispensing optician, who is in possession of an in-date contact lens prescription from within two years. However a number of online lens retailers operate from outside the UK and therefore outside the UK's regulatory framework.

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### *Case study: Vision Direct BV*

In 2008, following a private prosecution brought by the GOC, Vision Direct were convicted of breaching the Opticians Act by selling contact lenses without verifying the wearer's contact lens specification.

Following this conviction, Vision Direct transferred their sales operations from the UK to Holland, and they are continuing to supply contact lenses without verifying the wearer's specification.

The GOC has contacted Vision Direct to point out concerns over the possible health risks, as well as criminality, of sale practices that breach the requirements of the Opticians Act. This

legislation was passed in order to protect the public, and the health risks for users would be the same irrespective of the criminal jurisdiction in which the supply is made.

Vision Direct has not given any indication that they will amend their practices, and there seems little likelihood that they will be bringing their processes within the requirements of the Opticians Act.

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It is difficult to use UK law to prosecute an overseas company even where the purchaser is in the UK. Even in cases where it might be legally possible to prosecute a non-UK company under UK legislation, there would be practical

problems in doing so without the power to compel the defendant to attend a UK court. It would also be extremely to enforce any conviction or court order.

This is an example where being able to take action at a national level is dependent on cooperation across the EU or internationally. This can be difficult if other countries have less stringent rules to deal with particular issues, such as the sale of contact lenses online, as the case study highlights.

This can potentially lead to health risks and cause confusion for customers. We are monitoring the impact of the growth of online sales on the health and safety of the public and carrying out research to better understand the risks to the public from different kinds of illegal practices. This will inform our thinking on whether the public would benefit from changes to the legislation, including potentially greater harmonisation across the EU.

More generally, the GOC is continuing to consider ways in which we can improve public awareness of the importance of professional eye care, for example, by publishing a leaflet<sup>2</sup> for the benefit of consumers who are considering buying zero powered (cosmetic) contact lenses.

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[http://www.optical.org/goc/filemanager/root/site\\_assets/publications/patient\\_leaflets/GOC\\_Contact\\_acts.pdf](http://www.optical.org/goc/filemanager/root/site_assets/publications/patient_leaflets/GOC_Contact_acts.pdf)

## General Pharmaceutical Council

### Introduction

The General Pharmaceutical Council is the regulatory body for pharmacists, pharmacy technicians and registered pharmacies in England, Scotland and Wales. We are very pleased to be able to respond to the Department of Health's call for evidence: EU balance of competence review.

In the following, we will briefly outline our role and functions and then address the areas where the EU has an impact on our regulatory remit.

### Our role and functions

We are the newest of the nine statutory health professional regulators in the UK. The Pharmacy Order 2010, endorsed by both the UK and Scottish Parliaments, set out the regulatory powers of the General Pharmaceutical Council in Great Britain and brought regulation of the pharmacy professions in Great Britain into line with other health professions, with a statutory regulatory body quite separate from the professional leadership body. The Pharmaceutical Society of Northern Ireland retains both roles in Northern Ireland.

Consistent with the other health professional regulators our legislation makes explicit that our purpose is that of patient protection. Specifically, the Pharmacy Order sets out our role as being:

*"...to protect, promote and maintain the health, safety and well-being of members of the public, and in particular of those members of the public who use or need the services of registrants, or the services provided at a registered pharmacy, by ensuring that registrants, and those persons carrying on a retail pharmacy business at a registered pharmacy, adhere to such standards as the Council considers necessary for the safe and effective practice of pharmacy."*

Our principal functions are set out in Article 4 (3) of the Pharmacy Order 2010. These cover:

- Approving qualifications for pharmacists and pharmacy technicians and accrediting education and training providers;
- Maintaining the register of pharmacists, pharmacy technicians and pharmacy premises;
- Setting standards for conduct, ethics, proficiency, education and training, and continuing professional development (CPD);
- Establishing and promoting standards for the safe and effective practice of pharmacy at registered pharmacies;
- Establishing fitness to practise requirements, monitoring pharmacy professionals' fitness to practise and dealing fairly and proportionately with complaints and concerns.

We are unique amongst the UK health professional regulators as we also have a statutory role in relation to 'system' regulation that consists of the regulation of registered pharmacies from which pharmacy services are provided.

Our response is based on comments made previously to European consultations and calls for evidence.

Below we have considered;

1. Current challenges relating to implementation of European Directives.
2. Future opportunities.
3. Future challenges.

## **1. Current challenges relating to implementation of European Directives**

### **Section 13 – Implications of free movement of persons: healthcare professionals – The Recognition of Professional Qualifications (RPQ) Directive.**

#### **Automatic recognition**

Regulators must efficiently manage the registration process in accordance with domestic and EC law and assure themselves that the professionals they register are fit to practise and will not put patient safety at risk.

We have considerable experience with high levels of mobility both from Europe and internationally. The numbers of European qualified pharmacists registered from 2001 to 2012 under the automatic route to recognition of qualifications provided by the Recognition of Professional Qualifications (RPQ) Directive is provided in Annex 1.

From a patient safety perspective, automatic recognition based on diploma compliance with the minimum training requirements takes no account of whether an applicant has maintained their professional competence since qualification or of the steps they have taken to keep their knowledge and skills up-to-date.

The concept that primary qualifications have decreasing value over time as a measure of evidence for initial registration when not associated with relevant work experience is an accepted principle and also critical in assuring public confidence. This is one of the principles which underpin the move to require continuing professional development.

We remain concerned that an EU national with a qualification listed in the Annex and started after 1 October 1987 reference date and awarded in 1992 for example, which complies with the minimum training requirements of Article 44 is entitled to automatic recognition of that qualification and registration (provided they satisfy health and character requirements) even though they may have not practised at all in their home or any other member state since qualification. In the interests of patient safety such individuals should also be required to satisfy the national competent authority's 'return to practice' requirements that includes providing evidence of any completed continuing professional development activities since qualification before being granted registration and a licence to practise. This would align with what is

required of a UK qualified person who had completed a degree in 1992 and had not practised as a pharmacist since.

## Language

From a patient perspective, communication is key to building trust in the patient-practitioner relationship. It also goes without saying that clinical information and advice must be communicated clearly and accurately to patients. Robert Francis QC, in his report of the Mid Staffordshire NHS Foundation Trust Public Inquiry included at recommendation 172, a recommendation that *'Government should consider urgently the introduction of a common requirement of proficiency in communication in the English language with patients and other persons providing healthcare to the standard required for a registered medical practitioner to assume professional responsibility for medical treatment of an English-speaking patient'*.

The implementation of the RPQ Directive in our governing legislation prevents us requiring 'exempt persons' (i.e. EEA nationals) from meeting any requirements to demonstrate that they have reached an adequate standard of proficiency in the knowledge and use of English. This provision does not, however, apply to non-EEA Nationals.

We agree that language competency is not a relevant consideration when determining whether an applicant holds a qualification which entitles them to mutual automatic recognition; the 'recognition stage' of an application.

Similarly, the standard of an applicant's language competency is not a factor to be considered when comparing an applicant's qualification with the national requirements for registration under the general system of recognition to ascertain whether compensation measures are required prior to registration.

However, once we are satisfied that the applicant holds a qualification which complies with the requirements of the Directive (or following completion of any compensation measure) an applicant will move to the second stage – the registration stage.

According to Article 53 of the Directive such an applicant would have benefited from the recognition of professional qualifications and *'shall have knowledge of languages necessary for practising the profession in the host member state'*.

We are therefore firmly of the view that, following recognition but prior to registration, we should be able to require applicants to provide some assurance or evidence of their language competency necessary for safe and effective practice in the UK.

We acknowledge the important role played by employers ensuring that professionals are fit for a particular position but would like to highlight that a significant number of the professionals we

regulate carry out work in a self-employed capacity. We believe that a regulator must ensure that all professionals are fit for practice at the point of registration, including their ability to effectively communicate.

We have anecdotal evidence that language competence is an issue for a number of EEA applicants seeking registration with us. We provide information on our website about the importance of having the necessary language skills to communicate and work effectively with patients and colleagues. <http://www.pharmacyregulation.org/registration/registering-pharmacist/eea-qualified-pharmacists>

We have also conducted a limited review of fitness to practise cases between 2008 and early 2011 and identified two cases where our inability to refuse registration on grounds of a lack of English language proficiency posed a risk to patients. These cases are summarised in Annex 2.

### **Exchanging Fitness to Practise information**

With increasing movement of healthcare professionals around Europe, there is clearly an increasing risk that some health practitioners may seek registration in other parts of Europe when they have been erased or suspended from the register or in order to avoid disciplinary action in their home country. We have worked with colleagues as part of the Healthcare Professionals Crossing Borders (HPCB) initiative. HPCB is an informal partnership of professional healthcare regulators from within Europe. HPCB works to ensure that health professionals can effectively take up their rights of free movement whilst emphasising the importance of regulators being able to share fitness to practise information on both a reactive and proactive basis to establish that these healthcare professionals are fit and safe to practise. We remain concerned that member state regulators do not readily share fitness to practise information with us.

### **Temporary service providers – Visiting EEA practitioners**

We believe that patients have the right, and a clear expectation, to be protected by the national regulatory system regardless of whether the healthcare professional treating them is in the country permanently or temporarily. It is therefore essential that pro-forma registration and the prior authorisation schemes (Article 7.4) are maintained to ensure that healthcare professionals practise in accordance with the professional standards of the host member states and that competent authorities can take fitness to practise action where required.

We view this as essential for protecting patients and maintaining public confidence in the system.

We are concerned that:

- we cannot require prospective temporary service providers to complete the same fitness to practise declarations prior to registration as we require of other applicants for establishment and
- a prospective temporary service provider's right to provide services outside their home member state is determined by the fitness to practise regime in the home member state, not that of the host member state where the services are to be provided.

## **Section 15: Implications of free movement of services: cross-border healthcare**

One of the principal functions of the GPhC as described above is to set and promote standards for the safe and effective practice of pharmacy. Under our Standards of Conduct, Ethics and Performance and the Standards for Registered Pharmacies, the care, well-being and safety of patients is at the heart of professional practice. Pharmacy professionals must make sure that the services they provide are safe and of acceptable quality and to use their professional judgement to act in the best interests of individual patients and the public.

UK legislation and our standards are there to ensure that the right patients receive the right medicines, at the right time, in the right way, with the right information and advice so that medicines can be used safely and in a way that works.

Although the Directive on the application of patients' rights in cross-border healthcare (2011/24/EU) is to be implemented by 25 October 2013 prescriptions given in an EEA member state or Switzerland are already recognised for dispensing in this country.

For patient safety our national legislation<sup>26</sup> stipulates that the following must appear on prescriptions written by UK prescribers

- the patient's name, address and age if under 12,
- the prescriber's signature,
- address of the prescriber,
- particulars that indicate whether the prescriber is a doctor or a dentist etc,
- appropriate date (when the prescription becomes valid).

It is therefore a continuing concern that European prescriptions for dispensing in the UK do not have to include the patient's address or the date of birth.

Pharmacy professionals, when supplying the medicine they have dispensed, check not only the patient's name but also address details as written on the prescription to make sure that the dispensed medicine is supplied to the correct person.

The absence of a date of birth can potentially lead to the pharmacist being unable to readily verify the clinical appropriateness of the prescribed medicine.

From a patient safety perspective, there can be no justification in enabling doctors or dentists from EEA member states to write prescriptions for dispensing in this country that contain less information than is required from UK prescribers.

Additionally pharmacy professionals may encounter difficulties in deciding on the right medicine to dispense because of differences in the names, dosage and forms of the medicine available between member states. Brand A may contain one drug (X) in one member state but may

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<sup>26</sup> The Human Medicines Regulations 2012

contain a completely different drug (Y or Z) in other countries. In the past this has been the case with the brand Acepril containing either enalapril, captopril and lisinopril depending on the member state in which it is marketed.

Prescribers should be required to prescribe using the generic (rINN) name of the medicinal product. Brand names should only be included where, for reasons of differing bioavailability of the product, profile of release or route of administration, it is important for the patient to continue on the same brand of medicine.

Pharmacy professionals also need to assure themselves that the medical prescription presented to them for dispensing is authentic and that the prescriber is authorised to prescribe in the member state where the prescription is given.

It would assist pharmacy professionals if member states were required to have real-time web-based publicly searchable lists of registered professionals who are authorised to prescribe within their jurisdiction similar to the details provided by the General Medical Council on their website [www.gmc-uk.org](http://www.gmc-uk.org)

It should be noted that in the UK in addition to doctors and dentists a number of supplementary prescribers and appropriately qualified nurses, optometrists and pharmacists can also write prescriptions for patients.

## **2. Future opportunities**

### **Section 13 – Implications of free movement of persons: healthcare professionals - Proposed amendments to the RPQ Directive**

#### **Language**

We have been following the proposed amendments to the RPQ Directive with interest and welcome the amendments clarifying that language assessment can take place after recognition of the professional qualification but before access to the profession by or under the supervision of the competent authority for all healthcare professionals.

#### **The proposed alert mechanism**

We also welcome the proposed amendments to the RPQ Directive that introduce an alert mechanism in the revised RPQ Directive but consider that it should be extended to all health and social care professions, regardless of whether they have had their qualifications recognised under automatic recognition or general systems. Alerts about all healthcare professionals should be treated with the same urgency as the risk to patient safety is the same.

Additionally any alert mechanism should cover any restriction on a professional's licence to practise. Restrictions short of removal from the register or suspension, such as conditions on a licence or limitations to scope of practice, can indicate serious issues about a professional's practice and these should be communicated to all other competent authorities.

#### **Administrative co-operation**

In our experience the implementation of the internal market information (IMI) system has improved administrative co-operation between us and home member state competent authorities.

We welcome the extension of IMI to competent authorities for all healthcare professions, mandatory registration with IMI and the proposed enhanced role for the IMI system in the alert mechanism.

### 3. Future challenges

#### **Section 2: Medicinal products – Directive 2011/62/EU amending Directive 2001/83/EC (The Falsified Medicines Directive)**

As explained above we have the dual role of regulating pharmacy professionals and pharmacies and because of this we have powers to set standards for registered pharmacies.

In the UK medicinal products for human use are divided into prescription only medicines and non-prescription medicines with the non-prescription medicines category further subdivided into medicinal products that can only be purchased from a pharmacy (P medicines) and medicinal products known as General Sale List (GSL) medicines that can be purchased not only from pharmacies but also from non-pharmacy retailers.

A pharmacy must be registered with the GPhC because the supply of Pharmacy (P) medicines and Prescription only Medicines (POMs) is restricted by law to being supplied from registered pharmacies only. There are exemptions from this restriction and it is because of these that the GPhC does not register dispensing doctors' practices or hospital pharmacies that only make supplies that are defined as being made *'in the course of the business of the hospital'*. General Sale List (GSL) medicines on the other hand can be sold from other retail outlets apart from registered pharmacies, such as supermarkets and petrol stations, when the appropriate legal conditions are met.

We have therefore contributed to the recent MHRA consultation on the transposition of the Falsified Medicines Directive into national legislation. This Directive introduces a mandatory EU internet logo that is to be displayed on websites supplying medicinal products (including GSL) medicines on line.

A key consideration for the GPhC will be the impact this has on the current voluntary internet logo which we issue to pharmacies registered with us that sell or supply medicinal products over the internet; whether this should be discontinued following the introduction of the EU logo scheme and how it will be possible, in future, for patients to distinguish easily between registered pharmacies whose services are fully regulated by the General Pharmaceutical Council), other healthcare providers who may supply medicines over the internet such as doctors providing online consulting, prescribing and supply from hospitals or clinics directly to patients of that doctor where there is no pharmacy involvement and non-healthcare retail organisations who retail GSL medicines over the internet. It is unclear to us how the mandatory logo applied to websites linked to nonpharmacy retailers will benefit patients or promote patient safety.

We support the desire to provide greater assurance to the public when purchasing medicinal products over the internet but remain concerned that the EU logo could give false assurance as

it appears that the logo can be copied onto websites that have not been approved by the relevant national competent authority. Additionally in the UK the appearance of the logo may give the public false assurance that they are purchasing medicinal products from regulated pharmacies when this will not always be the case.

### **Section 13 – Implications of free movement of persons: healthcare professionals - Proposed amendments to the RPQ Directive**

#### **The European Professional Card proposed in amendments to the RPQ Directive**

We remain sceptical as to whether the proposed European Professional Card will deliver real benefits for the profession and competent authorities.

We consider that the most effective way to ensure the successful implementation of the proposed professional card would be to have a number of pilot projects before being fully introduced to ensure that the proposed system and timelines are safe, robust and realistic.

We consider that responsibility for recognising qualifications under the card should lie exclusively with the host Member State to ensure professionals are appropriately qualified in the country in which they intend to practise. This must be the case irrespective of whether the individual applicant seeks to establish themselves permanently in the host member state or to provide services on a temporary or occasional basis.

We are also firmly of the view that the professional card must only be used for the recognition process and not as a way to confirm the registration status of a professional with patients or employers because of the potential risk of abuse or fraud.

The Directive should not mandate the means by which member states make registration information available to patients and employers. In the UK, healthcare professional regulators make web-based searchable lists of registration and disciplinary information freely available to the public. These are live and updated daily. We consider this is a much more effective and safe way to confirm the status of a professional than checking the authenticity of a 'card' which would be in effect out of date as soon as it is printed.

On average we recognise and register over 400 European qualified pharmacists under the automatic route to recognition each year. This represents approximately 15% of all new registrants each year. We do this well within the 3 month time limit provided by the current Directive (in most cases within 6 weeks from initial enquiry to registration). We would be very concerned if this were to be reduced to two weeks as proposed we would not have the resources to meet such a reduced time limit.

We look forward to seeing the final agreed text of the amended RPQ Directive and to working with both the Department of Health and the Department for Business, Innovation and Skills (BIS) on its implementation.

### **Section 15: Implications of free movement of services: cross-border healthcare**

We have responded to the EC's consultation on measures for improving the recognition of prescriptions issued in another member state that was undertaken under the Directive on the application of patients' rights in cross-border healthcare (2011/24/EU). In our opinion, if a standardised format for these medical prescriptions is to be developed it should comply with the legislative requirements for prescriptions in all of the member states. Measures should also be introduced to reduce the current challenges described in the first part of this response.

### **Summary**

The structure of health care, how it is provided and regulated is a member state competence. EU action in the area of health sometimes fails to take sufficient account of this and mandates solutions such as the European Professional Card and the EU logo for example that when implemented in the UK could potentially undermine the existing safeguards we already have to protect public and patient safety.

## **Annex 1**

### **Numbers of EEA Applicants Registered – automatic recognition based on diplomas and ‘acquired rights’ 2001 – 2012**

## **Annex 2**

### **Case 1**

Mr Y 's case was heard by the Disciplinary Committee on 23 May 2011. The Committee found that there were sustained examples of sloppy and incompetent management of his pharmacy practice. There was a deliberate flouting of his undertaking not to act as his own superintendent pharmacist, and he failed to reach the level in English within the three year time limit allowed by his undertaking. Further, in the knowledge that he had not reached the required level of competence in English, he dishonestly produced a forged certificate to pretend that he had. He denied the subsequent charge in respect of that at trial, but he was convicted. The Committee found the level of dishonesty in attempting to deceive the pharmacy regulator into believing that his English had reached a safe standard when it had not the most important and serious of the allegations. The Committee ordered Mr Y to be removed from the Register of Pharmacists. The Direction was made on 23 May 2011 and an interim order imposed until the direction for removal comes into effect.

### **Case 2**

The case of Mr M concerns allegations of a number of dispensing errors and of a lack of competency in the English language. The case concluded with the Disciplinary Committee directing Mr M's removal from the Register of Pharmacists. The language allegations were that he accepted employment as a locum pharmacist at three pharmacies when he did not have the requisite skills and fitness for the task to be performed, contrary to part 2A1(a) of the code, in that he lacked sufficient competency in the English language. The evidence of lack of competency was provided by his colleagues and one patient; one colleague said that, in her view, Mr. M had difficulty in making himself understood, a patient said that Mr. M's command of English was not very good; another colleague said that Mr. M's English would be best described as broken, and there were gaps when he spoke while he appeared to think what he was going to say; another colleague said "I do not think that his English was very good. I sometimes found him difficult to understand".

There were however evidential difficulties in establishing that the registrant's command of English was so deficient that he was guilty of misconduct by virtue of having accepted locum work as a community pharmacist. The committee did not find any of the language allegations proved, on the ground that Mr M had been interviewed before being offered work and the interviewers had considered Mr M's English language skills to be sufficient.

## Genetic Alliance UK

### Intro

1. Genetic Alliance UK is the national charity of over 150 patient organisations supporting all those affected by genetic conditions. The majority of genetic conditions are rare, with less than 1 case in 2,000, and many are very rare with less than 1 case in 100,000.
2. We welcome the opportunity to respond to this consultation.

### Rare diseases

3. The consultation document identifies the 2009 EC Recommendation on Rare Diseases as a stimulus for the UK's ongoing development of a National Plan for Rare Diseases. The development of this plan involved a consultation in the spring of 2012, which was a significant focus of interest to the rare disease community in the UK, generating an unexpectedly high rate of response. This demonstrates the level of expectation within the community for the delivery of the National Plan, and the appetite for initiatives in this area. The EC Recommendation has certainly raised the profile of rare disease within the UK, to the benefit of the whole rare disease community, which includes patients, families, carers, clinicians, researchers, industry, and healthcare commissioners.
4. The UK is well represented on the European Union Committee of Experts on Rare Diseases (EUCERD) which advises the European Commission on issues relating to rare diseases. This membership demonstrates the expertise within the UK on rare disease issues. Involvement at this level furthers relationships in the research and treatment spheres, where the UK is one of a few nations taking the lead in innovation in this area.
5. Issues surrounding rare diseases are relevant to many more of the areas outlined in the consultation. Broadly speaking the rare disease issue benefits from the increase in critical mass delivered by being a part of Europe in many different senses. Unlike the majority of common conditions, patient populations of individual rare diseases are very low. There may be too few patients with any particular rare disease in a single member state to be able to make progress in treatment in research. The sheer number of individual rare diseases mean that experts cannot be in every member state and travel may be necessary for patients to access effective treatment. Patient communities may be too small in individual member states, and benefit from making contact and collaborating across borders.
6. Many of the health competencies of the EU allow European patients to join into a single critical mass for their mutual benefit. A single research framework allows the critical mass necessary for research to be shared. A single medicinal product regulatory system enlarges the market for medicines for rare diseases and incentivises the marketing of rare disease treatments in the EU.
7. Every section of this consultation to which we respond here is relevant to the rare disease community.

### Medicines and Medical Devices

8. The European Medicines Agency's (EMA) regulation of medicine in Europe creates the largest single regulatory environment for developed nations' populations. This infrastructure is attractive to pharmaceutical companies wishing to bring medicines to markets, and allows UK patients access to all medicines marketed in the EU intended for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases and for all designated orphan medicines intended for the treatment of rare diseases. The EMA can leverage this critical mass to provide

incentives for the development of orphan medicines and for advanced therapy medicinal products.

9. States outside of the EU (such as Norway and Iceland) may still benefit from the EMA's regulatory environment, but they cannot have any influence in decisions made by EMA.

10. Though differences in member states' health technology and reimbursement systems add an element of complexity to the European medicine market, we strongly believe that our patient group membership benefits significantly from the UK's membership of the EMA regulatory system.

### **Organs, blood, tissues and cells**

11. The European Union Tissue and Cells Directive regulates haemopoietic stem cell transplantation (HSCT) in the UK and the EU. HSCT is one of very few effective treatments for genetic conditions currently available, with the potential to treat many genetic immunodeficiencies and anaemias. The European regulation allows cross-border transfer of cells for clinical use, which is highly beneficial to the search for a matching donor.

12. The UK's membership of the EU Tissue and Cells regulatory system increases the potential pool of donors for HSCT for UK patients and is therefore a significant benefit to our patient group membership.

13. The Advanced Therapy Medicinal Product Directive regulates the development of gene therapy, stem cell therapy and tissue therapy in the EU. These are three highly complex innovative areas of technology development. The Directive prompted to the creation of the EMA's Committee for Advanced Therapies which provides a forum for European experts in these areas to share scarce knowledge and deliver the best possible regulation of an emerging field. Alongside good quality regulation, the Directive also allows for incentives to be provided to drive innovation in this area.

14. We believe the framework provided by the Advanced Therapy Medicinal Product Directive has the potential to benefit patients affected by genetic conditions in the UK.

### **Health research**

15. All health research is an international activity; collaboration, peer review and research dissemination all take place in an international context. This is especially the case for research into rare diseases. Expertise is scarce, and in many cases patient numbers are too low for research to progress on a solely national level.

16. Though the majority of international research collaboration occurs outside the context of EU specific structures, it is important to recognise those EU initiatives that do facilitate cross border collaboration. One of these is research funding. A significant source of funds for health research in the rare disease field comes from European sources such as the Seventh Framework Programme, the Innovative Medicines Initiative and in the future Horizon 2020. These are not solely a source of funding, but also a significant driver in the formation of partnerships across the EU.

17. A second EU specific structure that facilitates collaboration in the research field is the regulatory structure which aims to provide a unified approach to research regulation across the

EU. Though some components can be rightly criticised for reasons such as high levels of bureaucracy, the unified framework makes cross-border research projects significantly more straightforward. This is particularly valuable for research into rare diseases.

## 1. Introduction

GSK contributed to and fully supports the ABPI submission to this consultation. However, as the ABPI response focused predominantly on legislative initiatives, we would like to provide supplementary comments on the broader areas of the single market, trade, intellectual property and other legal issues and finally, the EU's role in engaging with multilateral institutions.

## 2. About GSK

GSK is a science-led global healthcare company that researches and develops a broad range of innovative medicines, vaccines and consumer healthcare products used by people around the world. Globally, GSK employs over 99,000 people in over 100 countries, with nearly 39,000 of these employees being based in Europe. GSK is British-owned, and headquartered in the UK where we have 16 sites (3 commercial, 6 R&D and 9 manufacturing sites) and employ around 15,000 people.

## 3. Summary of comments

**The Single Market:** GSK believes that a functioning Single Market will be positive for business. However, in the area of pharmaceuticals it is distorted and imperfect due to the complexities and interplay between national pricing systems and the free movement of goods. External price referencing, and particularly in the current context of austerity measures, is creating a 'race to the bottom' for prices paid for pharmaceuticals by European countries, with the obvious negative implications for future innovation and on patient access to medicines. Due to national competency, the EU's role in this is limited, and the UK (and other Member States) must therefore be willing to encourage and initiate discussions to address this challenge.

**Trade:** We believe that the EU creates opportunities to improve market access and address trade issues faced by the UK and other Member States. The EU's actions complement and strengthen the UK's influence in this sphere. The UK is in a good position to drive the EU trade agenda, which would clearly be beneficial to UK business.

**Multilateral organisations:** In the area of multilateral organisations, such as the WHO and WTO, the EU, due to the size of population and trade area it represents, is a powerful force in negotiations. This power must be harnessed by the UK: the UK must ensure it uses its expertise and influence in the development of EU positions to avoid the risk of the adopting a 'lowest common denominator' approach that does not fully serve UK interests.

**IP protection and other legal issues:** The EU has a key role to play in crafting good IP policy and legislation for the EU that will create incentives for innovation and has done so in the past for the pharmaceutical sector. However, we are concerned about a deterioration in the quality and effectiveness of legislative outputs and believe that the UK should play a greater role in this space.

## 4. Areas for comment:

### ***The Single Market***

GSK supports the submission by the ABPI, which highlights a number of important milestones towards completion of the single market, as well as key challenges.

One of the Single Market's key objectives was to drive the introduction of competitive markets in the European Union for the benefit of consumers. In the area of pharmaceuticals, EU legislation was designed to safeguard patient health and rapid access to innovation, create equitable and transparent access conditions for manufacturers of medical technologies and to encourage innovation through a clear regulatory framework.

Some progress has been achieved over the last years, for example with the introduction of minimal procedural guarantees and time limits for market access through the Transparency Directive of 1989. This has contributed to speed up national pricing and reimbursement processes, although delays remain considerable in a number of member states due to lack of compliance. EU legislation has also brought important improvement in areas such as regulatory marketing authorisation procedures and the harmonisation of data protection.

Achieving the right legislative and policy framework is essential for maintaining Europe's attractiveness to this industry. The Europe 2020 Agenda endorsed by the EU heads of state and government in June 2010, outlines a set of actions for growth and reiterates the EU's ambition to achieve a target of 3% of the EU's GDP to be invested in R&D. If the conditions are right, the pharmaceutical industry has the ability to be a key driver of growth in Europe. Today, it invests €27.5 billion in R&D in Europe per year, and employs directly 660,000 people (generating three to four times more employment indirectly). It is also the leading high-technology sector in terms of trade surplus (amounting to €48.3 billion in 2011).

However, the environment for medicines in Europe is very challenging. It is right that Member States retain the power to set prices of medicinal products, provided that these prices are set in a way that does not discriminate between domestically manufactured and imported products. However, a consequence of this is that the pharmaceutical market in the EU is uniquely distorted as a result of direct or indirect controls on pricing and/or reimbursement measures by every member state in one way or another. This creates parallel trade flows that are of little benefit to anyone but the parallel trader, as very little (if any) of the price difference is recouped by healthcare systems or patients. In addition, the highly diverse healthcare systems, funding structures and pricing and reimbursement systems at national, and in some cases, regional level further contribute to market fragmentation.

The wide-spread practice of international reference pricing aggravates this fragmentation and remains a sub-optimal pricing system which reduces the attractiveness of Europe and negatively impacts levels of medicine access across the EU.

Inequalities and delays in access are further exacerbated by today's context of austerity. We agree that it is necessary and appropriate for Member States in the current financial crisis to take steps to control public spending and restore fiscal credibility. However, measures being taken by Member States to manage healthcare costs often take a short-term perspective and fail to strike the right balance between managing budgets and securing current and future patient access to medicines and vaccines. The impact is particularly severe when such decisions have extra-territorial impact, as with international reference pricing.

For example, some 26 countries inside and outside Europe reference their medicines prices to Greece in some way. The impact of a price cut in Greece taken to address exceptional circumstances therefore resonates across the EU and globally, with implications for patient access and the attractiveness of Europe for investment.

Different national pricing and reimbursement schemes have created a highly complex landscape in the EU. Healthcare system management remains a largely national competence yet choices by national authorities in terms of medicine pricing and reimbursement have an

increasingly above country dimension. While GSK does not question the balance of competence in healthcare between national and EU authorities, this above-country dimension requires a higher level of awareness and understanding by both the member states and the European Commission. More differentiated and strategic approaches towards pharmaceutical policy are needed. Pricing and reimbursement policies can no longer be conducted in isolation from each other.

In view of national competence issues, we believe the way forward lies in identifying areas for non-legislative cooperation and dialogue, including with industry. We believe the UK and other national governments have a critical role to play in initialising and encouraging this dialogue, and the extent to which this is happening is not clear.

There have in the past been a number of non-legislative initiatives, such as the High Level Pharmaceutical Forum, that have aimed at fostering improved dialogue and developing a policy framework to address some of the key challenges remaining in completing the single market for pharmaceuticals. While these reached balanced and constructive conclusions, implementation has been patchy.

We are also following with interest progress towards the European Commission's updated industrial policy, which we understand will include a specific initiative for the pharmaceutical industry as a key sector of the EU's economy. But even here, we observe a lack of 'common purpose' in the initiatives and policies originating from different parts of the European Commission. The EU should speak with one clear voice if it is to develop a well linked-up industrial policy for the pharmaceutical sector.

Given the situation currently facing the Pharmaceutical industry in Europe, the effort for dialogue has to be increased and set within the context of Europe's ambition as set out in its Agenda 2020. The issue of demand-side policies has to be addressed in a much more strategic way, as well as looking at a trade agenda for the knowledge economy and defining a smart and efficient regulatory system for the 21<sup>st</sup> century.

We also support further European collaboration in some elements of Health Technology Assessments (HTA), to improve early advice procedures, explore further scope for increased cooperation on relative clinical-effectiveness assessments, with the aim to ensure rapid market entry and improved access for products that add value over existing therapies through reducing the number of disparate data requests and identifying common approaches across the EU. Decisions on relative cost-effectiveness are best taken at national level.

## ***Trade***

The EU has a Common Commercial Policy to govern its trade relations with non-EU markets. This means common customs tariffs, a common import and export regime and the undertaking of uniform trade liberalisation measures, as well as trade defence instruments. The fact that the EU negotiates as a trading bloc gives it the position of one of the critical players in the international trade scene, bringing significant opportunities for all EU member states, including the UK.

The EU is a major trade partner for key emerging markets and is highly respected as an international global trade actor. The BRIC countries and others are increasingly vocal in

international forums, and it is essential that the EU continues to play a full and supportive role in policy negotiation and decisions.

The EU has developed an extensive External Trade Strategy in the past few years, which has a competitiveness-driven agenda and a focus on support for market access for priority sectors, including the pharmaceutical industry. This encompasses the negotiation of ambitious 'new generation' FTAs (with US, Japan, Canada, India, ASEAN & Mercosur and other key markets), and high level dialogues with key partners such as China and Russia.

Significant efforts are also being deployed by the EU to deal with growing protectionism and market access barriers encountered by European business in countries outside Europe, including direct production investment requirements, as well as more subtle indirect measures disproportionately impacting foreign companies operating in those markets.

Protectionism brings instability, limits access to important markets and can seriously impact patient care. As an industry, we value the continued support of the Commission and particularly the leadership of its trade services in these matters, including efforts made to escalate action at global level forums such as the G20 (the European Commissioner for Trade led the discussions on protectionism last June that ended in a joint declaration to increase action against protectionism).

In addition to protectionist policies impacting market access, we have also seen a deterioration of the Intellectual property environment in key markets. While more support is probably needed on this area, the EU has been able to engage in constructive dialogues with third markets, which is key for European research-based companies.

There are also increasing demands from foreign governments and agencies to cooperate with European authorities, since Europe represents both a key market for them and a leading reference point for countries carrying out their own reforms, particularly on healthcare and regulatory areas. The regulatory dialogues and cooperation established by the European commission health services with key emerging markets is key to aligning regulatory processes and standards, ultimately improving the access of innovative medicines to the patients in these markets.

The EU can therefore leverage his position as a key global market to take strong action when needed to remove trade barriers, set up global standards, and create opportunities to improve European business access to developed and fast growing developing markets. The UK is well positioned to drive a strong EU trade agenda as it is one of the key EU markets (politically, strategically and economically). Its opinion is always taken into account. The UK must to use its influence to ensure UK business continues to benefit from the opportunities arising from a strong and ambitious EU competitiveness driven trade agenda.

### ***Engagement with multilateral organisations***

The EU's competency on trade issues is very clear and longstanding. There is real benefit in a strong unified EU position on key issues. When negotiating at the WTO the interests of the UK are normally well covered by the competency of the EU. However, the UK must play a key role in the development of EU-wide consensus positions and negotiating fallbacks. However, building consensus takes time and means that the EU may not be as nimble when responding to dynamic situations as other negotiators. This may lead to situations where the EU-wide approach may not be in the UK's best interests if last minute horse trading occurs at various summits and conferences. There is a risk that the UK's more balanced and considered

approach may be over-riden by ill-thought through eleventh hour concessions to get a deal done. These risks exist in other forums such as WIPO or the Convention on Biological Diversity.

For the WHO, the situation is less clear. The EU has traditionally not held a competency in health and so is much less savvy when it comes to working with and understanding the nuances of the WHO governance and decision-making mechanisms. This means that when the WHO strays into areas of EU competency, such as trade and IP, the EU is on the back foot and has been slow to respond. This situation has been exacerbated by Member States often not having representatives of the relevant ministries in their delegations at negotiating sessions of the Executive Board and World Health Assembly. The UK has led the way in improving this situation, regularly including representatives of the IPO in its delegations, and has done much to bring the EU up to speed on these issues. However, it is clear that the EU has been slow to engage in the discipline of Global Health Diplomacy compared to Member States such as Brazil, India and Thailand.

Even on pure health issues the EU Member States (and accession countries) seek consensus positions on agenda items at the EB and WHA. Although there is real value in this, there can also be drawbacks. In the discussions on individual agenda items, whoever holds the Presidency tends to speak on behalf of the EU as a whole, and it is rare for individual member states to make individual interventions. This can cause three main problems.

Firstly, because the wording of the EU statement is pre-agreed it means that there may not be flexibility to allow the EU intervention to reflect the actual debate as it unfolds, and the EU may be slow to respond to developments in the debate or to counter contrary positions. Secondly, the strength of feeling of individual EU member states on specific issues may be lost and points lack reinforcement. Thirdly, there is a key issue about 'share of voice' in debates. Because the Presidency makes an intervention and the other member states do not, the EU can appear to be a lone voice. This is particularly apparent because other groupings, such as the AFRO Region of WHO, or UNASUR, will have one member state who speaks on behalf of the grouping, but then many individual countries will also then make interventions which skew the apparent centre of gravity of many debates.

Whilst this situation is acutely apparent at the WHO, there is a risk of a similar dilution of the EU message at other UN bodies and multi-lateral forums. The EU and its Member States must ensure that its consensus driven approach strengthens, rather than weakens the impact of their position in key debates. The UK should underline the key points made by the EU through the judicious use of additional interventions.

### ***IP protection and other legal issues***

IP is a critical incentive for innovation in many sectors, including and in particular, the pharmaceutical sector. Good harmonised IP laws in the EU will not only promote the single market but will encourage innovation in the EU.

IP policy and its reflection in legislation involve consideration of various factors and many interests can be involved. It can also be very technical. If new legislation is sub-optimal, its beneficial impact on innovation can be significantly reduced and indeed it can even make things worse than before introduction of the new legislation.

The EU has introduced important IP legislation which is helpful to pharmaceutical innovation; for example, strong regulatory data protection laws and the creation of a supplementary protection certificate.

However, we are increasingly concerned that in seeking to complete legislative initiatives, compromises are made which significantly reduce the value of EU legislation. EU officials are sometimes heard to say, in effect, that because no-one likes a proposal, it must be a good compromise. It might be a “good compromise” from a political perspective but it does not necessarily make good law, particularly when, as is the case for IP law, the law directly impacts the rights and obligations of individuals and companies.

This problem is exacerbated by the fact that on occasion unclear drafting is used either inadvertently or sometimes deliberately to mask disagreement. Clear drafting is particularly important when the law directly impacts the rights and obligations of individuals and companies.

The project to create a unitary patent and unified patent court is a good example of how compromises and poor drafting create problems. At best, this series of legislative measures leaves many commercially important uncertainties for those involved in innovation; at worst, many fear that the new system will be worse than the one it replaced.

Additionally, policy initiatives in one area can often have IP implications, which are not immediately obvious to those with responsibility for the policy area of the initiative. It is important that connections to IP issues are identified as soon as possible in the policy formulation process as it is often more difficult to change a policy proposal once published to deal with an unappreciated IP issue than it would have been to adapt the policy before publication.

So while we believe there are clear potential benefits for EU competence in the IP area, much more care must be taken to ensure that these benefits are realised. The UK, with its policy focus on innovation, has a significant role to play in this space and should seek to increase its influence.

The same applies in other areas where harmonisation of laws makes it easier to carry out business throughout the EU, for instance with regards to the forthcoming data privacy regulation.

The EU has also had a major impact in the field of competition laws, with each member state individually adopting competition laws that principally reflects the main EU competition provisions, in order to harmonise the application and interpretation of these rules throughout the EU, whether at a national or EU level. This is strengthened by the close cooperation between the European Commission’s Directorate General for Competition and the national competition regulators, and enables companies acting in several EU member states to predict the legal boundaries in this area of law. As a member of the EU, the UK is given the opportunity to play a role in the implementation of a uniform competition policy through the Office of Fair Trading and its successor, in particular in areas of significant impact to the industry where there is currently a focus such as patent settlement agreements or parallel trade of pharmaceutical products.

### **How does the EU's competence in health affect the Trust?**

The EU sets out arrangements for temporary visitors from other EEA states to access healthcare within the UK and allows for means to reclaim the costs of providing such healthcare to these people. This provides a transparent method for the Trust to recover its costs in relation to the treatment of these people rather than the Trust having to seek payment for such treatment from these people direct.

EEA nationals right of free movement around the EEA including rights to residency within the UK allows them to be entitled to healthcare on the same basis as any other resident. Again, this allows the Trust to get reimbursed for treatment provided via the local PCT as though locally entitled residents rather than having to bill individuals directly if they were non-entitled.

The Cross Border Healthcare Directive clarifies patients' rights to access safe and good quality treatment across EU borders and sets out the arrangements under which member states provide treatment to citizens from other EEA states. It also sets out how member states should provide for its citizens to access their rights to cross-border healthcare and specifies information they are required to provide to citizens of other states considering coming to their country. The directive also clarifies the rules for reimbursement of eligible treatment costs. The Trust sees this as an opportunity to promote its specialist services to a wider market and attract additional referrals to its specialist services to enhance the sustainability of its specialist services.

### **How might the Trust benefit from the EU taking more/less action in health and how could action in this area be undertaken differently?**

- Improved education of EEA members around the requirement to have an EHIC or E112 prior to receiving treatment within the UK or at the Trust. This would avoid delays in treatment and additional administration requirements by ensuring that patients have the correct paperwork available to them.
- A clearer approach as to how Trusts can market specialist services to other EEA members to ensure the Trust maximises its opportunities to attract additional patients from outside the UK. Clear arrangements around the provision of information will be key to attracting patients from other EEA states.

## Health & Social Care Information Centre

Thank you for the opportunity for contributing to this Review.

The Health and Social Care Information Centre (HSCIC), is the central authoritative source of health and social care data and information in England, including a wide range of national statistics and publications.<sup>1</sup> As such, our interest is mainly in seeing a consistency of approach for the use of technology, the coding and recording of data, the design and construction of indicators, and consistent policies regarding data protection, statistical and information governance.

Given the nature of our work our interactions with the EU are around access to, use and reporting of healthcare data, with the Open Data agenda providing a further impetus for greater collaboration across member states for dissemination and use of health related data. The HSCIC is committed to releasing aggregate and anonymised data (particularly those underpinning our statistical publications), in to the public domain.<sup>2</sup>

We contribute to Eurostat, OECD and WHO statistics, coordinating returns across all 4 UK countries. As with other member states we provide whatever data that is sufficiently close to the definition (i.e. "best fit" data), for descriptive or comparative purposes. So far this has not necessitated any new data collection or production of new statistics. If data collection did become part of any regulations then this would potentially have a huge impact on what we collect and the resource within the NHS to collect it.

Our data and quarterly reports on NHS funded services for mental health provided by the Mental Health Minimum Dataset (MHMDS)<sup>3</sup> and the Improving Access to Psychological Therapies (IAPT)<sup>4</sup>, are unique within the EU, and have highlighted the observed excess mortality associated with mental health<sup>5</sup>. These and other findings have been presented by the DH and the Kings Fund at OECD.

We commission and manage a range of population-based surveys in health and social care in England<sup>6</sup>, providing insights into population health and well-being, as well as trends in life style factors influencing health, e.g. the Health Survey for England (HSE)<sup>7</sup> which is highly regarded within the EU. EU legislation requires all Member States to conduct the European Health Interview Survey (EHIS) during 2014-15.<sup>8</sup> EHIS was piloted during 2008/9 and in the UK, ONS have been commissioned by DH and the devolved administrations to run a UK wide survey in 2014 to meet this requirement, utilising a database of respondents to the Labour Force Survey who had agreed to be contacted again. As EHIS will be running alongside the current national health survey programme; there may be some impact on the HSE sample for 2014 but we anticipate that this will be minimal, as contractors will be alerted and aware so that their selection processes are adapted to ensure the required HSE sample size is achieved.

With the achievements so far in all of these areas, the UK is well placed to advise and lead on similar developments in other member states, should there be an opportunity or policy incentive to do so, with the only limitations being availability of appropriate resources and capacity to undertake this.

We are currently engaged in the ongoing review and reform of the European Statistical Law. However, we understand that there is also separate Competency Review for Statistics planned for the fourth semester (spring 2014), and we would welcome the opportunity to be invited to contribute more specifically to this also in due course.

### References.

1. [www.ic.nhs.uk](http://www.ic.nhs.uk)
2. <http://www.data.gov.uk/publisher/nhs-information-centre-for-health-and-social-care>

3. <http://www.ic.nhs.uk/article/2021/Website-Search?q=mhmds&topics=13201&sort=Relevance&size=10&page=1&area=both#top>
4. <http://www.ic.nhs.uk/article/2021/Website-Search?q=iapt&area=both>
5. <http://www.ic.nhs.uk/article/2021/Website-Search?q=mental+health+mortality&area=both>
6. <http://www.ic.nhs.uk/article/2021/Website-Search?q=survey+programme&infotype=13370&sort=Relevance&size=10&page=1&area=both#top>
7. <http://www.ic.nhs.uk/article/2021/Website-Search?q=HSE&area=both>
8. [http://epp.eurostat.ec.europa.eu/statistics\\_explained/index.php/Glossary:European\\_health\\_interview\\_survey\\_\(EHIS\)](http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Glossary:European_health_interview_survey_(EHIS))

## Health Education England

### **Overall Position**

We recognise the benefits of EU legislation, specifically around the free movement of workers, mutual recognition of qualifications and the Working Time Regulations. However, our view is that greater flexibility is required for the UK to derogate where this is in the interests of the UK. The publication of the Francis report emphasises the need for such flexibility – for example around value-based selection rather than eligibility based on EU-defined minimum training periods.

### **Specific Directives**

#### ***Free movement of workers***

We support the free movement of workers across the EU. The benefit of free movement is, of course, recruitment of staff and the UK has been a beneficiary of this. However, we also recognise the potential impact that unpredictable and unplanned movement may have on planning, service delivery and employment opportunities for UK health graduates.

For example, there is a need to ensure that UK graduates can secure training as provisionally registered doctors in the UK (i.e. F1) – this is an area where we think member states should be allowed to derogate from freedom of movement and ensure that their own graduates can complete basic medical education (or equivalent qualifications for other healthcare workers).

There is little long term analysis on the extent to which migrant staff from the EU stay in the professions and for how long. With some future/recent accession countries, the issue of ethical recruitment within the EU is now becoming an issue. The impact of large percentages of migrants within some areas with respect to organisational or practice culture is not known (whether as a positive or a negative factor).

The option for UK staff to practise in the EU could be regarded as providing valuable opportunities to develop skills and experience – or as a potential drain of skills from UK!

The other issues with free movement are mutual recognition of qualifications and language competency – see below.

#### ***Mutual Recognition of Qualifications***

(This has been answered in light of the Directive that relates to doctors and nurses. For healthcare scientists and AHPs they are subject to the General Directive. This means that when they apply to the regulator the Health and Care Professions Council (HCPC) they are assessed on a case by case basis on application to the statutory register).

We support the mutual recognition of qualifications - but this must be as a result of a rigorous evaluation process. The consumer/patients' rights to know transparently the competences and skills of the person treating them has to be preserved.

But qualifications are only one element of selection and must also include (for all) a proper assessment of candidate competence and, in light of the recommendations in the Francis report, values. Francis also highlights standards of English language which is also relevant.

#### **Benefits**

The breadth of its geographical impact beyond the European continent and the wider benefits the directive has had, particularly in Central Europe, for women, for democracy and for health care reform is important to recognise.

With regard to nursing, from a broader 'political' EU perspective for many it may be viewed positively as:

- the only reason that nursing has been reformed
  - the only reason training is taken seriously
  - the pivotal reason why nursing can be taught in Higher Education
  - important in establishing the rights and equality of a female population/workforce.
- Directive 2005/36/EC has opened HE and development opportunities to women in countries where equality of access to HE did not/does not exist and has been part of the mechanism for addressing the democratic deficit in countries where democracy has been a recent phenomenon

### Concerns

It is important to note the challenge of defining minimum standards (agreeable across all countries) whilst we strive for the highest standards here in the UK and the obvious dislocation between the EU defined minimum standards and the acceptable/desirable minimum standards across the UK (for example, a degree level qualification in nursing).

Then, it is questionable whether the current minimum requirements, for example for nurse education in the Directive, are always being implemented. So is there sufficient convergence in Europe that we are really comparing like with like when we talk about the generalist nurse, and are the boundaries blurred with healthcare assistants and specialist nurses? One country's nurse may be seen as performing at the same level as another's health care assistant for example.

Consequently, we believe in relation to health related education and training, where the UK has established funding arrangements which extend beyond general higher education funding, the UK should have the right to constrain access or set conditions to access. This would mean that UK, through DH/HEE, has the right to set conditions to the access to nurse bursaries, or HEE funded medical training etc.

The language test is important and concerns have been well publicised. We believe it must encompass an ability to communicate in the particulars of the 'technical' language of the profession as well as an ability to communicate effectively in 'everyday' terms.

From a UK perspective the Directive may be viewed as out of date and unnecessarily focused on training not education and is preoccupied by numbers of hours in training. The role of values and cultural competencies are also important and a focus on technical competencies is reductionist and possibly unhelpful as the context of care is critical.

This links back to the recommendations in the Francis report and the need to focus on values – such an approach might not be compatible with the measures defined in the Directive. These regulations take no account of the context (culture) in which healthcare will be practised nor whether healthcare staff have been trained to work to the concepts of the NHS Constitution. The EU regulations are all about the system and not about the culture – so it seems odd that if the NHS is going to change by influencing staff values, behaviours and beliefs we would find it difficult to accept staff from other EU countries who have not been “trained” to work within the NHS – and potentially thereby perpetuating the current problems identified by Francis. This is not to suggest that EU nationals could not work in the NHS, but that they would not have the right to work in the NHS without some induction or assessment of competence which conforms to the NHS Constitution/recommendations of the Francis Report.

There is also a need to ensure that there is a streamlined process for mutual recognition of qualifications to ensure that shortage specialties can fill vacancies.

### Going Forward

Given the needs of patients and the service in future, we are challenged to develop a framework that will be robust and yet agile enough to address workforce issues. We also need to consider whether it is possible to legislate for competencies until there is a common understanding of scope of practice in Europe. Even if this is agreed, quality assurance mechanisms need to be in place as well and the implications here are enormous. This leads us down the path of considering the considerable transactional issues involved, some of which are highlighted below:

- effectiveness (and monitoring) of registration
- problems of recognition of migrants
- language problems
- inadequacy of alert (safety) mechanisms
- challenges of devolved regulation versus centralised regulation
- resourcing of regulation
- public perception and acceptability.

### ***Working Time Directive***

The merits of the working time directive have been well rehearsed especially for junior doctors. With respect to doctors in training we believe there should be no hint that increasing junior doctors hours is anything other than dangerous to patients and themselves.

However, whilst we believe workers hours must be regulated, the current requirements are insufficiently sensitive to recognise the significant variation in workload and intensity between roles and specialties. The regulation must also recognise the necessity to balance the needs of the individual, training (in the case of trainees) and service contribution. Specifically, the Jaeger' or 'Simap' rulings have forced Trusts to organise medical staffing in full shift systems restricting the ability to work in clinical/medical firms. This also restricts handover and provides a lack of flexibility for medical education and training (for example, providing sufficient opportunities for daytime training) as well as incurring significant costs to employers.

Working time clearly has an impact on the current junior doctor contract discussions so should be addressed as a matter of urgency.

### **Questions**

#### ***How does the EU's competence in health affect you/your organisation?***

HEE has a remit within England to ensure the development and delivery of healthcare staff in the right numbers, with the right skills, values and behaviours. Changes in the EU's laws and directives have an influence on the planning and delivery of this as it affects the movement and skills of staff available. These actions can have predictable outcomes, but also unpredicted and unintended consequences.

While there is a national derogation of health, the Professional Qualifications and Services directives have major implications for mobility of health goods, staff and minimum training requirements. Some of the current proposed changes will address threats to patient safety regarding language ability, but this needs to be tested both by the employer and at registration

point. Others are of concern in that incoming registrants may not meet the standards expected of UK qualifying registrants and the difference may not be apparent to employers who have a responsibility for appropriate induction. This is particularly relevant in the nursing and midwifery professions and in light of the Francis report and the expectations that registrants should be accountable and responsible for preventing and addressing poor standards of care etc. In many countries, nurses and midwives do not have an academic training and are not enabled nor legally allowed to have autonomy.

### ***What evidence is there that EU action in health advantages or disadvantages?***

#### General

There are demonstrable differences that EU action can make to the supply of healthcare staff in England. Whether these are advantageous or disadvantageous or not depends on the nature of the action, the requirements of England's healthcare labour market and the economics of different members states.

To use an example of nursing (based on information provided in the RCN Nursing Labour Market review 2012 - Buchan and Seccombe), in recent years the UK has gone from being in a position of net inflow of nurses to one of net outflow. Between 1998 and 2006, roughly 100,000 new non-UK nurse registrations with the NMC took place. The proportion of international nurses (EU and non EU) comprised more than half of all new annual registrants with the NMC in 2002, but numbers had significantly dropped by 2010.

Freedom of movement within the EU means that there are generally no restrictions for EU nationals to move within the wider labour market and EU nurses now comprise the majority of nurses in a position to seek work in the UK. Indeed increases in inflows from EU countries experiencing economic difficulties (for example the number of nurses gaining admittance to the NMC UK register from Portugal rose from 20 in 2006/7 to 550 in 2011/12) combined with the addition of EU 'accession countries' (who joined in 2004 and 2007) has contributed to a more recent increase in new international registrants (double that of 2010).

#### Advantages

Good practices from Europe can be shared, for example work on health care assistants DG SANCO provides some useful models for consideration as we review the regulation and training of health care assistants.

Research from the EU has also provided good evidence for decision making, RN4Cast & Prometheus studies for example on staffing, mobility, skill mix and profiles.

Regulatory initiatives to address cross border challenges relating to fitness to practice are welcome ways forward.

The workforce green paper of the EU health action plan, has the potential to inform decision making over the longer term. The globalisation of workforces and health tourism within and external to the EU means that shared data implies better market intelligence for workforce and service design.

#### Disadvantages

Time and energy expended in 'solidarity' initiatives that are not particularly relevant to UK.

Drivers for the free movement of capital, people, services and trade sometimes appears at the expense of patient safety. One is not always aware that initiatives in the broader trade field have an implication for the delivery and supply of health care services.

### ***How might the UK benefit from the EU taking more action in health?***

The UK could benefit from the EU taking more action in health where this specifically supports the shifting focus of workforce planning of healthcare services in England post the Francis Inquiry, in particular in relation to ensuring the right values and behaviours, as well as developing the role of healthcare support workers.

More extensive research in areas of public health and cross border initiatives could strengthen our understandings of how to more effectively manage services and staff thereby improving public health and managing costs.

Good practice models developed and shared could provide time saving initiatives for the challenges of long term conditions and older people in particular

Development of cross border systems and initiatives to protect consumers from point of care problems versus point of residence needs.

Development of CPD models and accreditation beyond initial qualification may aid mobility, reduce costs of training and duplication.

### ***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

It is likely that more action being driven at a national level would align more closely to the specific requirements of the healthcare labour market particularly in England, and arguably would allow a greater degree of certainty over workforce planning and strategy development.

Services can be more focused and customised. More EU awareness at national level may have a positive effect and enable targeted interventions. On the other hand, this could lead to isolation.

### ***In health, how could the EU act differently in your area of interest?***

By allowing the UK, and England in particular, to set its own standards in terms of competence to deliver healthcare, which may have an impact on free movement of healthcare professionals.

Regulation more concerned with patient safety.

Development of standards that can be applied and be audited.

### ***How else could the UK implement its current obligations?***

No comments to date.

### ***What future challenge/opportunities might we face in EU health competence and what impact might these have on the national interest?***

It is possible that Health Education England and other bodies may decide to include specific requirements for the recruitment of staff into education, training and employment that include behaviour and attitude testing. There may also be specific requirements around competencies in the English language that are developed in response to the Francis Inquiry report. It will be

important that such necessary introductions would not be inhibited by the EU as it could mean that a doctor who has recognised qualifications throughout the EU may not be able to practise in England if they fail to meet those tests.

Increasing politicisation of health together with drive from some countries to create European mandates at the expense of countries with more autonomous staff and services.

***What impact would any future enlargement of the EU have on health competence?***

The same principles would apply, but obviously any future enlargement could have a range of predictable and unpredictable consequences and would need to be carefully considered in future workforce planning.

The key issues are the increasing divergence in the standards of health training and health services from some, but not all, potential accession countries. Managing the labour market, the quality of services and migration.

***Is there evidence of any other impacts resulting from EU action in health that should be noted?***

The action on health initiatives are generating better understandings of different models of care and delivery from which learning can occur.

The free movement of individuals within the EU and their rights to healthcare could lead to changes in demand within individual members states and therefore have an impact on future workforce planning and strategy.

***Are there any general points you wish to make which are not captured above?***

From an education perspective, alignment with accreditation and recognition processes, not just regulatory but in the education market \*(Bologna and Copenhagen) mean that recognition of learning through training and experience can be offered with a more sophisticated resources. E-learning platforms for induction, common procedures etc. are possible.

We do not perhaps exploit funds available under the other DGS to the benefit of UK staff and services (e.g. training funds, staff exchange).

***Are there any published sources of information to which you would like to draw our attention for the purposes of this review?***

- 'Health Education England: Our Strategic Intent' - <http://www.hee.nhs.uk/2013/01/31/our-strategic-intent/>
- Francis Inquiry Report - <http://www.midstaffspublicinquiry.com/report>
- Kings Fund Report – 'Transforming the Delivery of Health and Social Care' <http://www.kingsfund.org.uk/publications/transforming-delivery-health-and-social-care>
- EU-Project: Creating a pilot network of [www.nursehca-network.eu/](http://www.nursehca-network.eu/)
- RN4CAST: nurse forecasting in Europe [www.rn4cast.eu/en](http://www.rn4cast.eu/en)
- Prometheus [www.fp7-prometheus.eu/](http://www.fp7-prometheus.eu/)

## Competency

The call for evidence asked us to consider who should be the competent authority to make decisions – and provided three options:

- only the EU can act;
- either the EU or the Member States may act, but Member States may be prevented from acting once the EU has done so (either they may not be able to legislate contrary to the EU or they may no longer be able to legislate nationally);
- both the EU and the Member States may act, but action by the EU does not prevent the Member States from taking action of their own.

Our responses above show that we favour the third option with respect to Freedom of movement, mutual recognition of qualifications and the Working Time Directive.

Health Food Manufacturers' Association

## Executive Summary

- The natural health products industry in the UK faces distinct threats from European legislation relating, in particular, to health claims and to food supplement products. Specifically, the Food Supplements Directive and Nutrition and Health Claims Regulation are covered by Article 114 of the Treaty on the Functioning of the European Union in relation to “harmonising Member States’ laws by adapting measures which have as their object the establishment and improved functioning of the internal market”
- ‘Harmonisation’ is a flawed concept for this particular industry, because it does not take into account the regional variation in nutritional intake across the EU, or the divergent implementation of regulation by Member States
- Government efforts to support SMEs and drive economic recovery are being undermined by poorly implemented EU regulations
- EU legislation is currently reducing the availability of sound, helpful information to consumers which could result in less effective self-care and limited access to popular and safe products

## Introduction

### 1. HFMA – the Voice of the Natural Health Industry

The Health Food Manufacturers' Association (HFMA) is a not-for-profit organisation that was founded in 1965, and is the authoritative and responsible voice for the UK natural products industry. We promote and protect the general interests of members of the industry and promote high standards of product manufacture and presentation to ensure consumer safety, responsible and informative communications and compliance with applicable legislation.

We represent over 120 manufacturers and suppliers of specialist health products, notably food supplements, herbal products, natural remedies, sports nutrition products, natural cosmetics,

and health foods including: organic foods, vegetarian and vegan foods, functional food, and foods for particular nutritional uses.

## **Main Response**

*How does the EU's competence in health affect your organisation?*

### **2. The EU's competence in health has a significant impact on the HFMA and the industry**

The EU's competence in health policy has a very strong impact on the HFMA's member companies. The natural health products industry has become increasingly over-regulated by the European Union, particularly since the implementation of the Food Supplements Directive (FSD), and more recently, the Nutrition and Health Claims Regulation (NHCR). The nature of these regulations is increasingly leading to disadvantages for consumers and businesses alike. The regulations in question include:

- Regulation (EC) 1924/2006 on nutrition and health claims made on foods
- Directive 2002/46 EC on the approximation of the laws of the Member States relating to food supplements & subsequent implementing Regulations
- Directive 2009/39/EC on foodstuffs intended for particular nutritional uses
- Regulation (EC) 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods
- Regulation (EU) 1169/2011 on Food Information to consumers

### **3. The quest for 'harmonisation' has created unnecessary legislation**

The industry now faces increasing amounts of regulation from the EU, which is less about protecting the health of consumers, and more about creating 'harmonisation' of regulation. The health of UK consumers is already protected by domestic regulation. The drive for harmonisation at a European level has introduced additional legislation that now limits the information available to customers and threatens the availability of safe, popular products.

The HFMA is a strong supporter of a well-regulated and responsible industry. The natural health industry has developed a good reputation over many decades, for example over 17 million consumers in the UK alone now take food supplements at least 4 times a week. The safety of food supplements is already controlled in the UK under the Food Safety Act 1990. Section 8 of that legislation states that products must not be "injurious to health" or "unfit for human consumption" and applies penalties if they are. Similarly, consumers are protected by the Trade Descriptions Act 1968, which regulates against the mis-description of products.

Food supplements in the UK have an excellent history of safety. In 2006, the Food Standards Agency Regulatory Impact Assessment on the Food Supplements Directive showed that there had been only 11 reported adverse reactions to food supplements over the previous 11 years, with most of these being in the lowest category of harm. Supplements produced by the natural products health sector are already very safe.

*What evidence is there that EU action in health advantages or disadvantages:*

*Business and industry:*

#### **4. UK businesses are hurt by inefficient implementation**

From our experience of working with attempts to regulate the natural health products industry we see examples of legislation that begin with good intentions, but then through development and implementation lose their original purpose. This is a result of political compromise and stakeholder lobbying, which has led to legislation originally designed to protect the industry and consumers becoming something that is damaging for both parties.

Three examples are:

- The FSD 'positive list' for ingredients was based on a list developed for entirely different legislation therefore UK industry (partly subsidised by the FSA who belatedly recognised the problem) submitted several dossiers for the inclusion of safe, popular specialist ingredients
- At one stage, the DH were planning to submit an application for a claim based on longstanding health advice relating to folic acid/NTD but subsequently became reluctant to do so because of the assessment method employed by EFSA. Now, industry has developed an appropriate dossier, with input from DH
- For well over two years, the Commission has been pondering how to align NHCR food legislation with Traditional Herbal Medicinal Products Directive since the latter allows for the validity of 'traditional use' evidence for herbal products but the former does not

#### **5. UK businesses were misled about the impact of the Nutrition and Health Claims Regulation**

There is a strong feeling among HFMA members that recent European legislation covering nutrition and food supplements was presented to industry in a way that led to agreement in the belief that new regulation would be good for businesses. In practice, there were unforeseen circumstances.

For example, industry was led to believe, in a 2007 review conducted by the UK's Food Standards Agency, that most generic health claims under Article 13.1 of the NHCR would be retained after assessment by the European Food Safety Authority (EFSA). The reality was completely different, with 95% of claims for 'other substances' (i.e. those other than vitamins and minerals) being rejected. The rejection of so many claims will have a devastating impact on the natural health products industry across Europe, as many companies will lose the ability to inform consumers about their products. Herbal food supplements are a particular case in point: the majority of claims for such products have not yet been reviewed by EFSA because the current claims assessment process would seem to be inappropriate for this particular form of 'other substance', which in itself encompasses a very wide and diverse range of substances.

#### **6. EU regulation is particularly damaging for SMEs**

Over 75% of HFMA member companies are Small and Medium-sized Enterprises (SMEs), and many of these would be defined as 'micro' businesses. This is typical of the industry as a whole, which is characterised by small firms driven by passion and enterprise. UK and EU Governments have made clear that supporting SMEs is an important part of securing a healthy

economic recovery. However, European regulation is hampering this effort by damaging the businesses that we need to protect.

An EU-wide Economic Impact Assessment from the European Health Claims Alliance investigated the impact of the health claims regulation. The findings of this research anticipate a total loss of sales of €1 billion, resulting in lost profits of €242 million, additional implementation costs of €291 million, and the loss of 13,300 jobs. This clearly indicates that SMEs in the UK, as well as across the EU, will not benefit from any reduction in compliance or regulatory costs at this crucial time.

Similarly, in the UK a study of the potential impact of the setting of restrictive Maximum Permitted Levels for food supplements indicated that over 700 health stores could close with the loss of 4,000 jobs exclusive of ripple effects.

## **7. 'Harmonisation' is often ineffective because of Member State differences and varying approaches of Member States towards implementation**

Attempts to harmonise EU legislation in relation to the natural health products industry is a problem for UK business. Our experience operating across the EU has shown us both that Member States defend national interests and that not all Member States enforce regulation to the same degree.

An example of the former is the German Government's intervention to protect traditional German brown bread with high salt content from nutrient profiling planned under the NHCR.

Traditionally, the UK has been quite strict with its implementation of EU regulation, however, this can be to the detriment of UK businesses if other Member States do not act in the same way. Different levels of implementation have undermined the Commission's attempts at harmonisation, making the current ill effects being felt by UK businesses and consumers even more unnecessary. The HFMA would encourage the application of Mutual Recognition of products as an alternative way to promote harmonisation. This would still allow Member States to prohibit products on demonstrable public safety grounds.

*Patients and citizens:*

## **8. 'Harmonisation' ignores regional differences across the EU**

The HFMA understands reasons for the drive for regulatory harmonisation across the EU to ease cross-border trade and reduce administration costs. However, this effort is sometimes not appropriate, and this is particularly the case for the natural health products industry.

In the case of industry in general, harmonisation assumes a uniformity of need among citizens throughout the European Union. However, in the case of natural health products, this is not realistic. There is a great deal of variance between diets, public health problems and climate across the European Union. This means that certain groups of citizens across the EU have different nutritional needs, depending on cultural differences across Member States. For example, the nutritional requirements of someone living in the North of Scotland will be very different to someone living in the Mediterranean. Harmonising regulation often ignores these natural differences and this will increasingly lead to an industry that is unable to cater for the specific requirements of particular groups.

This, again, is a particular issue for herbal food supplements: in terms of understanding of the fundamental role of such products, in many Member States the concept of food playing a major role in promoting health is part of the national culture, and herbal food supplements have traditionally played a strong role in the maintenance of health; in others this is not the case, and, particularly the UK, there tends to be a 'medicinal mindset' where such products are considered as only being appropriate for the treatment, cure or prevention of disease or adverse effect.

Other population groups are also vulnerable to specific low nutrient intake. Data from the Food Standards Agency's National Diet and Nutrition Survey identifies specific groups who lack particular nutrients. These groups include pregnant women, children and teenagers, older people, dieters, vegetarians, vegans and ethnic groups. This adds to the different requirements of the population across the EU, which a vision of harmonisation does not always cater for.

## **9. Consumer protection is being limited by new regulation**

The adoption of the NHCR has had a dramatic impact on the availability of information to consumers. The rejection of thousands of health claims by a flawed authorisation process at the European level has resulted in companies being unable to describe in much detail how their most popular products contribute to people's good health. This is limiting consumer choice because there is now less information on products to help inform about their beneficial effect. In the long-term, these marketing restrictions are likely to reduce the number of products that are available as businesses suffer from being unable to communicate effectively.

The reduction of information directly available may have detrimental impacts on the health of consumers. When product information is not available consumers will turn to other less-regulated sources of references and supply, such as the internet. This obviously creates a situation where consumers are making purchase decisions about products using sources that industry and regulators have no control over. This is not a desirable situation and is an unforeseen and unintended consequence of new EU regulation.

*Future options and challenges*

*How could action in this area be undertaken differently?*

## **10. The UK Government must take action to support the industry on MPLs**

There is the potential for the Commission to introduce proposals to set Maximum Permitted Levels (MPLs) for vitamins and minerals in food supplements under the Food Supplements Directive. Such proposals would very probably result in the prohibition of thousands of long-established products.

This area is already subject to a code for Upper Safe Levels that was pioneered by the HFMA. There is now an industry agreement with the Food Standards Agency, which both limits specific levels and applies "advisory statements" on labels that are triggered by threshold levels on 11 different nutrients. This is another example of the industry demonstrating its responsibility and determination to create safe products for consumers through joint working with regulatory bodies.

The HFMA would also suggest that the UK encourages a more general reassessment of the Article 13 claims assessment process, particularly given the on-going impasse around the assessment of botanical claims.

## INTRODUCTION

The Foreign Secretary launched the balance of Competence Review in parliament on 12 July 2012, taking forward the coalition commitment to examine the balance of competencies between the UK and the European Union. The review will provide an analysis of what the UK's membership of the European Union (EU) means for the UK national interest. It aims to provide a constructive and serious contribution to the national and wider European debate about modernising, reforming and improving the EU.

Department of Health is leading the review into competencies related to health. A call for views was launched on the 28 November 2012 with a closing date of the 28 February 2013.

The following represents views expressed by experts within the Health Protection Agency. The Health Protection Agency will join other sender bodies and will be established as Public Health England from the 1 of April 2013.

### 1. MEDICAL DEVICES

This response is in relation to examples pertinent to blood borne viruses.

The *in vitro* diagnostics directive (IVDD) was set in place to promote a commonality for the registration and the functionality of *in vitro* diagnostics. Whilst desirable, it does not take into account the considerable variance in skills in microbiology across all member states. Further, there is a failure to recognise that CE marking is not always synonymous with quality, and quality is not always synonymous with appropriateness and fitness for purpose.

A recent example of where this is the case is this is the persistent failure of the current Roche Diagnostics PCR HIV, an assay which is based a single gene target which is subject to considerable genetic variance, suggesting that it is not fit for purpose despite being CE marked.

The entrepreneurial development of novel and important diagnostics in the UK is crucial. Whilst the current IVDD incorporated the potential for derogation allowing the use of in-house assays within the geographic boundaries of the legal entity of the "in-house" institution (provided that institution is constituted principally for the provision of medical healthcare), the intended rework of the IVDD is going to remove this exemption. Whilst it is possible to claim exemption on the basis of urgent need, for example as happened with a series of major respiratory pathogens including SARS Coronavirus, influenza H1N1 and most recently novel Coronavirus, this exemption is granted for a short period of time only. The *in vitro* diagnostic industry is understandably not always willing or able to invest in 'niche markets' despite a clinical need.

The move to include any assay involving any component for a group D diagnostic agent (essentially the original annex II component) in the IVDD will remove many of the novel diagnostics developed and widely used within HPA laboratories, and have a strong negative impact on reference work relating to any of the major blood borne viruses.

In addition, the financial requirements for third-party investigations of annex II diagnostics led to a number of very useful kits being removed from the market, as the manufacturers were not prepared to make the investment necessary for CE marking of kits which are widely used elsewhere in the world. A prime example of this is the gelatin particle-based Fujirebio kit range of assays.

Looking at the Food and Drug Administration regulations in the US for comparison, the level of control has led to the US market being perceived to be considerably behind Europe and other countries in the proficiency of their HIV screening assays. For example, there was a time delay of around ten years before a P24 component was introduced into HIV screening tests in the US which may have caused considerable population damage in the failure to identify early infections (in the window period).

Finally, despite input into the common technical specifications (laying down the protocols necessary for the investigation of IVDs), the final versions did not reflect what we would have liked and led to the removal of some valued assays from the marketplace. These technical specifications were further transformed into protocols for amplification-based assays which were felt to be inappropriate.

## **2. ORGANS, BLOOD, TISSUES AND CELLS**

### *Tissues and Organs*

The tissue directive and the more recent organ directive were brought into existence to facilitate improvements on all aspects of tissue and organ use within the community, and brought together materials which the transplant community would consider as tissues, i.e. bone and connective tissue and skin, materials which are very different in the form of stem cells including expanded pluri-potential cell lines and specific stem cell lines. The position of advanced therapy medicinal products remains anomalous. These are new medical products based on genes (gene therapy) cells (cell therapy) and tissues, (tissues engineering) and the whole range of reproductive cells.

One disadvantage of this is that it provides a very complex and difficult framework in which to work. It also, particularly in relation to reproductive cells, does not take account of the societal issues which vary greatly between member states. Neither do the directives truly facilitate the transfer of materials between member states, as some of the regulations work as strong disincentives.

Advantages of the European Commission tissue and organ directives include facilitating the introduction of protocols for the recognition of serious adverse events and serious adverse reactions, and the long term documentation of donors and recipients. There had been some reluctance in the UK transplant community to make the commitment to this important activity.

The directives also facilitated the establishment of a framework, encapsulated in the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) guidelines, relating to the microbiological screening of tissues and organs. The prescriptive nature of the directives does not take into account the complexity of transplant microbiology and the need for facilitating transplantation. If followed to the letter, they would significantly reduce transplant activity in the UK. This dichotomy puts the competent authority, MHRA, potentially in a difficult position. The guidelines also are extremely difficult to alter, favouring stasis rather than evolution.

### *Blood transfusion practice*

Extensive discussions have taken place between NHSBT and DH in relation to this.

One important threat is the *in vitro* diagnostics directive (IVDD), which does not take into account the unique nature of many of the reagents used in transfusion practice for the

characterisation of rare antigenic variants on red cells, all of which would be captured under group D because they relate to the qualification of a donation intended for human use. Again, the blood directive does not take into account the environmental and societal differences between various member states. A recent example of the impact of this was the threat to the UK supply through any attempt to comply with the blood directive relating to West Nile virus screening. The particular clause relating to the West Nile screening was inappropriate to the situation arising in north west Europe and the UK, and the anomaly was only brought under control through a plead by NHSBT on the grounds of blood sufficiency to MHRA.

### **3. HEALTH SECURITY**

#### *Impact on the national interest*

How does the EU's competence in health affect you/your organisation?

The EU's competence in the field of infectious disease threats to health largely derives from Decision 2119/98/EC of the European Parliament and the Council. This Decision defines a range of surveillance, communication and coordination activities that fall within the competence of the EU, and is the basis for the creation and support of a network for epidemiological surveillance and the establishment of the European Centre for Disease Control and Prevention (ECDC).

#### **What evidence is there that EU action in health advantages or disadvantages?**

##### *The UK national interest*

EU action under these Decisions provides substantial health advantages to the UK national interest. The establishment of ECDC provides a source of technical expertise and capacity that the UK is able to, and has often, called upon in dealing with infectious disease threats. Examples that provide evidence to demonstrate the extent to which the EU's role in public health supports member state actions effectively and efficiently include:

##### *Detection and response to outbreaks*

The disease specific networks that are coordinated by ECDC, and prior to the establishment of ECDC were supported by the Commission; deliver a well proven effective mechanism for the early detection and the rapid investigation of cross-border outbreaks (see references in 'General' section below). These networks have been particularly important in enabling the rapid identification of outbreaks of legionnaires' disease, which is an uncommon but severe form of pneumonia, and as a result the prevention of morbidity and mortality through the early control of the source. This has been achieved by collating data on seemingly sporadic cases in different countries and identifying that those cases share a common exposure related to travel e.g. outbreaks associated with hotels in Spain and Turkey. There are also examples of the value of these networks in improving the speed of identification of the cause of outbreaks occurring in the UK, such as an outbreak of Salmonella Newport in November 2011 with 63 lab confirmed cases in UK (England, Wales, Scotland and Northern Ireland), Germany and the Republic of Ireland. Data were distributed to the EU salmonella network via ECDC. Cases were reported from the Republic of Ireland and Germany, where trace back investigations identified a common producer in Brazil. FSA subsequently confirmed that two suppliers in Brazil distributed implicated water melons to two different retail chains in the UK.

##### *Early Warning and Response System (EWRS)*

The EU (Commission DG Sanco and ECDC) manage and maintain the EWRS that is used for rapid and confidential sharing of information about cross-border threats and response. The availability of this system greatly reduces the time and effort required in communicating with the relevant national authorities (administrations and public health bodies) that is required for the investigation and control of infectious disease (and other) threats that are not limited to the UK. The UK public health authorities regularly use this system to share confidential information with other EU public health bodies in the response to significant threats e.g. most recently it was the system used to trace contacts of a case of novel coronavirus infection who had been symptomatic, and hence posed an infectious risk, on a flight into the UK.

#### *Olympics Epidemic Intelligence Support*

The effectiveness and efficiency of UK national preparedness and monitoring processes for threats during the 2012 Olympics was significantly enhanced by the collaborative working of the HPA and the ECDC. ECDC provided expert and comprehensive epidemic intelligence support, undertaking scanning for potential health threats at a global level, using their international links and dedicated resources to augment the international surveillance and risk assessment team within the HPA. This not only broadened the range of intelligence sources available for this important part of the Olympics epidemic intelligence response, but also reduced the level of expert resource that the HPA needed to dedicate to this function. (see reference in 'General' section)

#### *Risk Assessments and Guideline Development*

ECDC provides supports Member States in assessing the need for a response to new and emerging infectious disease problems through its Rapid Risk Assessment publications. Through its coordination of the EU Disease Specific Networks, ECDC is able to identify experts in a wide range of diseases (some of which are rarely seen in the UK, and so there is relatively little expertise in the UK e.g. West Nile Virus). The Disease Specific Networks are also an important source of expert guidance that ensure a consistent approach to the investigation and management of infectious disease threats across the EU. References providing examples of a Rapid Risk Assessment and EU Network guidelines are provided in the 'General' section below.

#### *Joint Procurement of Countermeasures*

New EU Health Security legislation, which it is anticipated will be enacted later in 2013, includes provision for the EU Commission to coordinate joint procurement of vaccines and medicines used as countermeasures to pandemic agents and other serious threats to health. While the UK has opted out of the initially proposed joint procurement of pandemic vaccine, there is significant potential for efficiency in the procurement of expensive countermeasures that are used rarely and have a short shelf life.

### **Future options and challenges**

#### **How might the UK benefit from the EU taking more action in health?**

The addition of provisions for joint procurement of countermeasures in the health security legislation that is due to be enacted later in 2013 could benefit the UK in terms of more rapid and less costly access to infrequently used and expensive vaccines or biological products (such as the immunoglobulin that is used for eating infant botulism).

Greater regulation and collaboration between the health, veterinary and food standards agencies of the EU could benefit the UK in reducing the risks associated with foodborne infections (e.g. salmonella infections that have previously been associated with eggs imported

from Spain) and antimicrobial resistance (i.e. that element arising from use of antimicrobials in animals).

**How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?**

At present the EU competence in the field of infectious disease is largely confined to surveillance and coordination of measures, which is appropriate. Any legislative changes that might extend those competences to risk management could have disadvantages (see below).

**How could action in this area be undertaken differently e.g. Are there ways of improving EU legislation in health, e.g. revision of existing legislation, better ways of developing future proposals, or greater adherence to the principle of subsidiarity and proportionality?**

At present the EU competence in the field of infectious disease is largely confined to surveillance and coordination of measures, which is appropriate. Any legislative changes that might extend those competences to risk management could have disbenefits.

**Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest?**

Greater regulation and collaboration between the health, veterinary and food standards agencies of the EU could benefit the UK in reducing the risks associated with foodborne infections (e.g. salmonella infections that have previously been associated with eggs imported from Spain) and antimicrobial resistance (i.e. That element arising from use of antimicrobials in animals).

**Could action be taken at any other international level i.e. by the WHO?**

There is, in general, good coordination between the EU agencies and the WHO in Europe. The WHO's resources and focus on countries not currently part of the EU make it unlikely that the WHO could deliver to the same (adequate) level the functions currently provided by ECDC.

**What future challenge/opportunities might we face in EU health competence and what impact might these have on the national interest?**

At present the EU competence in the field of infectious disease is largely confined to surveillance and coordination of measures, which is appropriate. Any legislative changes that might extend those competences to risk management could have disadvantages. A particular concern would be in respect of any attempts to enforce changes to the timing and composition of the childhood immunisation programme.

**What impact would any future enlargement of the EU have on health competence?**

It could improve the capacity and effectiveness of infectious disease threat detection and response at the borders of Europe, through the support that can be provided by ECDC to Member States.

#### **4. HEALTHCARE ASSOCIATED INFECTIONS (HCAI) AND ANTIMICROBIAL RESISTANCE (AMR)**

##### **How does the EU's competence in health affect you/your organisation?**

EU have promoted and written a number of important council recommendations on HCAI and AMR.

These have influenced England's surveillance strategies and the implementation of these.

For example the COUNCIL RECOMMENDATION 2002/77/EC on the prudent human antimicrobial agent use.

Article 2e: implement hygiene and infection control standards in institutions (hospitals, child care facilities, nursing homes etc.) and in the community and assessing their impact Article 3b: enhance training on hygiene and infection control standards

##### *The UK national interest*

These EU actions are advantageous to England and promote the importance of these areas. The UK (as a whole) as developed these actions.

In addition EU, via ECDC has promoted, funded and developed a number of key surveillance initiatives:

1. ECDC point prevalence survey on Healthcare associated infection and antimicrobial use in acute hospitals
2. ECDC point prevalence survey on Healthcare associated infection and antimicrobial use in long term care facilities

##### **Patients and citizens**

There are a number of EU initiatives related to the field of HCAI and AMR that are advantageous for patients and citizens, for example:

e-Bug is a European-wide antibiotic and hygiene teaching resource for junior and senior school children. It is led by the HPA's Primary Care Unit in England and involves a consortium of 28 international partner countries. The main aim of the project is to educate children and young people across the globe, at junior and senior school level, about microbiology, hygiene and the spread, treatment and prevention of disease. e-Bug also aims to reinforce an awareness of the benefits of prudent antibiotic use and how inappropriate use can have an adverse effect on antibiotic resistance in the community. e-Bug resources comprise teacher and student educational packs reinforcing an awareness of essential hygiene and antibiotic issues through detailed interactive lesson plans and an interactive website hosting complementary games, interactive quizzes, disease fact sheets and more. For more information see <http://www.e-bug.eu/>

The European Antibiotic Awareness Day (EAAD) is an annual European public health initiative that takes place in November to raise awareness about the threat to public health of antibiotic resistance and prudent antibiotic use. The latest data confirms that across the EU the number

of patients infected by resistant bacteria is increasing and that antibiotic resistance is a major threat to public health. Prudent use of antibiotics can help stop resistant bacteria from developing and help keep antibiotics effective for the use of future generations. EAAD resources include toolkits for the general public, primary care prescribers and hospital care prescribers. In addition, a number of national campaigns take place across the EU as part of EAAD. For more information see <http://ecdc.europa.eu/en/EAAD/Pages/Home.aspx/>

The extent to which the EU's role in public health supports member state actions effectively and efficiently

EU Community network on Communicable Diseases: 1998

- 2119/98/EC ("21 19") of the European Parliament and the Council defines a network for epidemiological surveillance and control of CD in the Community
- Addresses need for co-ordinated action:
  - Member States (MS) are to communicate to Community network relevant information
  - Commission should coordinate information and action
- "DG SANCO" from the French for "Directorate General for Health and Consumer Protection": (DG V and XXIV)
- "DG R&D": (DG XII)

Commission Decision 2000/96/EC

Specifies list of 44 CDs and 2 special health issues (Hospital Acquired Infections/AMR) to be placed progressively under EU-wide surveillance

- The Community network shall be put in place by:
  - integrating existing Community-supported surveillance networks and
  - by building new networks for diseases not yet covered by surveillance networks: "Network of Networks"

Promotes a number of important initiatives e.g.

HARMONY (1999-2001) incl MRSA typing network Harmonisation of Antibiotic Resistance measurement, Methods of typing Organisms and ways of using these

and other tools to increase the effectiveness of Nosocomial infection control

ARPAC (2002-2005) Very useful papers Antibiotic Resistance Prevention and Control

ARMed (2002-2006)

Antibiotic Resistance in Mediterranean Countries

MOSAR (2007-2012)

Mastering hOSPital Antimicrobial Resistance in Europe

BURDEN 2008-2013 Very useful data

Burden of Resistance and Disease in Europe

IMPLEMENT 2008-2013 (www site?) Implementing Strategic Bundles for Infection Prevention & Management.

PROHIBIT 2008-2013

Analyses existing guidelines and IPC practices

SATURN 2010-2015

Impact of Specific Antibiotic Therapies on the prevalence of hUman host ResistaNt bacteria

R-GNOSIS 2011-2016 Studies in Multidrug-resistant GNRs

## **How might the UK benefit from the EU taking more action in health?**

The document indicates that the UK received €380 million, which was 16 per cent of the total available funds in the 'Life sciences, genomics and biotechnology for health theme' of Framework Programme 6. As the 7th Framework Programme for research and technological development, (launched in 2007) comes to an end in 2014, the UK has to ensure that it is able to maximise on the monies available from the Horizon 2020 Programme (replacement for Framework Programme 7) which will be beneficial to the research and surveillance programmes undertaken by Public Health England (PHE).

## **5 IMPLICATIONS OF FREE MOVEMENT OF HEALTHCARE PROFESSIONALS**

The EU wide requirement for appropriate checks on medical professionals to be carried out is of benefit to the Health Protection Agency / Public Health England in that it helps recruiters to assess the competence of prospective new employees from within the EU. This should assist in ensuring that the widest talent pool is considered and at the same time offers assurance that any non UK qualified staff possess the necessary high competency levels required. This should help to ensure that we continue to deliver high quality services to patients and the wider population.

## **6 GENERAL**

### **Are there any published sources of information to which you would like to draw our attention for the purposes of this review?**

- Jones J, Lawrence J, Payne Hallström L, et al (in press). International infectious disease surveillance during the London Olympic and Paralympic Games 2012; process and outcomes. *Eurosurveillance* 2013; 18 (In Press)
- Fisher IS. Salm-Net: a network for human salmonella surveillance in Europe. *Euro Surveill.* 1995;0(0):pii=194. Available online: <http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=194>
- Ricketts KD, Joseph CA. Legionnaires' disease in Europe: 2005-2006. *Euro Surveill.* 2007;12(12):pii=753. Available online: <http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=753>
- The European Working Group for Legionella Infections. The European Guidelines for Control and Prevention of Travel Associated Legionnaires' Disease. Available from: [http://www.ewgli.org/data/european\\_guidelines.htm](http://www.ewgli.org/data/european_guidelines.htm)
- European Centre for Disease Control and Prevention, Robert Koch Institute, Rijksinstituut voor Volksgezondheid en Milieu. Joint Risk Assessment: New Orthobunyavirus isolated

from infected cattle and small livestock – potential implications for human health. ECDC, Stockholm, 2012. <http://ecdc.europa.eu/en/publications/publications/ter-joint-ecdc-rivm-rki-rapid-risk-assessment-schmallenberg-virus-may-2012.pdf>

## APPENDIX 1

### Eurosurveillance, Volume 18, 2013 (In Press)

#### International infectious disease surveillance during the London Olympic and Paralympic Games 2012; process and outcomes.

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Keywords; surveillance, epidemic intelligence, infectious disease, Olympics, mass gatherings

**Abstract:** Surveillance for possible international infectious disease threats to the Olympic and Paralympic Games in London was conducted from 2 July to 12 September 2012 by a collaborative team comprising representatives from the Health Protection Agency, the European Centre for Disease Prevention and Control, and the National Travel Health Network and Centre. Team members enhanced their usual international surveillance activities and undertook joint risk assessments of incidents identified as relevant through an agreed set of criteria designed for the Games, and using tools developed for this purpose. Although team members responded to a range of international disease incidents as part of their routine roles during this period, none were identified that represented a threat to London 2012. Six incidents were highlighted by the team that were likely to attract media attention and hence could generate political and public concern. Responding to such concern is an important aspect of the overall public health management of mass gathering events. This paper outlines the enhanced international surveillance undertaken so as to share lessons learned about its process and outcomes and help inform planning by future hosts of similar events.

Eurosurveillance, Volume 0, Issue 0, 01 September 1995

Surveillance report

## **SALM-NET: A NETWORK FOR HUMAN SALMONELLA SURVEILLANCE IN EUROPE**

*Fisher Ian, PHLS Communicable Disease Centre, London, England*

Salm-Net aims to prevent human salmonellosis within the EU by strengthening international laboratory based human salmonella surveillance and creating an on-line European database of compatible data available to all participants. Salm-Net is funded by DG XII of the European Commission under the BIOMED 1 programme. The network consists of microbiologists and epidemiologists responsible for national salmonella surveillance in 14 European countries. Salm-Net's also aims to harmonise the schemes for the phage typing of *Salmonella enteritidis*, *S. typhimurium*, and *S. virchow*.

Salm-Net became operational in January 1994 and has already facilitated the recognition and investigation of two outbreaks. An outbreak of infection with *Shigella sonnei* was linked to iceberg lettuce (1) and one with *S. agona* was linked to an imported snack food (2). In March 1995 the Swiss participant reported six cases of infection with *S. tosamanga* which had not previously been seen in Switzerland. A request for information was immediately sent to the other participants. England and Wales, having reported no cases since 1962, reported four cases. Sweden reported nine cases (the first for many years), Ireland three, Germany two, and France one. Switzerland finally identified nine cases. An investigation was coordinated by the PHLS CDSC, and a questionnaire was administered to 13 cases. No definite evidence could be found to implicate any single product. The question remains why an extremely rare salmonella should appear in 28 human cases in six geographically separate countries in Europe within five months?

As travel increases and trade barriers across Europe are removed, the opportunities for microorganisms to cross borders and the potential for international outbreaks have become greater. Collaborative surveillance schemes such as Salm-Net are an extension of national schemes, rather than a replacement of them, and aim to assist international surveillance and protect public health.

1. CDSC. A foodborne outbreak of *Shigella sonnei* infection in Europe. *Communicable Disease Report* 1994; 4: 115

2. CDSC. An outbreak of *Salmonella agona* due to contaminated snacks. *Communicable Disease Report* 1995; 5: 29

## **Eurosurveillance, Volume 12, Issue 12, 01 December 2007**

Euro roundup

### **LEGIONNAIRES' DISEASE IN EUROPE: 2005-2006**

KD Ricketts, CA Joseph on behalf of the European Working Group for Legionella Infections (EWGLI)

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Once a year, every country that participates in the European Surveillance Scheme for Travel Associated Legionnaires' Disease (EWGLINET) is asked to submit a dataset comprising all

cases of Legionnaires' disease (not only travel-associated) with date of onset in the previous year. This paper presents the data collected for 2005 and 2006. In this period, 11,980 cases were reported by 35 countries, showing a continued increase compared with earlier years. 214 outbreaks or clusters were reported, involving 1028 cases. 377 cases died, giving a case fatality rate of 6.6%. The highest incidence rates in both years were recorded in Spain, while six countries reported a rate of less than one case per million population in at least one of the years. Incidence rates by age group were included in the dataset for the first time, showing an increase of the overall rate with age. Main method of diagnosis was the urinary antigen test (76.0%), whilst the percentage of cases diagnosed by culture fell from 10.0% in previous years to 8.9% in 2005-2006.

## Introduction

Legionnaires' disease is an atypical pneumonic illness caused by the *Legionella* bacteria. These bacteria can be found naturally in environmental water sources such as rivers, lakes and reservoirs, usually in low numbers. The organism favours warm, stagnant waters, and becomes infective when aerosolised. Poorly maintained aerosol-generating devices can act as a source of the disease, and have been responsible for outbreaks affecting up to 400 cases [1]. Wet cooling systems, water systems and spa pools are all well documented sources of Legionnaires' disease [1].

The identification of Legionnaires' disease in 1977 led to the establishment of the European Working Group for Legionella Infections (EWGLI) in 1986. The group aimed to share knowledge and to monitor trends in legionella infections across Europe. Currently, 35 countries are members of EWGLI.

Every year the EWGLI participating countries are asked to submit data on the cases of Legionnaires' disease that have been diagnosed in their residents during the preceding year to the co-ordinating centre in London. This allows for analysis of this disease on a European level and for comparison of trends between countries. Data from the years 1996 to 2004 have been published previously [2-7].

This paper presents the dataset for the years 2005-2006.

## Methods

Participating countries submit an aggregated epidemiological and microbiological dataset using standardised reporting forms. The following data is collected: the number of confirmed and presumptive cases diagnosed in the reporting country during the preceding year, how many died, and the population base covered by the reporters; the method of diagnosis and the species and serogroup of any isolates obtained; age group and sex of the cases (age standardised rates were introduced into the dataset for the first time in 2005); category of exposure (nosocomial [hospital-acquired], travel or community); countries of travel for the travel-associated cases; outbreaks by type, size and suspected source.

Cases are classified as confirmed or presumptive, based upon the EWGLI case definitions [8]. If the method of diagnosis is not known, the case is classified as 'diagnosis not known'.

Each case is further categorised by exposure history into 'travel', 'nosocomial' and 'community' cases. This is determined for each case by the country of report according to national

definitions. In instances where there is insufficient evidence to allocate a case to one of the existing categories (e.g. cases that spent part of their incubation period both in hospital and travelling), the case is categorised as 'other', and if there is no exposure information available, the case is allocated to the 'not known' category.

Where incidence rates per million population are calculated, they are based upon the reported population size. Regional rather than national incidence rates were obtained for six countries in 2005 (Bulgaria, Croatia, Czech Republic, Lithuania, Romania, Russia) and four in 2006 (Bulgaria, Lithuania, Russia, Romania), and it should be noted that these data may not be representative of the entire country.

In this report, the term 'outbreak' is used to describe outbreaks in hospitals or community settings, whereas the term 'cluster' is used to describe this type of incident when associated with hotels or other tourist accommodation sites. Every country defines its outbreaks independently, whilst clusters are defined as 'two cases associated with the same accommodation site within two years', based upon EWGLINET's definition.

## Results

In 1993, only 19 countries reported a dataset to EWGLI. The response rate has risen significantly since then to 35 countries in both 2005 and 2006. The number of cases reported was 5,700 in 2005 and 6,280 in 2006. In the fourteen years for which this dataset has been collected, 41,627 cases have been reported (Table 1). [Note that in previous publications, the number of cases for 1993 was erroneously reported as 242 instead of 1,242]

*Incidence per million population* In both years the highest incidence rates were reported by Spain (28.4/1,000,000 population in 2005 and 30.0/1,000,000 in 2006), followed in 2005 by France (24.8/1,000,000 in 2005 and 23.0/1,000,000 in 2006) and in 2006 by the Netherlands (16.7/1,000,000 in 2005 and 26.9/1,000,000 in 2006). Five countries reported incidences of less than one case per million population in 2005 (Latvia, Malta, Poland, Slovakia and Turkey), in comparison with four countries in 2006 (Latvia, Romania, Slovakia and Turkey). Table 2 shows rates of Legionnaires' disease per million populations for 10 countries, selection based upon their consistent rates, and in order to allow comparison with previous papers.

The overall incidence for Europe was 10.3/1,000,000 in 2005 (based on a denominator population of 550.8 million) and 11.2/1,000,000 in 2006 (based on a denominator of 562.7 million) (Table 1).

*Category of cases* For the two years 2005-2006, 629 cases were reported as nosocomial, 7,041 as community cases, 1,395 as associated with travel abroad, 1,227 as associated with travel within the country of residence, 126 as 'other' and 1,562 as 'not known' category of infection (Table 3).

*Age of cases* A breakdown of cases by age group was available in both years for all countries except Czech Republic, Former Yugoslav Republic of Macedonia, Germany, Iceland and Israel\*. National demographic data on population size by age group were also provided in order to calculate age standardised rates. The peak age group of cases was 50-59 in both years; 1,164 cases in this age group were reported in 2005 and 1,289 cases in 2006. Whilst in both years the number of reported cases in the older age groups decreased with age (60-69 years: 1,076 in 2005, 1,170 in 2006; 70-79 years: 914 in 2005, 1,026 in 2006; 80+ years: 639 in 2005, 726 in 2006), the overall age standardised incidence rates increased with increasing age (60-69 years: 2.6 cases per 100,000 in 2005, 2.86 in 2006; 70-79 years: 2.91 in 2005, 3.32 in 2006;

80+ years: 3.83 in 2005, 4.32 in 2006). This increase in incidence rate with age was seen for some individual countries (e.g. France, Italy), but did not hold for all (e.g. England and Wales, The Netherlands) (Table 4).

*Outbreaks* During the two years, there were a total of 214 outbreaks or clusters, detected by 18 countries and involving 1,028 cases, 8.6% of the total dataset (Table 5). Countries reported 408 cases associated with 107 outbreaks in 2005, and 620 cases associated with 107 outbreaks in 2006. The outbreaks ranged in size from two to 146 cases. The largest outbreaks in both years occurred in Spain and were attributed to wet cooling systems; involving 50 cases in 2005 [9] and 146 in 2006 [10]. The number of deaths associated with these outbreaks could not be determined from the information collected in this dataset.

Nineteen outbreaks (8.9%) involving 66 cases were linked to hospitals or healthcare facilities and occurred in Austria, Denmark, England and Wales, France, Germany, Ireland, The Netherlands, Poland, Portugal and Spain. Fifteen of these were attributed to contaminated hot or cold water systems, two to wet cooling systems, and two to an unknown source. These sources are as reported by collaborators, and the standard of investigation may vary between countries.

Forty-four outbreaks (20.6%) were linked to community settings, and involved 522 cases. They occurred in Austria, England and Wales, France, Germany, The Netherlands, Northern Ireland, Poland, Portugal, Scotland and Spain. Wet cooling systems were identified as the source in 19 outbreaks, five were attributed to hot or cold water systems, four to whirlpool spas, 15 to an unknown source and one to the sediment at the base of a pressurised water tank [11].

One hundred and forty-three clusters (66.8%) were associated with travel; 94 (44%) with travel outside the country of residence, and 49 (23%) with travel within the country of residence. Hot or cold water systems were responsible for 52 of the clusters, a wet cooling system in one cluster, and whirlpool spas in three. No source was identified for the remaining clusters.

Two outbreaks (one in each year) were linked to prisons, and in both the source of infection was identified as the hot or cold water system. One 2006 outbreak was associated with a nursing home, for which the source was not identified, and the remaining five outbreaks (one in 2005, the rest in 2006) were associated with private homes or buildings. In two of these latter outbreaks, the hot water systems were identified as the source; for the remaining three no source was identified.

*Travel-related legionella infection* Altogether in 2005-2006, 26 countries reported a total of 2,622 travel-associated cases; 1,395 were classified as 'travel abroad' and 1,227 were associated with travel in the patient's country of residence (Table 3). Nine countries in 2005 and five countries in 2006 reported no travel-associated cases. Travel within Europe accounted for 89.2% of the travel-associated cases in 2005 (1142 cases) and 90.0% in 2006 (1208 cases). Travel on cruise ships was associated with two cases in 2005 and 11 in 2006.

Spain was associated with the most travel-related cases over this two-year period (545 cases), followed by France (497 cases) and Italy (450 cases). These countries may be disproportionately represented as countries of infection because they reported the highest number of cases in general, and the majority of the travel-associated cases in these countries (59.6%, 77.3% and 53.3%) occurred as a result of domestic travel.

A more detailed analysis of travel-associated cases of Legionnaires' disease is published each year from EWGLI's surveillance scheme (EWGLINET) [12]. EWGLINET operates a strict case definition for travel-associated infections, and so not all cases reported as travel in this dataset are reported to the EWGLINET travel dataset. EWGLINET's case definition excludes patients who had stayed in private accommodation, patients for whom travel information was incomplete, or those for whom travel did not fall within the strict 2-10 day incubation period. EWGLINET does not include these cases because it would not be possible to investigate them further or to link them to other cases who shared the same accommodation site.

*Main method of diagnosis:* EWGLI collaborators allocate a main method of diagnosis to each reported case, taking culture as the 'gold-standard' test. The majority of cases in 2005 and 2006 were primarily diagnosed by urinary antigen detection (9,100 cases, 76.0%), followed by isolation/culture for 1,067 cases (8.9%), single high antibody titres in 716 cases (6.0%), and a fourfold rise in antibody detection levels for 274 cases (2.3%). The remaining cases were diagnosed by respiratory antigen detection, PCR, other methods or the method was unknown (Table 6). In 2006 compared with 2005, the percentage of cases diagnosed primarily by culture fell from 9.3% to 8.6%, whilst the number of cases with urinary antigen detection as the main method of diagnosis increased from 71.3% to 80.2%. The proportion of cases diagnosed serologically (including both seroconversions and single high titres) fell from 8.8% to 7.8%.

'*Legionella pneumophila* serogroup 1' accounted for 9,219 cases (77.0%) over the two years, '*L. pneumophila* other serogroup or serogroup not determined' accounted for 1,862 cases (15.5%), and 899 (7.5%) were reported as 'other *Legionella* species' or 'species not known'.

Of the 1,067 isolates obtained, 862 (80.8%) were identified as *L. pneumophila* serogroup 1, 94 (8.8%) were *L. pneumophila* serogroups 2-16 and 74 (6.9%) were *L. pneumophila* serogroup unknown. Seventeen isolates were diagnosed as other species of *Legionella*. These were reported as *L. anisa* (1), *L. bozemanii* (2), *L. brunensis* (1), *L. cincinnatiensis* (1), *L. feeleii* (1), *L. jordanis* (1), *L. longbeachae* (4), and *L. micdadei* (6). For 20 isolates, the *Legionella* species was not known.

*Deaths* There were 377 deaths reported in 2005 (case fatality rate of 6.6%) compared with 387 deaths in 2006 (case fatality rate of 6.2%). In some countries it is not compulsory to report deaths, and so these figures may underestimate the true mortality attributable to Legionnaires' disease.

## Discussion

The number of cases reported each year to the scheme continues to increase. This rise in case numbers can be partly attributed to increasing ascertainment as national surveillance schemes strengthen. It is especially notable that awareness of Legionnaires' disease is rising in the newer European Union member states. Invitation to submit annual datasets of cases each year appears to be helping in raising the profile of the disease in these countries, whereas comparison of the rates between countries can highlight the extent of the under-ascertainment. EWGLI hopes that the number of cases reported by these countries in the future annual datasets will increase to better reflect the true number of cases.

Every year, the number of nosocomial cases reported to the dataset remains relatively static (between 300 and 350 since 2003 [7]). In the context of increasing overall case numbers this stability is an encouraging trend, especially since case fatality rates are higher amongst nosocomial cases than amongst other categories [13]. Also, the number of large community outbreaks has been decreasing in recent years. Community outbreaks are unpredictable, so it is

difficult to determine whether this decrease is real or artifactual. However, more extensive legislation has been introduced across Europe in recent years for the control and prevention of Legionnaires' disease, which is probably having a beneficial effect [14-16]. Authorities should be encouraged to ensure that national or WHO guidelines are being utilised in national health care systems [1].

EWGLI has repeatedly raised the problems associated with a decrease in the number of clinical isolates being obtained but, despite this, the number fell again during 2005-2006 to 8.9% (in comparison with 10.0% in 2003-2004 [6]). Lack of clinical isolates can cause difficulties for public health authorities when investigating clusters; with no clinical isolate to compare with any environmental isolates obtained, the suspected source of the outbreak cannot be microbiologically confirmed. As Legionella is a relatively ubiquitous organism in the environment, microbiological confirmation is an important step in determining the source of infection. As the urinary antigen test becomes ever more widespread, this problem is likely to become exacerbated. The increasing use of the urinary antigen test probably also accounts for the high proportion of *L. pneumophila* serogroup 1 reported to EWGLI, since the test almost exclusively detects these organisms.

The overall incidence rates recorded in this dataset show an increasing rate with increasing age. This is a new variable collected in the dataset and the resulting figures have important implications for Europe's aging population. Countries should expect an increase of case numbers and a greater demand for health services due to Legionnaires' disease in the future. There are some countries that do not show this increasing rate with age, however, it is difficult to determine whether this is due to different testing policies or to true trends in the incidence rates.

In 2010, EWGLINET and the collection of this annual dataset will transfer to the European Centre for Disease Prevention and Control (ECDC). This annual dataset has now been collected for fourteen years, to comprise the largest dataset of cases of Legionnaires' disease in the world and should be continued. EWGLINET itself has been a valuable tool in raising awareness of the disease among members and national surveillance structures, and has contributed to the introduction of regulations and guidelines across Europe. This type of European surveillance is especially important for preventable diseases with environmental sources, as prompt action can tackle these sources as they emerge. With the ageing of populations across Europe, and therefore more people at risk from Legionnaires' disease, EWGLINET's importance will only increase.

EWGLI hopes that the ECDC will encourage countries, especially the new EU Member States, to develop their national surveillance schemes and submit their annual data so that surveillance of the Legionnaires' disease across Europe can continue unabated.

#### *Acknowledgements*

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\*Authors' correction:

1) In Results, the sentence: "A breakdown of cases by age group was available in both years for

all countries except Czech Republic, Former Yugoslav Republic of Macedonia, Germany, Iceland, Israel and Portugal." was corrected to: "A breakdown of cases by age group was available in both years for all countries except Czech Republic, Former Yugoslav Republic of Macedonia, Germany, Iceland, and Israel."

2) Data for Portugal were added in Table 4.

These corrections were made on 21 May 2008.

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## Human Fertilisation & Embryology Authority

Thank you for the opportunity to comment on this consultation. This short statement represents the position of the Human Fertilisation and Embryology Authority (HFEA) on the value to the UK of EU legislation and activity in the field of assisted fertility treatments (ART) and embryos for human application.

### Summary

- EU law in the field of ART is set out in the European Tissue and Cells Directive (EUTCD) which regulates gametes and embryos for human application. The EU also funds a number of projects to develop a harmonised approach to these issues across Member States.
- In the UK which has regulated ART since 1990, the EUTCD can be said to have merely codified much of what was already standard practice in UK fertility clinics. But any rounded assessment of the Directive would also need to acknowledge its role in levering up standards both within UK clinics and across the EU.
- Moreover, although the rules relating to gametes in the EUTCD are more prescriptive than is arguably necessary, any change in those standards would impose costs on the UK fertility sector.
- ART is increasingly a cross border activity with patients and gametes moving between Member States. There is therefore a good argument in favour of common standards; they can reduce bureaucracy.
- Taken together, we are of the view that the advantages of the EUTCD and other EU activity in this area outweigh the disadvantages.

### Detail

#### *Background*

The HFEA is one of the Competent Authorities in the UK under the European Union Tissue and Cells Directives (EUTCD) and has responsibility for regulating gametes and embryos for human application. The EUTCD was transposed into UK law in 2007, becoming an integral part of the existing regulatory regime established under the Human Fertilisation and Embryology Act 1990 (HFE Act). The Human Tissue Authority (HTA) is the other Competent Authority in the UK and is responsible for the regulation of tissues and cells (other than gametes and embryos) for human application.

The EUTCD set out to establish a harmonised approach to the regulation of tissues and cells across Europe. The Directives set a benchmark for the quality and safety standards that must be met when carrying out any activity involving tissues and cells for human application (patient treatment). The Directives also require that systems are put in place to ensure that all tissues and cells used in human application are traceable from donor to recipient.

The HFEA, as a Competent Authority, has a duty to do the following:

- Implement the EUTCD
- Accredite, designate, authorise or license tissue establishments\*
- Inspect tissue establishments\*
- Authorise import and export of tissue and cells outside the EEA\*

Establish and maintain a publicly accessible register of tissue establishments and specify the activities for which they have been accredited, designated, authorised or licensed\*

Report certain serious adverse events and serious adverse reactions to the European Commission on an annual basis

(NB. \* These duties were already required by the HFE Act)

One of the objectives of the EUTCD was to introduce a harmonised approach to the regulation of tissue and cells, including gametes and embryos. To achieve this objective the European commission has funded three projects:

EUSTITE – this project developed guidance and training for competent authorities on the inspection of tissue establishments, including ART centres.

Vigilance and Surveillance in substances of human origin project (SOHO V&S) – the aim of this project was to address the harmonisation of terminology, documentation and to develop a consensus on how information should be exchanged between Member States, the European Commission and third countries, to enhance efficient management of incidents involving cross-border distribution of tissues and cells.

EUROCET 128 – this project will develop a single European coding system for all tissue and cells, to support the traceability of human tissues and cells that are applied to patients in the EU.

#### *Judgement*

Any assessment of the EUTCD must be a balanced one. On the one hand it can be argued that the Directive adds little to previous UK law in this area and is more cumbersome or prescriptive than is ideal. The UK was arguably the first country to introduce a regulatory regime for ART and human embryo research (in 1990) and the EUTCD merely codifies much of what was already in place in the UK; although it should be noted that the Directive did bring previously unregulated services (IUI centres which only carried out insemination of husband / partner sperm) into the scheme of regulation. It is also true that the EUTCD was drafted with human tissue for transplantation in mind, rather than gametes, and as a result some of the screening and traceability requirements are more detailed than is necessary, eg. for ART involving partners.

On the other hand, the EUTCD has usefully raised standards in relation to air quality, and has driven a focus on quality management and continuous improvement. Moreover, all licensed clinics in the UK now comply with the standards set in the EUTCD. Any change in those standards would impose a cost burden on the UK fertility sector. Although we have not consulted with the sector in respect of this particular exercise (there has not been time) we are not aware of any significant feeling within the sector that the EUTCD needs radical revision, although some clinics have raised discrete issues over time. Indeed, were the EUTCD not in force there are good arguments that many of the areas it covers ought to be captured in UK law.

It is also important to recognise that ART is increasingly a cross border activity. Patients and gametes do move across the countries of the EU. As a consequence, common standards are useful and can reduce bureaucracy; for example, in the import or export of gametes between the UK and other EU Member States.

The projects referred to above, play their part in the development of such common standards.

## Human Tissue Authority

### **The Human Tissue Authority's (HTA) submission to the Department of Health's EU balance of Competency Review**

The Human Tissue Authority (HTA) is an Executive Non-Departmental Public Body (ENDPB) sponsored by the Department of Health. The HTA was established under the Human Tissue Act (HT Act) 2004 (which covers England, Wales and Northern Ireland). As well as licensing under the HT Act, the HTA is the Competent Authority (CA) in the UK responsible for ensuring the safety of human tissue and cells used for patient treatment, in compliance with the European Union Tissue and Cells Directive (EUTCD). We are also the CA for the European Union Organ Donation Directive (EUODD), ensuring the quality and safety of organs used intended for transplantation

With the interests of the public and those we regulate at the centre of our work, the HTA aims to maintain and build confidence by making sure that human tissue is used safely and ethically, and with proper consent. We regulate organisations that remove, store and use tissue for research, transplantation, medical treatment, post-mortem examination, teaching and display in public. We also give approval for organ and bone marrow donations from living people.

#### **HTA's areas of EU Competence**

1. Directives 2004/23/EC, 2006/17/EC and 2006/86/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells
  - Transposed into UK law by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (S.I. 2007/1523).

These directives set a benchmark for the standards that must be met when carrying out any activity involving tissues and cells for patient treatment. The directives require that systems are put in place to ensure that all tissues and cells used in patient treatment are traceable from donor to recipient and that action can be taken quickly to address serious adverse events or reactions.

The directives recognise that donors/recipients and tissues and cells are exchanged across national boundaries. The directives aim to ensure that human tissues and cells, whatever their intended use, are of comparable quality and safety across the European Union (EU), and including member states of the European Economic Area (EEA). The parent directive (2004/23/EC) maintains that the establishment of such standards will help to reassure the public and increase public confidence.

2. Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation
  - Transposed into UK law by the Quality and Safety of Human Organ intended for Transplantation Regulations 2012 (S.I. 2002/1501).

The Directive has three main objectives

- increasing organ availability;
- enhancing the efficiency and accessibility of transplantation systems;

- improving quality and safety.

As well as legislative implementation, there are various voluntary initiatives and projects across the EU. There is a six-year (2009 – 2015) Action Plan that supports activities across the EU to strengthen organ donation and transplantation programmes. There are also a number of complementary Joint Actions which provide European funding to support work focusing on living donation; on strengthening the interface between intensive care units and organ donation; and supporting specific twinning projects between individual member states to improve aspects of their donation or transplantation programmes.

The Department of Health has invited respondents to the review to consider a number of questions. The HTA submits the following information in response to those questions.

### **How does the EU's competence in health affect you/your organisation?**

The HTA is a Competent Authority (CA) for all four UK countries under the EUTCD and EUODD. The HTA licences and inspects 259 establishments under the Tissues and Cells Directives and 36 under the Organ Directive.

As the CA for these directives we have a number of statutory obligations to meet. The overarching obligation is to ensure compliance with the requirements of the directives. This obligation is met through a process of licensing and inspection, the follow up of non-compliances and the investigation of serious adverse events and reactions.

In addition, to the regulatory oversight of licensed establishments the HTA under the Tissues and Cells directives is required to submit information on licensed establishments to the European Commission (EC) on an annual basis. To comply with these data submissions the HTA collects annual activity data from licensed establishments. The data collected includes the numbers of tissues and cells procured, tested, processed, stored, distributed and imported or exported. The data is published in an anonymised format on an EU website called Eurocet - see <http://www.eurocet.org>.

The HTA also submits an annual report to the EC on the numbers of serious adverse events and reactions reported. The EC uses the annual activity data to act as a denominator for interrogating the serious adverse event and reaction data e.g. the percentage of events or reactions related to cornea transplants. To date, the quality of the data has not been sufficiently robust to provide confidence in use; however, the quality of data submissions is improving and the aggregated European data will provide an increasingly valuable resource for improving the quality and safety of tissues and cells.

The HTA also sends a representative to the EU CA meetings; these occur twice yearly under each set of directives. The meetings are an extremely valuable and important function for a CA. In particular, they provide an opportunity for member states to raise questions of interpretation, influence change to the Directives, and provide a rich source of access to international expertise across a number of relevant disciplines. The HTA has been influential in informing and directing the development of policy at an EU level. The UK has successfully brought about one legislative change to the EUTCD and is currently working with the EC to identify further changes in order to ensure the directives keep abreast of scientific developments.

In addition to the formal CA meetings, the HTA has also participated in a number of EU projects. Most recently, the HTA worked as an associate partner on a three year vigilance and surveillance project. The project is now drawing to a close and the project outcomes are being prepared for dissemination across members states, for further information see <http://www.sohovs.org/soho/>

The EC provides funding for a number of initiatives and projects as well as providing the resources for an IT platform to report serious adverse events and reactions that could affect one

or more member states. This platform is of fundamental importance to ensure information is exchanged efficiently and effectively between member states, and that a rapid recall of tissues or cells can be initiated across a number of member states when necessary, preventing tissues and cells that may be implicated in an adverse event or reaction being used in patient treatment.

Looking to the future, the EC has made it clear that it will seek to improve lines of communication and engagement between related areas of healthcare. For example, there are areas of common interest between the medicines legislation and the tissues and cells directives, in particular through the emergence of regenerative medicine and advanced therapy medicinal products.

The HTA views participation and co-operation at a European level, between member states and their designated CAs, as essential to guaranteeing that tissues and cells imported or distributed into the UK are of equivalent standards in quality and safety to those that are procured, tested and processed here.

### **What evidence is there that EU action in health advantages or disadvantages:**

#### *The UK national interest*

The setting of common standards across the EU should ensure that UK patients who are receiving treatment involving the use of organs, tissues or cells will be treated with products that meet high standards of quality and safety irrespective of whether they are treated in the UK or in an EU member state. The systems and processes that are in place at a European level for recalling defective products imported into the UK provide an important national safeguard.

#### *Business and industry*

The introduction of common standards across the EU enables a culture of mutual recognition between member states, which in turn should facilitate and ease the movement of tissues, cells and organs across member states. For example, if tissues or cells are imported to the UK from another member state an import licence is not required as the tissues/cells will already have been assessed as meeting the regulatory requirements by the CA of another member state.

#### *Patients and citizens*

Patients can be assured of equivalent standards of healthcare where tissues, cells or organs are used in patient treatment irrespective of which member state provides the treatment or which member state supplies the tissues, cells or organs. There is also evidence<sup>27</sup> that indicates that citizens are more likely to donate their tissues, cells or organs if they have confidence in the regulation. Ensuring a sufficient supply of donated tissues, cells and organs is key to being able to treat patients for number of conditions, both life-enhancing and life-saving.

### **Please consider what evidence there is to demonstrate;**

#### *the extent to which the EU's role in public health supports member state actions effectively and efficiently*

The EU provides an opportunity for member states to access and learn from the experiences of each other and creates a wider pool of expertise to draw upon. Tapping into this EU-wide

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<sup>27</sup> [HTA Public Evaluation 2010](#) showed that about half of respondents agree they would be more confident to donate their tissue (49%), organs (52%) or body (43%) for transplants or medical research knowing that there is a regulator in place.

knowledge base should enable member states to pool resources, increasing effectiveness and efficiency. For example, the recently-completed vigilance and surveillance project, using EU resources and funding, was able to draw upon expertise not just from within the EU but also upon the expertise of organisations such as the World Health Organisation and the Council of Europe.

*the extent to which health objectives are effectively and proportionately taken into account in wider EU policies*

The HTA's experience of working within the EU is that there is a commitment to facilitating an ethos of collaboration between member states to influence policy development. For example, the HTA is currently working with an EU expert working group to develop policy on the import and export of tissues and cells. The policy that is developed by the working group will be presented to all member states for comment and revision. This review process will ensure that the interests of all member states are considered.

In conclusion, the HTA's experience of working with the EU as a CA has been a positive one. It is vital to be an active participant at the EU CA meetings to influence and affect change, and the EU has been willing to listen and where possible and necessary, has brought about change.

Our experience of the processes for consulting on the development of policy has been that it is inclusive and encourages participation.

## Imperial College

In this article, I will try to explain in lay-person's language how weak electromagnetic fields from cell phones, cordless phones and WiFi can have serious effects on human and animal health. These include damage to glands resulting in obesity and related disorders, chronic fatigue, autism, increases in allergies and multiple chemical sensitivities, early dementia, DNA damage, loss of fertility and cancer.

All this happens at levels of radiation that the cell phone companies tell us are safe because the radiation is too weak to cause significant heating. **This is the only criterion that they use to assess safety.** In fact, the direct electrical effect on our cells, organs and tissues do far more damage to us at energy levels that may be hundreds or thousands of times lower than those that cause significant heating. These are termed non-thermal effects. As yet **our governments and health authorities are doing nothing to protect us from them.**

**This need not be so. By understanding the mechanisms of these non-thermal effects, it is possible to put most of them right, as I will show in the following article.**

### Abstract

*Many of the reported biological effects of non-ionising electromagnetic fields occur at levels too low to cause significant heating; i.e. they are non-thermal. Most of them can be accounted for by electrical effects on living cells and their membranes. The alternating fields generate alternating electric currents that flow through cells and tissues and remove structurally-important calcium ions from cell membranes, which then makes them leak.*

*Electromagnetically treated water (as generated by electronic water conditioners used to remove lime scale from plumbing) has similar effects, implying that the effects of the fields can also be carried in the bloodstream. Virtually all of the non-thermal effects of electromagnetic radiation can be accounted for by the leakage of cell membranes.*

*Most of them involve the inward leakage of free calcium ions down an enormous electrochemical gradient to affect calcium-sensitive enzyme systems. This is the normal mechanism by which cells sense mechanical membrane damage. They normally respond by triggering mechanisms that stimulate growth and repair, including the MAP-kinase cascades, which amplify the signal.*

*If the damage is not too severe or prolonged, we see a stimulation of growth and the effect seems beneficial, but if the exposure is prolonged, these mechanisms are overcome and the result is ultimately harmful. This phenomenon occurs with both ionising and non-ionising radiation and is called radiation hormesis. Gland cells are a good example of this, since short term exposures stimulate their activity but long term exposures cause visible damage and a loss of function. Damage to the thyroid gland from living within 100 metres of a cell phone base station caused hypothyroidism and may be partially responsible for our current outbreak of obesity and chronic fatigue.*

*Secondary effects of obesity include diabetes, gangrene, cardiac problems, renal failure and cancer. Cell phone base station radiation also affects the adrenal glands and stimulates the production of adrenalin and cortisol. Excess adrenalin causes headaches, cardiac arrhythmia, high blood pressure, tremors and an inability to sleep, all of which have been reported by*

people living close to base stations. The production of cortisol weakens the immune system and could make people living near base stations more susceptible to disease and cancer.

Inward calcium leakage in the neurons of the brain stimulates hyperactivity and makes it less able to concentrate on tasks, resulting in attention deficit hyperactivity disorder (ADHD). When this happens in the brains of unborn babies and young children, it reduces their ability to concentrate on learning social skills and can cause autism. Leakage of the cells of the peripheral nervous system in adults makes them send false signals to the brain, which results in the symptoms of electromagnetic intolerance (aka electromagnetic hypersensitivity). Some forms of electromagnetic intolerance may be due to cell phone damage to the parathyroid gland, which controls the calcium level in the blood and makes cell membranes more inclined to leak. Further exposure could then tip them over the edge into full symptoms of electromagnetic intolerance.

Cell phone radiation damages DNA indirectly, either by the leakage of digestive enzymes from lysosomes or the production of reactive oxygen species (ROS) from damaged mitochondrial and plasma membranes. The results are similar to those from exposure to gamma rays from a radioactive isotope.

Effects of DNA damage include an increased risk of cancer and a loss of fertility, both of which have been found in epidemiological studies. The effects of cell phone and WiFi radiation have also been determined experimentally using ejaculated semen. The results showed the production of ROS, and a loss of sperm quality and, in some cases, DNA fragmentation.

The inward leakage of calcium ions from electromagnetic fields also opens the various tight junction barriers in our bodies that normally protect us from allergens and toxins in the environment and prevent toxic materials in the bloodstream from entering sensitive parts of the body such as the brain. The opening of the blood-brain barrier has been shown to cause the death of neurons and can be expected to result in early dementia and Alzheimer's disease. The opening of the barrier in our respiratory epithelia by electromagnetic fields has been shown to increase the risk of asthma in children and the opening of the blood-liver barrier may be partially responsible for the current outbreak of liver disease. The opening of other barriers, such as the gut barrier allows foreign materials from the gut to enter the bloodstream, which may also promote allergies and has been linked autoimmune diseases.

Cell membranes also act as electrical insulators for the natural DC electric currents that they use to transmit power. Mitochondrial membranes use the flow of hydrogen ions to couple the oxidation of food to the production of ATP. The outer cell membrane uses the flow of sodium ions to couple the ATP produced to the uptake of nutrients. If either of these leak, or are permanently damaged, both of these processes will be compromised leading to a loss of available energy, which some people believe to be a contributory factor to chronic fatigue syndrome.

The mechanism underlying electromagnetically-induced membrane leakage is that weak ELF currents flowing through tissues preferentially remove structurally important calcium ions, but they have been shown to do so only within certain amplitude windows, above and below which there is little or no effect. This means that there is no simple dose-response curve, which many people find confusing, but a plausible theoretical model is described. The mechanism also explains why certain frequencies especially 16Hz is particularly effective.

Living cells have evolved defence mechanisms against non-ionising radiation. These include pumping out surplus calcium that has leaked into the cytosol, the closure of gap junctions to isolate the damaged cell, the production of ornithine decarboxylase to stabilize DNA and the production of heat-shock proteins, which act as chaperones to protect important enzymes. However, this is expensive in energy and resources and leads to a loss of cellular efficiency. If

*the exposure to the radiation is prolonged or frequently repeated, any stimulation of growth caused by the initial ingress of calcium runs out of resources and growth and repair becomes inhibited. If the repairs fail, the cell may die or become permanently damaged.*

*To some degree, we can make our own electromagnetic environment safer by avoiding ELF electrical and magnetic fields and radio waves that have been pulsed or amplitude modulated at ELF frequencies. The ELF frequencies that give damaging biological effects, as measured by calcium release from brain slices and ornithine decarboxylase production in tissue cultures, lie between 6Hz and 600Hz. It is unfortunate that virtually all digital mobile telecommunications systems use pulses within this range. The Industry clearly did not do its homework before letting these technologies loose on the general public and this omission may already have cost many lives.*

*Even now, it may be possible reverse their effects by burying the pulses in random magnetic noise, as proposed by Litovitz in the 1990s or by cancelling out the pulses using balanced signal technology but, at present, the Industry does not seem to be interested in either of these.*

*Until the mobile telecommunications industry makes its products more biologically friendly, we have little alternative but to reduce our personal exposure as far as possible by using cell phones only in emergencies, avoiding DECT cordless phones and substituting WiFi with Ethernet . The only DECT phones that are even remotely acceptable are those that automatically switch off the base station between calls; e.g. the Siemens Gigaset C595 operating in Eco Plus mode. If you are highly electromagnetically intolerant, you may need to screen your home or at the very least your bed from incoming microwave radiation and sleep as far away as possible from known sources of ELF.*

## **INTRODUCTION**

There have been many instances of harmful effects of electromagnetic fields from cell phones (aka mobile phones), DECT phones (aka cordless phones), WiFi, power lines and domestic wiring. They include an increased risk of cancer, loss of fertility, effects on the brain and symptoms of electromagnetic intolerance. Many people still believe that, because the energy of the fields is too low to give significant heating, they cannot have any biological effect. However, the evidence that alternating electromagnetic fields *can* have non-thermal biological effects is now overwhelming. See [www.bioinitiative.org](http://www.bioinitiative.org) and [www.neilcherry.com](http://www.neilcherry.com) . The explanation is that it is not a heating effect, but mainly an electrical effect on the fine structure of the electrically-charged cell membranes upon which all living cells depend.

Alternating electromagnetic fields can induce *alternating currents* to flow through living cells and tissues. These can interfere with the normal *direct currents* and voltages that are essential for the metabolism of all cells. Virtually every living cell is a seething mass of electric currents and electrical and biochemical amplifiers that are essential for their normal function. Some have tremendous amplifying capacity; e.g. it is claimed that a dark adapted human eye can detect a single photon (the smallest possible unit of light) and the human ear can hear sounds with energies as low as a billionth of a watt. We should therefore not be too surprised to find that our cells can detect and respond to electromagnetic fields that are orders of magnitude below the strength needed to generate significant heat.

My main objective here is to show how most of the adverse health effects of electromagnetic fields can be attributed to a single cause; that being that they remove structurally-important calcium ions (electrically-charged calcium atoms) from cell membranes, which then makes these membranes leak. I will explain the scientific evidence leading to this

conclusion and also how we can put matters right, but still keep on using cell phones and other wireless communications. I have included key references that should enable the more inquisitive reader to delve deeper. In many cases, you should be able to find the abstract of the paper in question by copying into Google its entry in the list of references.

### **Electromagnetic fields affect many but not all people**

Many of the experiments on the biological effects of alternating electromagnetic fields appear to give inconsistent results. There are many reasons for this, including differences in the genetic make-up, physiological condition and the history of the test material. In humans, reported effects include an increased risk of cancer, effects on brain function, loss of fertility, metabolic changes, fatigue, disruption of the immune system, and various symptoms of electromagnetic intolerance.

Not everyone is affected in the same way and some may not be affected at all. However, there is increasing evidence that the situation is getting worse. Our electromagnetic exposure is rapidly increasing and previously healthy people are now becoming sensitised to it. In this study, I am concentrating on the cases where there have been definite effects; since this is the most efficient way in which we can find out what is going wrong and what can be done to prevent it.

### **The frequency of the fields is important**

The fields that give the most trouble are in the extremely low frequency range (ELF) and also radio frequencies that are pulsed or amplitude modulated by ELF. (Amplitude modulation is where the strength of a *carrier wave* transmits information by rising and falling in time with a lower frequency that carries the information.).

### **Why microwaves are particularly damaging**

The frequency of the carrier wave is also important. Higher frequencies such as the microwaves used in cell phones, WiFi and DECT phones, are the most damaging. Our present exposure to man-made microwaves is about a million billion billion (one followed by eighteen zeros) times greater than our natural exposure to these frequencies. We did not evolve in this environment and we should not be too surprised to find that at least some people may not be genetically adapted to it. As with most populations faced with an environmental change, those members that are not adapted either become ill, die prematurely or fail to reproduce adequately. Ironically, those who are electromagnetically intolerant may be better equipped to survive since they are driven to do whatever they can to avoid the radiation.

The main reason why microwaves are especially damaging is probably because of the ease with which the currents that they generate penetrate cell membranes. Cell membranes have a very high resistance to direct currents but, because they are so thin (about 10nm), they behave like capacitors so that alternating currents pass through them easily. Since the effective resistance of a capacitor to alternating current (its *reactance*) is inversely proportional to its frequency, microwave currents pass through the membranes of cells and tissues more easily than radio waves of lower frequencies and can therefore do more damage to the cell contents.

### **Calcium loss from cell membranes explains most of the adverse health effects**

I became interested in this topic when I was working on the biological effects of physically (magnetically) conditioned water, which is widely used to remove lime scale from boilers and plumbing. It is made by allowing tap water to flow rapidly between the poles of a powerful magnet or by exposing it to a weak pulsed electromagnetic field from an electronic water conditioner. Water treated in this way can remove calcium ions (electrically charged calcium atoms) from surfaces, and the effect on the water can last for several days. I was following up some Russian and Israeli work that had shown that magnetically conditioned water could increase the growth of crops, but it turned out to be far more important than that. The underlying principle was also to explain the mechanisms by which weak electromagnetic fields can damage living cells and also what can be done to stop it.

### **Magnetically conditioned water and electromagnetic fields have similar effects**

Probably, our most important discovery was that when tap water was conditioned by weak electromagnetic fields, the treated water gave similar effects in yeast to those from exposing the yeast itself, amongst which was an increased permeability of their cell membranes to poisons (Goldsworthy *et al.* 1999). Since it had been known since the work of Bawin *et al.* (1975) that weak electromagnetic fields could remove calcium ions from the surfaces of brain cells, it seemed likely that both the conditioned water and the electromagnetic fields were working in the same way; i.e. **by removing structurally-important calcium ions from cell membranes, which then made them leak.** We now know that membrane leakage of this kind can explain most of the biological effects of both conditioned water and of direct exposure to electromagnetic fields.

### **The effects on growth depend on the length of the conditioning treatment**

We also showed that the effects of conditioned water on the growth of yeast cultures depended on the length of the conditioning process. Less than 30 seconds of conditioning stimulated growth but more than this inhibited growth. It was as if the conditioning process was steadily generating one or more chemical agents in the water. A low dose from the shorter conditioning period stimulated growth, but longer conditioning periods gave higher doses, which were inhibitory. This toxic effect of heavily conditioned water, where the water is recycled continuously through the conditioner, has now been exploited commercially to poison blanket weed in ornamental ponds ([www.lifescience.co.uk/domestic\\_blanketweed.htm](http://www.lifescience.co.uk/domestic_blanketweed.htm)). By the same token, blood continually circulating for prolonged periods under the pulsating fields from a cell phone or similar device could become toxic to the rest of the body. This means that no part of the body, from the brain to the liver and gonads, can be considered to be safe from the toxic effects of pulsed electromagnetic fields.

### **Radiation hormesis**

Many people have shown similar dual effects with direct exposure to both *ionising and non-ionising radiation*. Small doses of otherwise harmful radiation often stimulate growth and appear to be beneficial (a phenomenon known as *radiation hormesis*) but larger doses are harmful. It also explains why small doses of pulsed magnetic fields are effective in treating some medical conditions such as broken bones (Bassett *et al.* 1974) but prolonged exposure (as we will see later) is harmful.

It also explains some of the apparent inconsistencies found when comparing different experiments and why meta-analysis of the data should be treated with caution. Clear positive and clear negative results (depending on the dose and the condition of the material) when taken together could be mistaken for no effect, but with a high degree of variability.

### **Cells have tremendous powers to amplify and respond to weak signals**

We now know that electromagnetic growth stimulation is almost certainly due to electrochemical amplification followed by the activation of the MAP kinase cascades by free calcium ions leaking into the cytosol (the main part of the cell). The inward leakage of calcium ions is the normal mechanism by which a cell senses that it has been damaged and triggers the necessary repair mechanisms. This involves huge amplification processes so that even minor leakage (e.g. due to membrane perforation or weak electromagnetic fields) can give rapid and often massive responses.

The first stage in the amplification is due to the calcium gradient itself. There is an enormous (over a thousand fold) concentration difference for free calcium between the inside and outside of living cells. In addition, there is a voltage difference of many tens of mV acting in the same direction. This means that even a slight change in the leakiness of the cell membrane can permit a very large inflow of calcium ions. It's like a transistor, where a slight change in the charge in the base can allow a massive current to flow through it under the influence of a high voltage gradient between the emitter and collector.

The next stage in the amplification is due to the extremely low calcium concentration in the cytosol so that even a small ingress of calcium ions makes a big *percentage* difference, to which many enzymes within the cell are sensitive.

Even more amplification comes from the MAP-kinase cascades. These are biochemical amplifiers that enable tiny amounts of growth factors or hormones (perhaps even a single molecule) to give very large effects. They consist of chains of enzymes acting in sequence so that the first enzyme activates many molecules of the second enzyme, which in turn activates still more of the third enzyme etc. The final stage then activates the protein synthesising machinery needed for cell growth and repair.

At least some of these cascades need calcium ions to work (Cho *et al.* 1992) so the inward leakage of calcium through damaged cell membranes will increase the rate of these processes to stimulate growth and repair. However, these repairs can make deep inroads into the cell's energy and resources, and its ability to make good the damage will depend on its physiological and nutritional condition. This means that, if the damage is prolonged or persistent, sooner or later it runs out of resources and gives up, which is when we see the inhibitory phase, perhaps followed by apoptosis (cell death) or the loss of some of the cell's normal functions. We are now seeing this loss of function increasingly after prolonged human exposure to cell phone base station radiation; e.g. the loss of thyroid gland function after six years of exposure (Eskander *et al.* 2012).

### **Effects on Glands**

#### **Gland cells are particularly sensitive to radiation**

Gland cells may be particularly sensitive to radiation because their secretions are normally produced in internal membrane systems, which can also be damaged. Their secretions are usually released in vesicles (bubbles of membrane) that fuse with the external cell

membrane and discharge their contents to the outside (exocytosis). The vesicle membrane then becomes part of the external membrane. The resulting excess external membrane is counterbalanced by the reverse process (endocytosis) in which the external membrane buds off vesicles to the inside of the cell, which then fuse with the internal membranes. In this way, an active gland cell may internalise the equivalent of its entire surface membrane about once every half an hour. This means that if the surface membrane is damaged directly by the fields, or by electromagnetically conditioned blood, the damaged membrane rapidly becomes part of the internal membrane system, upon which its normal activity depends. If the damage is too severe, the whole gland may lose its normal function.

### **Electromagnetic effects on the endocrine system and obesity**

Although electromagnetic fields frequently stimulate glandular activity in the short term, long term exposure is often harmful in that the gland ceases to work properly. This is particularly serious for the glands of the endocrine system (those that coordinate our bodily functions) since it can affect many aspects of metabolism and throw the whole body out of kilter. For example it may be responsible, at least in part, for the current outbreak of obesity and the many other illnesses that stem from it.

A good example of this is the thyroid gland, which is in an exposed position in the front of the neck. Rajkovic *et al.* (2003) showed that after three months exposure to power line frequencies, the thyroid glands of rats showed visible signs of deterioration. They also lost their ability to produce the thyroid hormones, which they did not recover even after the fields were switched off. Esmekaya *et al.* (2010) found a similar visible deterioration of the thyroid gland in rats exposed to simulated 2G cell phone radiation for 20 minutes a day for three weeks. Eskander *et al.* (2012) found that people living for six years within 100 metres of a cell phone base station showed a significant reduction in the release into the blood of a number of hormones, including ACTH from the pituitary gland, cortisol from the adrenal glands, and prolactin and testosterone from organs elsewhere. However, the most highly significant loss was in their ability to produce the thyroid hormones. The expected consequence of this is hypothyroidism, the most frequent symptoms of which are **fatigue** and **obesity**. It may not be a coincidence that about a quarter of a million UK citizens are now suffering from what is being diagnosed as chronic fatigue syndrome, and about eight out of ten are either overweight or clinically obese.

The incidence of obesity may be exacerbated by effects on the release of the appetite regulating hormones ghrelin and peptide YY. Ghrelin is synthesised in the stomach wall and makes us feel hungry, whereas peptide YY is made in the intestine wall and makes us feel full. In normal people the level of ghrelin in the blood is high before a meal and goes down afterwards whereas peptide YY goes up, so we go from feeling hungry to feeling full, which stops us overeating.

However, in obese people the level of both hormones stays roughly the same throughout so that they never feel completely full and eat in an unregulated manner (Le Roux *et al.* 2005, Le Roux *et al.* 2006). If prolonged exposure to electromagnetic fields limits the release of these hormones in the same way as they affect the release of ACTH, cortisol, prolactin, testosterone and the thyroid hormones, it may explain why so many people find it difficult to stop eating and end up being clinically obese.

If you are affected in this way, you may be forced to go on a life-long diet, undergo gastric bypass surgery to drastically reduce the size of your stomach or risk the many serious

diseases that stem from obesity **AND IT MAY NOT HAVE BEEN YOUR FAULT**. Think twice before you use a cell phone or install a cordless phone or WiFi. The consequences are only now becoming apparent; neither the Government nor the telecommunications industry will tell you what they are, but they are not good.

### **Obesity can trigger many other illnesses**

The consequences of obesity include **diabetes, gangrene, high blood pressure, cardiac problems, renal failure and cancer**. Between them, they cause a great deal of human suffering and cost the nation's economy a great deal of money. The annual cost of obesity and related illnesses to the UK economy has been estimated as being around £6.6 – 7.4 billion (McCormick *et al.* 2007).

The annual cost of chronic fatigue syndrome is about \$20000 per affected person in the USA (Reynolds *et al.* <http://www.resource-allocation.com/content/2/1/4> ) and about £14000 in the UK (McCrone *et al.* 2003) so a fair estimate of the total annual cost of chronic fatigue syndrome to the UK economy would be somewhere in the region £3.5 billion. The total annual cost of both conditions together is about £10 billion. If part of this is due to microwave telecommunications, measures need to be taken to minimise their effects, and it would be only fair to ask the Industry to pay for this.

### **Electromagnetic effects on the adrenal gland**

**Cortisol:** - Augner *et al.* (2010) in a double blind study (where neither the subject nor the person recording the results knows whether the radiation is switched on or off) showed that short-term exposure to the radiation from a 2G (GSM) cell phone base station increased the cortisol level in the saliva of human volunteers. Cortisol is a stress hormone that is normally produced in the cortex of the adrenal glands and is controlled by the calcium level in its cells (Davies *et al.* 1985) so electromagnetically- induced membrane leakage letting more calcium into the cytosol should also have this effect.

Cortisol is part of a mechanism that puts the body into a “fight or flight” mode, in which more sugar is released into the blood, sensitivity to pain is reduced and the immune system is suppressed. In fact, cortisol and its relatives are used medicinally to relieve pain and also to suppress the immune system after transplant surgery. However, when exposure to base station radiation does it, it is not good news since the suppression of the immune system will also increase the risk of infection and of developing tumours from precancerous cells that might otherwise have been destroyed.

**Adrenalin:** - Buchner and Eger (2011) studied the effect of a newly installed 2G cell phone base station on villagers in Bavaria and found that it caused a long-lived increase in the production of adrenalin. This is an important neurotransmitter which acts on adrenergic receptors to increase the calcium concentration in the cytosol. It is also synthesised in the adrenal medulla in response to signals from the sympathetic nervous system. Adrenalin too puts the body into fight or flight mode by diverting resources from the smooth muscles of the gut to the heart muscle and the skeletal muscles needed for flight or combat. In addition, it stimulates the production of cortisol by the adrenal cortex, and indirectly reduces the activity of the immune system, resistance to disease and increases the risk of getting cancer.

Some people get pleasure from the “adrenalin rush” caused by doing energetic or dangerous things, and this could be a contributory factor to the addictive nature of cell phones. However, on the down side, known effects of excess adrenalin include, headaches, cardiac arrhythmia, high blood pressure, tremors, anxiety and inability to sleep. These results confirm

and explain some of the findings of Abdel-Rassoul *et al.* (2007) who found that people living near cell towers (masts) had significantly increases in headaches, memory loss, dizziness, tremors and poor sleep.

## **Effects on the Brain**

### **Calcium leakage and brain function**

Normal brain function depends on the orderly transmission of signals through a mass of about 100 billion *neurons*. Neurons are typically highly branched nerve cells. They usually have one long branch (*the axon*), which carries electrical signals as *action potentials* (nerve impulses) to or from other parts of the body or between relatively distant parts of the brain (a nerve contains many axons bundled together). The shorter branches communicate with other neurons where their ends are adjacent at *synapses*. They transmit information across the synapses using a range of *neurotransmitters*, which are chemicals secreted by one neuron and detected by the other.

Calcium ions play an essential role in brain function because a small amount of calcium must enter the cytosol of the neuron before it can release its neurotransmitters (Alberts *et al.* 2002). Electromagnetically-induced membrane leakage would increase the background level of calcium in the neurons so that they release their neurotransmitters sooner. This improves our reaction time to simple stimuli but it can also trigger the spontaneous release of neurotransmitters to send spurious signals that have no right to be there, which makes the brain hyperactive and less able to concentrate.

## **Autism**

Possibly, the greatest damage to the brain from microwaves is when it is first developing in the foetus and the very young child, where it can lead to autism. Dr Dietrich Klinghardt has shown a relationship between microwaves and autism; a summary of his work can be found at <http://electromagnetichealth.org/media-stories/#Autism> .

## **What is autism?**

Autism is a group of life-long disorders (autistic spectrum disorders or ASD) caused by brain malfunctions and is associated with subtle changes in brain anatomy (see Amaral *et al.* 2008 for a review). The core symptoms are an inability to communicate adequately with others and include abnormal social behaviour, poor verbal and non-verbal communication, unusual and restricted interests, and persistent repetitive behaviour. There are also non-core symptoms, such as an increased risk of epileptic seizures, anxiety and mood disorders. ASD has a strong genetic component, occurs predominantly in males and tends to run in families.

## **Genetic ASD may be caused by calcium entering neurons**

It has been hypothesised that some genetic forms of ASD can be accounted for by known mutations in the genes for ion channels that result in an increased background concentration of calcium in neurons. This would be expected to lead to neuronal hyperactivity and the formation of sometimes unnecessary and inappropriate synapses, which in turn can lead to ASD (Krey and Dolmetsch 2007).

## **Electromagnetic fields also let calcium into neurons**

There has been a 60-fold increase in ASD in recent years, which cannot be accounted for by improvements in diagnostic methods and can only be explained by changes in the environment. This increase corresponds in time to the proliferation of mobile telecommunications, WiFi, and microwave ovens as well as extremely low frequency fields from household wiring and domestic appliances. We can now explain at least some of this in terms of electromagnetically-induced membrane leakage leading to brain hyperactivity and abnormal brain development.

## **How membrane leakage affects neurons**

Neurons transmit information between one another in as chemical neurotransmitters that pass across the synapses where they make contact. Their release is normally triggered by a brief pulse of calcium entering their cytosols. If the membrane is leaky due to electromagnetic exposure, it will already have a high internal calcium concentration as calcium leaks in from the much higher concentration outside. This puts the cells into hair-trigger mode so that they are more likely to release neurotransmitters and the brain as a whole may become hyperactive (Beason and Semm 2002; Krey and Dolmetsch 2007, Volkow *et al.* 2011). This results in the brain becoming overloaded with sometimes spurious signals leading to a loss of concentration and attention deficit hyperactive disorder (ADHD).

## **How does this impact on autism?**

Before and just after its birth, a child's brain is a blank canvas, and it goes through an intense period of learning to become aware of the significance of its new sensory inputs, e.g. to recognise its mother's face, her expressions and eventually other people and their relationship to him/her (Hawley and Gunner 2000). During this process, the neurons in the brain make countless new connections, the patterns of which store what the child has learnt. However, after a matter of months, connections that are rarely used are pruned automatically (Huttenlocher and Dabholkar 1997) so that those that remain are hard-wired into the child's psyche. The production of too many spurious signals due to electromagnetic exposure during this period will generate frequent random connections, which will also not be pruned, even though they may not make sense. It may be significant that autistic children tend to have slightly larger heads, possibly to accommodate unpruned neurons (Hill and Frith 2003).

Because the pruning process in electromagnetically-exposed children may be more random, it could leave the child with a defective hard-wired mind-set for social interactions, which may then contribute to the various autistic spectrum disorders. These children are not necessarily unintelligent; they may even have more brain cells than the rest of us and some may actually be savants. They may just be held back from having a normal life by a deficiency in the dedicated hard-wired neural networks needed for efficient communication.

## **Autism costs the UK economy more than the tax income from cell phones**

The incidence of autism has occurred in parallel with the increase in electromagnetic pollution over the last thirty years. The chance of having an autistic child may now be as high as one in fifty. Apart from the personal tragedies for the affected children and their families, autism is of enormous economic importance. In the UK alone, the **annual cost to the Nation in care and lost production exceeds the annual tax revenue from the entire cell phone industry**, which is

about 20 billion UK pounds.

<http://www2.lse.ac.uk/newsAndMedia/news/archives/2009/05/MartinKnappAutism.aspx> If it were all due to cell phones, the Government could close down the entire industry and actually show a profit! There may be ways in which the modulation of the signal can be changed to avoid this (see later), but in the meantime, we should do whatever we can to minimise our exposure to information-carrying microwaves, including those from cell phones, DECT phones, WiFi and smart meters. Failure to do this could be very costly.

### **Electromagnetic intolerance (aka electromagnetic hypersensitivity or EHS)**

Electromagnetic intolerance is a condition in which some people experience a wide range of unpleasant symptoms when exposed to weak non-ionising radiation. About 3 percent of the population suffers in this way at present, although only a small proportion of these are as yet so badly affected that they can instantly tell whether a radiating device is switched on or off. At the other end of the scale, there are people who are sensitive but do not yet know it because they are chronically exposed to electromagnetic fields and accept their symptoms as being perfectly normal. Electromagnetic intolerance is in fact a continuum with no clear cut-off point. In some cases there may only be relatively mild symptoms on or after using a cell phone but in severe cases it can prevent people living a normal life and force them to live in almost total isolation. There is every reason to believe that prolonged exposure will increase the severity of the symptoms, so if you suffer from any of them you should do whatever possible to minimise further exposure.

### **Symptoms of electromagnetic intolerance**

Symptoms include skin rashes, cardiac arrhythmia, headaches (sometimes severe), pain in muscles and joints, sensations of heat or cold, pins and needles, tinnitus, dizziness and nausea. A more complete list can be found at <http://www.es-uk.info/info/recognising.asp> Most if not all of these can be explained by the radiation making cells leak.

**When skin cells leak**, it is perceived by the body as damage to the tissue. This increases the blood supply to the area to repair the damage and causes the rash.

**When the cells of the heart muscle leak** it weakens the electrical signals that normally control its contraction. The heart then runs out of control to give cardiac arrhythmia. This is potentially life threatening.

**When sensory cells leak**, they become hyperactive and send false signals to the brain. We have a variety of sensory cells, but they all work in much the same way. Whenever they sense what they are supposed to sense, they deliberately leak by opening ion channels in their membranes. This reduces the natural voltage across these membranes, which makes them send nerve impulses to the brain. Electromagnetically induced cell leakage would have the same effect, but this time it would make them send *false* signals to the brain to give the false sensations of electromagnetic intolerance. This could also be exacerbated by the nerve cells involved being made hyperactive due to calcium ingress.

**When leakage occurs in the sensory cells of the skin**, it can give sensations such as heat, cold, tingling, pressure etc, depending on which types of cell are most sensitive in the individual concerned.

**When leakage occurs in the sensory hair cells of the cochlea of ear** it gives tinnitus, which is a false sensation of sound. When it occurs in the vestibular system (the part of the

inner ear that deals with balance and motion) it results in dizziness and symptoms of motion sickness, including nausea.

### **Hypocalcaemia, electromagnetic intolerance and the parathyroid gland**

Symptoms of hypocalcaemia are very similar to those of electromagnetic intolerance and include skin disorders, pins and needles, numbness, sensations of burning, fatigue, muscle cramps, cardiac arrhythmia, gastro-intestinal problems and many others. A more comprehensive list can be found at <http://www.endotext.org/parathyroid/parathyroid7/parathyroid7.htm> . It is possible that some forms of electromagnetic intolerance are due to low levels of calcium in the blood. Electromagnetic exposure would then remove even more calcium from their cell membranes to push them over the edge and give the symptoms of electromagnetic intolerance.

The amount of calcium in the blood is controlled by the parathyroid hormone secreted by the parathyroid gland, which is in the neck, close to where you hold your cell phone. It is adjacent to the thyroid gland and, if it were to be damaged by the radiation in the same way, the production of the parathyroid hormone would go down, the amount of calcium in the blood would be reduced and the person concerned would become electromagnetically intolerant.

### **Effects on DNA**

#### **Cell phone radiation can damage DNA**

Lai and Singh (1995) were the first to show this in cultured rat brain cells, but it has since been confirmed by many other workers. A comprehensive study on this was in the Reflex Project, sponsored by the European Commission and replicated in laboratories in several European countries. They found that radiation like that from GSM (2G) cell phone handsets caused both single and double stranded breaks in the DNA of cultured human and animal cells. Not all cell types were equally affected and some, such as lymphocytes, seemed not to be affected at all (Reflex Report 2004).

In susceptible cells, the degree of damage depended on the duration of the exposure. With human fibroblasts, it reached a maximum at around 16 hours (Diem *et al.* 2005). However, It would be unwise to assume that exposures of less than 16 hours are necessarily safe since DNA damage may give genetically aberrant cells long before it becomes obvious under the microscope. It would also be unwise to assume that the damage would be restricted to the immediate vicinity of the handset since, as described earlier; the effects of the radiation can be transmitted in the bloodstream in the form of magnetically conditioned blood; so nowhere is safe, not even the sex organs.

#### **How the DNA is damaged**

Because of the very high stability of DNA molecules, they are unlikely to be damaged directly by weak radiation. The most plausible mechanism is that DNase (an enzyme that destroys DNA) and other digestive enzymes leak through the membranes of lysosomes (organelles that digest waste) that have been damaged by the radiation. Other mechanisms involve the leakage of reactive oxygen species (ROS) such as hydrogen peroxide from damaged peroxisomes and superoxide free radicals from damaged mitochondrial membranes and NADH oxidase in the plasma membrane. According to Friedman *et al.* (2007), the first to

respond to non-thermal cell phone frequencies is the NADH oxidase in the plasma membrane, which is activated within minutes of exposure.

However, all of these ROS can initiate peroxidation chain reactions in the polyunsaturated phospholipids of cell membranes (the same thing that makes fats go rancid) which disrupts the membranes further and exacerbates the effect. Only one molecule of ROS is needed to initiate a domino-effect chain reaction, in which each damaged lipid molecule generates a free radical that damages the next one. The process normally stops when it reaches an anti-oxidant molecule, which sacrifices itself by combining with the free radical in such a way that it does not generate a new one. Most of our anti-oxidants come from our diet (e.g. vitamin E) but the most important one that we make ourselves is *melatonin*. It's unfortunate that the production of melatonin by the pineal gland is also disrupted by electromagnetic fields (Henshaw and Reiter, 2005) which makes matters worse.

These ROS are highly reactive and can also damage DNA. In fact, much of the damage done to cells by *ionising radiation* such as *gamma rays* is due to damage to cell membranes and DNA by free radicals from the radiolysis of water. There may therefore be little difference between holding a cell phone to your head and holding a radioactive source of gamma rays. Both can damage cell membranes, cause the fragmentation of DNA and also do considerable collateral damage to other cellular components, which may either kill the cells or make them lose their normal function over time.

### **ell phones increase the risk of cancer**

If similar DNA fragmentation were to occur in the whole organism, we would expect an increased risk of cancer, since essential genes that control cell division may be either damaged or lost. Recent studies on the incidence of brain cancer are already beginning to show this. Heavy cell phone use roughly doubles the risk of getting brain cancers in adults on the side of the head used for the cell phone. For younger people, the risk increases to five times more (Hardell and Carlberg 2009). Since brain cancers normally take decades to develop, it is too soon to assess the final impact of the radiation, but the World Health Organisation has already classified cell phones as a Group 2B Carcinogen (possibly carcinogenic) similar to benzene and DDT. Other head cancers are also on the increase, including cancers of the parotid salivary gland (next to where you hold your cell phone) and the thyroid gland, which is in the neck.

### **Cell phones reduce male fertility**

We might expect DNA damage in the cells of the germ-line (the line of cells starting in the embryo that eventually gives rise to eggs and sperm) to result in a loss of fertility. A number of epidemiological studies have shown significant reductions in sperm motility, viability and quantity in men using cell phones for more than a few hours a day (Fejes *et al.* 2005; Agarwal *et al.* 2006) and the subject was reviewed by Desai *et al.* (2009). A common finding is that these effects were associated with the production of reactive oxygen species (ROS) which can damage many cellular components, including cell membranes and DNA.

More recently, Agarwal *et al.* (2009) found in controlled experiments that ejaculated sperm from healthy donors showed reduced viability and motility and an increase in ROS after one hour's exposure to a cell phone in talk mode. More recently still, Avandano *et al.* 2012 found that exposing ejaculated semen to a WiFi laptop for four hours gave a decrease in sperm motility and an increase in DNA fragmentation as compared with samples exposed to a similar computer with the WiFi switched off.

A similar relationship between sperm quality and electromagnetic exposure has also been found for low frequency alternating magnetic fields (Li *et al.* 2010). It is therefore advisable for men to avoid strong magnetic fields, restrict their cell phone calls to a minimum and keep them switched off (or in airplane mode if it has this facility). Otherwise, the phones transmit regularly at full power to the base station, even when not in use. If they have to be switched on for any reason, men should at least keep them out of their trouser pockets.

### **Possible effects on female fertility**

We do not yet know the effects of cell phone use on human female fertility, but . Panagopoulos *et al.* (2007) showed that exposing adult *Drosophila melanogaster* (an insect widely used in genetic experiments) to a GSM phone signal for just six minutes a day for six days fragmented the DNA in the cells that give rise to their eggs and half of these eggs died. We humans should therefore exercise caution since, although our sperm are produced in their countless billions and take about three months to mature, all the eggs that a woman will ever have were in her ovaries before she was born and will be exposed to the radiation (and electromagnetically conditioned blood) throughout her life. There could therefore be considerable cumulative damage, both to the eggs and the follicle cells that nourish and protect them. Damage to either, beginning when the child is in the womb, can be expected to cause a loss of fertility. Pregnant mothers should avoid all present forms of microwave telecommunications, including cell phones and WiFi. Her child could be damaged by their radiation, but she will not know until she reaches puberty and wants a child herself.

### **Effects on tight junction barriers**

Tight junction barriers are layers of cells where the gaps between them are sealed by *tight-junctions* to prevent materials leaking around their sides. They protect all of our body surfaces from the entry of unwanted materials and often protect one part of the body from being unduly influenced by the others. For example, the blood-brain barrier prevents toxins entering the brain from the bloodstream. Normally, these barriers are closed but they are programmed to open if calcium ions enter their cells. This was demonstrated by Kan and Coleman (1988) who showed that the calcium ionophore A23187 (an antibiotic that kills bacteria and fungi by letting calcium ions leak into their cells) opened tight junction barriers in the liver. The electromagnetic opening of the blood-liver barrier could be a contributory factor to the current outbreak of liver disease in the UK among the under forties (the cell phone generation), which is at present being blamed on alcohol abuse. Since all tight junction barriers have basically the same design, unscheduled calcium entry resulting from electromagnetic exposure is likely to open all of them in much the same way. The opening of our tight junction barriers by electromagnetic fields can account for many modern illnesses, ranging from asthma to multiple allergies and Alzheimer's disease.

### **The blood-brain barrier and early dementia**

The blood-brain barrier normally prevents possibly toxic large molecules from the bloodstream entering the brain. The radiation from cell phones, even at one hundredth of the permitted SAR value, can open the blood brain barrier in rats so that protein molecules as large as albumin could enter their brains (Persson *et al.* 1997). Later experiments by Salford *et al.* (2003) showed that this was associated with the death of neurons. We would not expect an immediate effect because the brain has spare capacity, but prolonged or repeated exposure to cell phone or similar radiation would be expected to cause a progressive loss of functional neurons and result in early dementia and Alzheimer's disease in humans. The extreme sensitivity of the blood-brain barrier to the radiation could mean that even sitting close to someone using a cell phone could affect you too. It may not be too surprising to find that early onset Alzheimer's disease is now on the increase in modern society.

### **The respiratory barrier and asthma**

Di *et al.* (2011) showed that exposure to weak ELF electromagnetic fields during pregnancy increased the risk of asthma in the offspring (they did not test microwaves). This can be explained by the radiation removing structural calcium from the cells of the tight junction barrier lining the respiratory tract, which then opens. This is supported by the findings of Chu *et al.* (2001) who showed that either low levels of external calcium or the addition of EGTA, both of which would remove structural calcium ions from cell surfaces, caused massive increases in its electrical conductance (a measure of its permeability to ions) and also to its permeability to much larger virus particles. We would therefore expect many allergens to enter by the same route and predispose the child to asthma. There are about 5.4 million people with asthma in the UK and the estimated annual cost to the NHS alone is about £1 billion ([http://www.asthma.org.uk/news\\_media/news/new\\_data\\_reveals\\_hig.html](http://www.asthma.org.uk/news_media/news/new_data_reveals_hig.html) )

### **The skin barrier, allergies and multiple chemical sensitivities**

The skin tight junction barrier is in the *stratum granulosum*, which is the outermost layer of *living* skin cells just underneath the many layers of dead cells (Borgens *et al.* 1989). Furuse *et al.* (2002) showed that mutant mice deficient in Claudin-1 (a vital component of the sealing mechanism) died within a day of birth and their skin barriers were permeable to molecules as large as 600D, which is enough to admit many unwanted foreign materials, including potential allergens. In humans, this could be the basis of *multiple chemical sensitivities*, where people have become allergic to a wide range of chemicals, although they leave most of us unaffected. People suffering from multiple chemical sensitivities are often also electromagnetically intolerant and many of their symptoms are very similar.

Virtually all of our body surfaces are protected by cells with tight junctions, including the nasal mucosa (Hussar *et al.* 2002), the lungs (Weiss *et al.* 2003) and the lining of the gut (Arrieta *et al.* 2006). An electromagnetically-induced increase in the permeability of any of these would allow the more rapid entry into the body of a whole range of foreign materials, including allergens, toxins and carcinogens.

### **Loss of barrier tightness can trigger autoimmune diseases**

An electromagnetically-induced increase in the permeability of any of the tight- junction barriers has been linked to the occurrence of autoimmune diseases, in which lymphocytes the immune system attacks the body's own components as if they were foreign materials or pathogens.

The immune system is quite complicated but basically lymphocytes (a type of white blood cell) are trained and selected before they mature to recognise the body's own cells, which are normally present in the bloodstream, by virtue of chemical patterns on their surfaces (the major histocompatibility complexes).

B-lymphocytes make specific antibodies that combine with foreign cells and substances that do not have this pattern, which marks them for eventual ingestion and digestion by phagocytes (another type of white blood cell). T-lymphocytes kill the body's own cells if they are infected with a virus, which is normally displayed on the cell surface. In both cases, the presence of the foreign material or infected cells trigger the rapid multiplication of a clone of lymphocytes that recognise them. They can then attack it in force.

However, if the substance concerned belongs to the body itself but is normally prevented from entering the bloodstream by a tight-junction barrier such as the blood-brain barrier, when that barrier opens, it increases the likelihood of its leaking unfamiliar materials into the

bloodstream and triggering an autoimmune response. For example, Grigoriev *et al* (2010) showed that 30 days exposure to unmodulated 2450MHz microwave radiation triggered a small but significant increase in anti-brain antibodies in the blood of rats. In other words, the radiation had sensitised the body's immune system to one or more components of its own brain, which could then result in an autoimmune attack on the brain and/or nervous system. An example of an autoimmune disease of the brain is Graves disease in which the pituitary gland (at the base of the brain) is affected.

In addition, an increase in the permeability of the gut barrier has been linked to several other autoimmune diseases, including type-1 diabetes, Crohn's disease, celiac disease, multiple sclerosis and irritable bowel syndrome (Arrieta *et al.* 2006).

### **Cell membranes as current generators and electrical insulators**

***Cell membranes not only keep apart materials that must not be allowed to mix, they also act as electrical insulators for the natural electric currents upon which all of our cells depend.***

### **Natural electric currents are important in power and information transfer**

Almost every living cell is a seething mass of electric currents and amplifiers. For example, these currents are important in energy production in mitochondria (the cell's power stations) and in cell signalling (the transfer of information within and between cells). They are carried as flows of ions, which are the normal ways in which electricity is carried through water and through living cells.

### **These natural currents are generated by cell membranes.**

Natural electric currents are normally generated by molecular ion pumps in cell membranes. These are proteins that use metabolic energy to transport specific ions, usually one or two at a time, from one side of the membrane to the other. This generates a voltage across the membrane (*the membrane potential*) and a chemical imbalance between the concentrations of ions on either side. Their combined effect gives an *electrochemical gradient*, which provides energy for other functions.

### **Mitochondria use electrochemical gradients to transmit power**

Mitochondria are tiny structures, about the size of bacteria, inside almost all of our cells. They evolved when an aerobic bacterium, which used oxygen to metabolise its food, was engulfed by an anaerobic organism, which could not do this, but was more efficient in other respects. From then on they lived together symbiotically, but are still separate in that the mitochondria are surrounded by two membranes; the inner one belonging to the bacterium and the outer one to its host.

The inner membrane does the electrical work by a process known as chemiosmosis. The inside of the mitochondrion contains enzymes that convert materials from our food into forms that can combine with oxygen. This combination with oxygen occurs using enzymes actually within the membrane, and the released energy is used to expel hydrogen ions to create an electrochemical gradient between the inside and the outside of the mitochondrion. They are then allowed back through another enzyme in the membrane called ATP synthase that uses the gradient to make ATP, which is the main energy currency of the cell. The cycle then repeats to give an electrical circuit with hydrogen ions carrying the electricity from where it is made to where it is used, with the membrane being the insulator (Alberts *et al.* 2002).

### **What happens if the mitochondrial membrane is damaged?**

Damage to the inner mitochondrial membrane can have two main effects. If it just leaked it would short circuit the system, reduce ATP synthesis and deprive the cell of energy. If the

damage were also to include the oxidising enzymes, they could release free radicals, which are normal intermediates in the process. This would damage both the inside of the mitochondrion (including its DNA) and also the rest of the cell. Mitochondrial dysfunction of this sort is thought to be a possible cause of chronic fatigue syndrome.

### **Other membranes also use ion currents to transfer energy**

Most other cell membranes use ion currents as a source of energy. For example, enzymes in the outer membrane of each cell (*the plasma membrane*) use energy from ATP to pump positively charged sodium ions out of the cell. This generates its own membrane potential, which typically makes the inside of the cell about 70-100mV negative to the outside. This provides energy for the active transport of other materials across the membrane against a concentration gradient. In this case, the sodium ions that have been expelled are allowed back in, through transporter enzymes, but they carry with them nutrients from the outside by a process called ion co-transport (Alberts *et al.* 2002) If this membrane leaks, it will short circuit the voltage across it and reduce nutrient uptake as well as a number of other processes which use this voltage as a source of energy.

### **Ion channels in cell membranes are used for cell signalling**

Ion channels are pores in cell membranes that can let large quantities of specific ions through very quickly, but only down their own electrochemical gradient. They normally open and close in response to specific stimuli; e.g. changes in voltage across the membrane or the presence of other chemicals. They can be thought of as amplifiers by which a tiny stimulus can cause a very large current to flow almost instantly to give a rapid biological effect. An example of this is the coordinated opening and closing of sodium and potassium channels that continuously amplify nerve impulses and enable them to travel from one end of the body to the other, both rapidly and without loss.

### **The mechanisms of cell membrane leakage.**

We have known since the work of Suzanne Bawin and her co-workers (Bawin *et al.* 1975) that electromagnetic radiation that is far too weak to cause significant heating can nevertheless remove radioactively labelled calcium ions from cell membranes. Later, Carl Blackman showed that this occurs only with weak radiation, and then only within one or more '*amplitude windows*', above and below which there is little or no effect (Blackman *et al.* 1982; Blackman 1990).

### **The apple harvester: an explanation for amplitude windows**

A simple way to explain the selective removal of divalent ions is to imagine trying to harvest ripe apples by shaking the tree. If you don't shake it hard enough, no apples fall off, but if you shake it too hard, they all fall off. However, if you get it just right, only the ripe ones fall off and are 'selectively harvested'.

We can apply the same logic to the positive ions bound to cell membranes. Alternating voltages try to drive these ions off and then back onto the membranes with each cycle. If the voltage is too low, nothing happens. If it is too high, all the ions fly off, but return when the voltage reverses. However, if it is just the right, it will tend to remove only the more strongly charged ones, such as divalent calcium with its double charge. If the frequency is low, at least some of these divalent ions will diffuse away and be replaced at random by other ions when the field reverses. There will then be a net removal of divalent ions with each successive cycle until enough have been removed to cause significant membrane leakage and give a biological effect, but only within a narrow range of field strength to give an *amplitude window*. Pulses are more effective than smooth sine waves because their rapid rise and fall times catapult the ions quickly

away from the membrane and leave more time for them to be replaced by different ions before the field reverses.

### **Frequency windows and resonance effects**

If a molecule or structure has a natural resonant frequency, it may respond selectively to that frequency. For example, if you keep giving a pendulum a gentle push at just the right time at the end of its travel, the energy of each push builds up and is stored in the ever increasing violence of its motion. If you were suddenly to stop it by putting your hand in the way, the combined energy of each push is released in one go and could do more damage to your hand than the energy you gave it from each individual push.

In the same way, if an electrically charged atom or molecule has one or more natural resonant frequencies and you give it an electromagnetic pulse at that frequency, it may store the combined energy of each pulse as some sort of vibration. This could enable it to bring about a chemical reaction that would not have been possible from the energy of each pulse alone, *but only at its resonant frequency*. Some frequencies are especially effective in giving biological effects. An example is 16Hz, which is the ion cyclotron resonance frequency of potassium ions in the Earth's magnetic field.

Ion cyclotron resonance occurs when ions move in a steady magnetic field such as that of the Earth. They are deflected sideways by the magnetic field and go into orbit around its lines of force at a frequency that depends on the charge to mass ratio of the ion and the strength of the steady field (see Liboff *et al.* 1990). If they are simultaneously exposed to an alternating field at this frequency, they absorb its energy and increase the diameter of their orbits, which increases their energy of motion and chemical activity. Potassium resonance is particularly important because potassium is the most abundant positive ion in the cytosols of living cells, where it outnumbers calcium by about ten thousand to one. It is therefore the ion most likely to replace any calcium that has been lost by electromagnetic exposure. An increase in the chemical activity of potassium will therefore increase its ability to replace calcium and so increase calcium loss from the membrane and further reduce its stability.

### **Calcium loss and leaky membranes underlie many biological effects.**

We have seen how the loss of calcium from cell membranes is enhanced at the 16Hz potassium resonant frequency. Also, any metabolic consequences of this calcium loss may be similarly enhanced. Any bioelectromagnetic responses that peak or trough at 16Hz is evidence that they stem from divalent ion depletion in membranes. In fact, many biological responses appear to peak at 16Hz.. These include stimulations of the growth of yeast (Mehedintu and Berg 1997) and higher plants (Smith *et al.* 1993), changes in rate of locomotion in diatoms (McLeod *et al.* 1987), and the especially severe neurophysiological symptoms reported by electrosensitive people exposed to the radiation from TETRA handsets (which is pulsed at 17.6Hz). All of this supports the notion that a large number of the biological responses to weak electromagnetic radiation stem from the loss of calcium (and possibly other divalent ions) from cell membranes.

### **How calcium removal makes cell membranes leak**

Positive ions strengthen cell membranes because they help bind together the negatively charged phospholipid molecules that form a large part of their structure. Calcium ions are particularly good at this because their double positive charge enables them to bind more strongly to the surrounding negative phospholipids by mutual attraction and hold them together like mortar holds together the bricks in a wall. However, monovalent ions are less able to do this (Steck *et al.* 1970, Lew *et al.* 1998, Ha 2001). Therefore, when electromagnetic radiation replaces calcium with monovalent ions, it weakens the membrane and makes it more likely to tear and form temporary pores, especially under the stresses and strains imposed by the

moving cell contents. Normally, small pores in phospholipid membranes are self healing (Melikov *et al.* 2001) but, while they remain open, the membrane will have a greater tendency to leak. This can have serious metabolic consequences as unwanted substances diffuse into and out of cells unhindered, and materials in different parts of the cell that should be kept separate, become mixed.

### **Demodulation**

Both extremely low frequencies and radio waves that have been amplitude modulated at extremely low frequencies give biological effects, but unmodulated radio waves are relatively (but not completely) innocuous. This implies that living cells can demodulate a modulated signal to extract the biologically active ELF. Furthermore, if they are to respond to cell phone and WiFi signals, they must be able to do it at microwave frequencies, but how do they do it?

The most likely explanation lies in asymmetric electrical properties of ion channels in cell membranes imposed by the *membrane potential* between the inside and outside of the cell. They will behave like electrically biased point contact Schottky diodes in which electricity passes more easily in one direction than the other. This is all that is needed to rectify and demodulate the signal. A non-biological example of this effect is a radio set that was made from a single carbon nanotube (see <http://tinyurl.com/m4u75o> ). The asymmetry induced by applying a DC voltage between its ends allowed it to demodulate and even to amplify radio signals, including those at microwave frequencies.

The nanotube has a similar diameter to a typical ion channel in a cell membrane, so it seems likely that the ion channels in cell membranes could perform a similar function, powered by the cell's membrane potential. The low-frequency component would then appear across the membrane, where it could do most damage. In as much as our *tight junction barriers* have a similar trans-barrier potential (around 70mV for the skin barrier with the inside of body positive) the ion channels of the whole barrier could act in concert to demodulate the signal, the damaging low frequency components of which could then be applied to and affect the whole body.

### **Natural defence mechanisms**

The body is able to detect electromagnetic radiation and so minimise resulting damage. This ability probably evolved over countless millions of years to mitigate the effects of ionising radiation from cosmic rays and non-ionising radio frequencies from lightning during thunderstorms. Some of them are as follows: -

#### **Calcium expulsion**

The concentration of free calcium in the cytosols of living cells is normally kept extremely low by metabolically-driven ion pumps in the cell membrane. Under normal circumstances, the entry of free calcium ions is carefully regulated and small changes in their concentration play a vital role in controlling many aspects of metabolism. These processes can be disrupted if electromagnetically-induced membrane leakage lets extra and unscheduled amounts of calcium into the cell, either from the outside or from calcium stores inside. To compensate for this, the mechanism that normally pumps surplus calcium out can go into overdrive. However, its capacity to do this is limited because, if the pumping were too effective, it would hide the small changes in calcium concentration that normally control metabolism.

**Gap junction closure:** - If calcium extrusion fails and there is a large rise in internal calcium, it triggers the isolation of the cell concerned by the closure of its gap junctions (tiny

strands of cytoplasm that normally connect adjacent cells) (Alberts *et al.* 2002). This also limits the flow of electric currents through the tissue and so reduces the effects of radiation.

### **Ornithine decarboxylase (ODC)**

The activation of the enzyme *ornithine decarboxylase* is triggered by calcium leaking into cells through damaged membranes and by nitric oxide produced by damaged mitochondria. This enzyme leads to the production of chemicals called *polyamines* that help protect DNA and the other nucleic acids needed for protein synthesis. One such polyamine is spermine, which normally protects the DNA of sperm and is also responsible for the characteristic smell of semen.

### **Heat shock proteins**

These were first discovered after exposing cells to heat, but they are also produced in response to a wide variety of other stresses, including weak electromagnetic fields. They are normally produced within minutes of the onset of the stress and combine with the cell's enzymes to protect them from damage and shut down non-essential metabolism (the equivalent of running a computer in "safe mode").

When the production of heat shock proteins is triggered electromagnetically it needs 100 million million times less energy than when triggered by heat, so the effect is truly non-thermal (Blank & Goodman 2000). Their production in response to electromagnetic fields is activated by special base sequences (the nCTCTn motif) in the DNA of their genes. When exposed to electromagnetic fields, they initiate the gene's transcription to form RNA, which is the first stage in the synthesis of the protein (Lin *et al.* 2001). The job of these heat-shock proteins is to combine with vital enzymes, putting them into a sort of cocoon that protects them from damage. However, this stops them working properly and also drains the cell's energy and resources, so it isn't an ideal solution either.

### **Our defences protect us from thunderstorm radiation but not from cell towers, DECT phones and WiFi**

As we can see, our natural defence mechanisms try to limit the electromagnetically-induced damage, but they cannot be deployed without using extra energy and disrupting the cell's normal functions. They originally evolved to protect us from occasional weak natural radiation, such as that from thunderstorms. However, prolonged or repeated exposure such as that from cell towers, WiFi and most DECT base stations is harmful because they normally run continuously and disrupt metabolism for long periods and is expensive in bodily resources.

These resources have to come from somewhere. Some may be drawn from our physical energy, making us feel tired, some may come from our immune systems, making us less resistant to disease and cancer. There is no hidden reserve. As it is, our bodies are constantly juggling resources to put them to best use. For example, during the day, they are directed towards physical activity but during the night, they are diverted to the repair of accumulated damage and to the immune system. Day and night irradiation from cell phone towers (which run continuously) will affect both, with little or no chance to recover. In the long term, this is likely to cause chronic fatigue, serious immune dysfunction (leading to an increased risk of disease and cancer) and many of the neurological symptoms frequently reported by people living close to mobile phone base stations (see Abdel-Rassoul *et al.* 2007).

### **How can we make our electromagnetic environment safe?**

Firstly, there may be no need to give up our electrical appliances domestic appliances or cell phones. It is possible to make most of them much safer. All that is needed with domestic

wiring is low-tech electromagnetic hygiene. As for cell phones, the operators have known for over a decade how to modify the radiated signal to make it safe; they have just chosen not to do so. I will deal with these one at a time.

### **Domestic wiring**

It is easy to screen the electrical field from wiring by enclosing it in earthed metal conduits or using screened cable with an earthed screen. We cannot screen the magnetic field in this way but by careful design of the circuits, we can make the magnetic fields of the live and neutral wires cancel each other out. To do this, all you need is to make sure that the live and neutral wires to any device are as close together as possible (preferably twisted together) with each device having its own connection to the main distribution panel. The cheap UK practice of using ring mains (where many plug sockets are connected in a ring, beginning and ending in the distribution panel) should be made illegal. This is because differences in the resistance of the conductors mean that electricity flowing to any plug socket may not flow back the way it came so that their magnetic fields do not cancel and there will be an unnecessarily high field surrounding the whole ring.

Another source of problems is the use of unearthed double insulated appliances. Although there is very little risk of shock, they still emit strong magnetic fields and electric fields at about half the supply voltage, which some people find intolerable.

### **Cell phones**

While we can block or cancel the electromagnetic fields associated with domestic wiring, we cannot do this with cell phones or DECT phones, which depend on radio frequency radiation transmissions if they are to work. However, we can make this radiation much less biologically active. There are at least two ways to do this. The first was devised tested and patented by Theodore Litovitz working at the Catholic University of America in the 1990s. All you have to do is to add low frequency electromagnetic noise to the signal.

### **The theory behind Litovitz's method.**

His idea was to add a random ELF (noise) magnetic field to the regularly repeating fields from power lines or cell phones. It works on the principle that most of the biological effects of electromagnetic fields are due to the relatively slow but progressive loss of calcium from cell membranes, which then makes them leak. However, the effect on any cell takes place only within certain amplitude windows, as I described earlier. We may not be able to prevent this leakage just by reducing the power of the field. All this might do is to put other cells (perhaps nearer the source) into their amplitude windows and we may be no better off.

However, if we add a second magnetic field with a randomly varying amplitude, cells are constantly being driven in and out of their amplitude windows and do not spend long enough in their windows to lose significant amounts of calcium before leaving their windows. The lost calcium then floods back and there is no biological effect. This theory has been tested in several biological systems and found to work.

Much of Litovitz's work used the in production of the enzyme ornithine decarboxylase (ODC) by tissue cultures as an indicator of radiation damage to living cells. The activity of this enzyme increases several fold when exposed to electromagnetic fields (Byus et al. 1987). ODC is part of a defence mechanism against the radiation and an increase in its production is taken as an indication that damage is occurring. Conversely, if the random signal prevents its production, it is an indication that damage is not occurring.

Work in Litovitz's laboratory was mainly concerned with mitigating the effects of 60Hz power line frequencies and he found that adding a random (noise) magnetic field of about the same strength completely reversed their effects on ODC production in mouse tissue cultures (Litovitz *et al.* 1994b) and also the deformities induced by 60Hz fields in chick embryos (Litovitz *et al.* 1994a)

They then went on to study the effects of modulation frequency on 845MHz microwave radiation on ODC production in mouse tissue cultures. They found that constant frequencies between 6 and 600Hz were harmful as measured by ODC production. Simple amplitude modulated speech (which is more random) did not stimulate ODC production, neither did frequency modulated microwaves and frequency modulated analogue phone signals. Continuous microwaves had only a slight effect.

### **Most microwave pulse frequencies are harmful**

Penafiel *et al.* (1997) working in Litovitz's laboratory concluded that there were only serious health problems when the microwaves were modulated to give pulses of a standard height (amplitude) generated at frequencies between 6 and 600Hz. There was virtually no effect above 600Hz. This corresponds to Blackman *et al.* (1988) observation that calcium release from brain tissue did not occur above 510Hz.

It would appear that the mobile telecommunications industry had not done their homework before selecting the pulse frequencies for their digital communications, since they virtually all fall within this biologically active range; e.g. 2G GSM cell phones (217Hz), TETRA (17.6Hz), DECT phones (100Hz), WiFi (10Hz), and 3G UMTS signals with time division duplex (100Hz and 200Hz) all of which are potentially harmful. There could be other harmful effects of the radiation that do not trigger ODC production or calcium release but, at the very least, these pulse frequencies should not have been used if the cell phone industry had acted due diligence. .

However, Litovitz (1997) found that even these could be made safe by superimposing a low frequency magnetic field on the signal. They found that it prevents the production of ornithine decarboxylase (ODC) by mouse tissue cultures in response to digital cell phone signals. For example, a random field between 30 and 100Hz with an RMS strength of 5 microtesla completely inhibited the ODC production induced by a cell phone signal with an SAR of about 2.5 W/kg. A coil within the handset could easily deliver a random magnetic field of this magnitude and probably protect the user from the harmful effects of its radiation.

Also Lai (2004) showed that a 6 microtesla random noise field completely reversed the deleterious effect of 2450 MHz continuous waves with an SAR of 1.2 W/kg on rat memory. In none of the above experiments did the random noise have any effect in its own right and, on these criteria, is completely harmless.

### **Balanced signal technology**

While Litovitz's method might protect the user from the radiation, because magnetic fields dissipate rapidly as you move away from the source, they may not protect other people nearby, who are out of range of the protective random field. By the same token, random low frequency magnetic fields emitted by a cell phone base station would not be able to protect most users. For this you may need something like a system that I devised myself, to which I gave the name "Balanced Signal Technology". I am not claiming any patent rights and anyone who wants to test and use it can do so free of charge.

The principle is very simple and involves transmitting two complementary mirror image signals on different carrier frequencies; i.e. when one has a pulse, the other has a gap. The base

station would have no problem with this since they would look like two separate phone calls. However, living cells would be unlikely to distinguish between the two carrier frequencies and the pulses on each would cancel and it would look like a relatively harmless continuous wave. It would need very little extra bandwidth since only one of the signals need be used, with the other one being effectively thrown away and they could all be dumped on the same frequency. In theory, this technology could be applied to both handsets and base stations, but has not yet been tested.

The cell phone companies should know about both methods to make cell phones safer but there is no evidence that they are interested, possibly because to implement them would cost money with no extra benefit to themselves. It looks very much as if they would prefer many people to become sick and perhaps die, rather than admit that their safety rules are based on false premises and that their current technologies are not yet safe.

### **What can we do about it ourselves?**

Very few people would want to give up their cell phones, but if you have one, for your own personal safety, keep your calls on it short and infrequent so that your body has a chance to recover in between times. Use text (which takes seconds to transmit) rather than voice calls and avoid unnecessary Internet downloads. The choice is yours, but spare a thought for the people living near the base stations. Some may be badly affected by their continuous radiation but they have no choice. Your cell phone calls will contribute to their problems, so your restraint may help them too.

Also, don't forget your own personal sources of continuous radiation such as WiFi routers and DECT phone base stations, which can be even more harmful since they are closer. Avoid using WiFi altogether. Ethernet connections via cable are not only safer, but faster, more reliable and offer greater security. Various "Homeplug" devices that connect an the Ethernet socket of your computer to the router via the household electricity supply are second best alternatives. They are not perfect since there is still some radiation from the wiring; especially with those offering faster speeds.

DECT phones should also be avoided if at all possible. But, if you must have one, a reasonable compromise is to use only one that switches off its base station automatically between calls. At the time of writing, the only DECT phones that do this are the Eco Plus models manufactured by Siemens; e.g. the Siemens Gigaset C595. However, make sure they are programmed to work in the Eco Plus mode since this is not the default setting.

### **Screening and its limitations**

Many electromagnetically intolerant people will want to screen themselves from the fields but we need to understand a little about them to get the best results.

#### **The near-field**

An alternating electromagnetic field consist of an electrical, field and a magnetic field. The electrical field is produced by a voltage gradient and is measured in volts per metre. The magnetic field is generated by a flow of current and is measured in tesla. When you are close to the source (typically within one wavelength) you are in the *near-field*, where the electrical and magnetic fields are mainly separate.

At power line frequencies, the wavelengths run into thousands of miles, so you are bound to be in the near field for power lines. For example, standing under an alternating power line would

expose you to a voltage gradient due to the difference between the voltage of the line (set by the power company) and the Earth. You would also be exposed to a *magnetic* field proportional to the current actually flowing through the line, which depends on consumer demand. Both the magnetic and the electrical fields can induce electric currents in your body and are potentially harmful, but the magnetic field is worse because it penetrates living tissues more easily, goes through most walls and aluminium foil as if they were not there, and is very difficult to screen.

### **The far field**

However, as you move away from the source, the two fields feed on each other's energy and combine to give photons of radio waves. This is usually complete within a few wavelengths, after which you are in the so called *far-field* where all the power takes the form of radio waves. Your exposure to these is usually measured in units of power (e.g. microwatts per square metre) or its associated voltage gradient (e.g. volts per metre).

The importance of this as far as we are concerned is that radio waves, are like light waves and are relatively easy to absorb and reflect. This can be done, using earthed metal foil or other electrically conductive materials such as carbon-based paints and metallised textiles. For practical purposes, this means that you can screen yourself against the radiation from a cell tower, WiFi router, or DECT phone base station if they are several wavelengths away (several tens of centimetres) but not from a cell phone held against your head, where you are in the near field and the raw magnetic component will penetrate deep into your brain.

To give an idea of the hazard, magnetic fields lower than one microtesla (a millionth of a tesla) can produce biological effects, but using a 2G (GSM) cell phone or a PDA exposes you to low frequency magnetic pulses that peak at several tens of microtesla (Jokela *et al.* 2004; Sage *et al.* 2007). These come mainly from the battery circuits and are well over the minimum needed to give harmful effects. When they are added to the damaging effects of their microwave fields themselves, these devices are potentially the most dangerous sources of electromagnetic fields and radiation that the average person possesses.

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## Imperial Tobacco Ltd

Imperial Tobacco is a FTSE-30 Company headquartered in Bristol, UK. Imperial Tobacco has sales operations in all EU Member States and factories in several others, including Nottingham in the UK with a total of 14,925 employees across the EU. Imperial Tobacco's sales in the UK account for approximately 46 per cent of the market making us the market leader at UK level.

Imperial Tobacco Ltd welcomes the opportunity to respond to your Department's Review and we would like to address the following points.

With regards to Article 114 TFEU it is our view that the Article has been, and continues to be, wrongly used as the basis for what is in fact public health legislation. The current draft revisions to the Tobacco Products Directive<sup>1</sup> (the "TPD") are a case in point. Proposed amendments to health warnings, ingredients and allowing for the introduction of standardised packaging by Member States are -given the fact that tobacco products can only be manufactured for (and bought in bulk within) individual Member States- clearly primarily public health measures.

For example, the proposal to remove products, such as "slim" cigarettes and menthol cigarettes, from sale will disadvantage EU citizens without any robust evidence base that this will improve the internal market. The unintended consequence will mean consumers are forced to source the products they want from the illicit market where there are no controls on quality with a reduction in Government revenues. Driving legitimate business towards the illicit trade will distort competition and the internal market meaning it is not beneficial for any party and does not promote the objectives of the TPD.

Our concern over the functioning of the internal market is reinforced when comments from EU Commissioners and Members of the EU Parliament - as to the motivation for the Directive - are considered. As Commissioner Borg said in January this year:

"My aim with this proposal is to make tobacco products and smoking less attractive and thus discourage young people in particular from starting to smoke."<sup>2</sup>

The aim is clearly not to improve the functioning of the internal market. We believe it is imperative that the UK Government does not allow the European Commission to subvert Member State competence via legislation based on inappropriate Treaty bases.

We believe it is important for innovation to be encouraged and the benefits of it made available across all Member States. We are, however, concerned that this is being hampered by the current approach of the European Commission. In the USA the FDA now recognise "harm reduction" as a viable tobacco control strategy. This is in stark contrast to what some tobacco control advocates describe as the 'quit or die' approach taken by the Commission and numerous Member States. Harm reduction for the tobacco sector (e.g. e-cigarettes and other non-tobacco nicotine containing products) opens up new avenues which would, as the Department of Health states<sup>3</sup>,

"gain the maximum potential public health benefit" for consumers | citizens. We

believe it important that, should the approach of the Commission not change, the UK retains competence to pursue its own approach in this area.

We would also like to address the consistency of application of EU Regulations across the EU. The UK has repeatedly pursued the implementation of Directives and Recommendations more rigorously and more onerously compared with other Member States, to the detriment of UK-based entities. We recognise and welcome the Coalition Government's commitments to ensuring such 'gold-plating' of EU measures no longer happens. We would wish, however, for the UK to review EU measures already implemented to remove 'gold-plating' that has already occurred.

International initiatives such as the Framework Convention on Tobacco Control ("FCTC") are interpreted and implemented differently by different Governments in the European Union, even though the EU (or EURO region) acts as 'one voice' in such fora. The UK tends to lean towards a more extreme approach to interpreting and implementing non-binding guidelines agreed and adopted at such initiatives. For example, the World Health Organisation (WHO) Guidelines under the FCTC are not binding on Article 5.3 which details guidance on engagement of and with the tobacco industry. The Article has been misinterpreted within the UK by a number of Government representatives who have referenced the Article as a reason for refusing to engage with the industry. In our view this acts to the detriment of the development of informed, proportionate and evidence based policy-making, particularly as it is unique to the UK. We would highlight this as a point of concern to be investigated as to why the UK Government adopts such an extreme approach in comparison to other member-states and the Commission. As evidence, I have attached, for your information, a detailed response from the Secretary General of the Commission, Catherine Day, (on behalf of President Barroso, dated 7th February 2013, to a letter written by Koen Roovers, dated 17th January 2013, of ALTER-EU) which explains fully how the Article should be interpreted by all Parties.

To conclude, if the EU competence was restricted to developing and agreeing the technical standards for products in the health arena, this would mean Member States can properly regulate health issues on their own market without having to duplicate the setting of technical standards that all Member States will need to complete their legislation. We believe that the EU should be limited to genuinely improving the internal market, such as through standards, but should not be taking over our health policy and provisions.

1 TPD proposal: [http://ec.europa.eu/health/tobacco/docs/com\\_2012\\_788\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/com_2012_788_en.pdf)

2 [http://ec.europa.eu/commission\\_2010-2014/borg/docs/speech\\_22012013\\_fight\\_against\\_cancer.pdf](http://ec.europa.eu/commission_2010-2014/borg/docs/speech_22012013_fight_against_cancer.pdf)

3 Explanatory Memorandum on European Union Legislation 18068/12 21 January 2013

## Institute of Alcohol Studies

The Institute of Alcohol Studies (IAS) welcomes the opportunity to respond as part of the Department of Health Balance of Competence Review process and to provide comment on the areas outlined in the consultation document.

The core aim of the Institute is to serve the public interest on public policy issues linked to alcohol, by advocating for the use of scientific evidence in policy-making to reduce alcohol-related harm. The IAS is a company limited by guarantee, No 05661538 and registered charity, No 1112671. For more information visit [www.ias.org.uk](http://www.ias.org.uk).

### **How has the EU competence in public health, including alcohol harm, affected IAS?**

The Institute of Alcohol Studies has a long history of involvement in alcohol policy, research and advocacy at the European level. In 1990, IAS worked alongside the French organisation ANPAA to establish [Eurocare, the European Alcohol Policy Alliance](#), to enable alcohol issues to be addressed at the EU level, and to make the case for an EU alcohol strategy on alcohol. For a number of years this absorbed a large proportion of IAS' staff and financial resources. It included acquiring a building in Brussels to facilitate this work.

Throughout this time, IAS was involved in a range of EU activities and projects, perhaps the most notable of which was being commissioned by the EC to undertake a major review of the alcohol issue to serve as the evidence-base for the EU alcohol strategy. This was published as Peter Anderson and Ben Baumberg: [Alcohol in Europe: A report for the European Commission](#). IAS London 2006.

IAS was also instrumental in the establishment of the [European Alcohol Policy Youth Network \(APYN\)](#), using funds from the EC. This organisation for young people was created in order to enable higher youth participation in the definition, implementation and evaluation of policies and programmes tackling the harmful consumption of alcohol in Europe.

Other projects funded by the EU that IAS has set up and/or facilitated include:

- [Bridging the Gap](#)
- [Building Capacity](#)
- [Vintage: Good health into older age](#)
- [Alcohol Problems in the Family: A report for the European Union](#)
- [EU-US Transatlantic dialogue on underage drinking](#)

IAS is also a member of the [European Alcohol and Health Forum](#) (EAHF).

### **What evidence is there that EU action in health advantages or disadvantages UK national interest, business and industry and patients and citizens?**

*Advantages of EU competences:*

As demonstrated by the number of EU-funded projects that IAS has been involved in (see above), there are many examples where the EU has been able to **provide resources to build**

**capacity, facilitate information sharing and fund research on effective alcohol policies across Europe.** In particular, projects designed to build capacity amongst the public health and NGO community have helped to create a more balanced European policy dialogue, that sees increasing involvement from representatives from different areas of the alcohol industry. The EAHF is one such example of this.

- The EU competence on health provides many **opportunities to create a framework for supporting national actions and dealing with cross-border issues** that impact on public health. A good example of this is the **EU competence on tobacco control** which is exercised with clear public health objectives and which has supported national action and addressed cross-border issues such as advertising and sponsorship.

The EU competence for alcohol has also provided a framework for dealing with cross border issues, including commercial communications. As outlined in this consultation document, the **advertising of alcohol and the labelling of alcoholic beverages are regulated by EU legislation.** The EAHF has the potential to be a useful forum for prompting cross border actions by producers etc regarding regulatory codes, and for dissemination of good practices.

EU competence could possibly be useful for prompting action in regard to, for example, workplace policies having cross border aspects. The current Joint Action in regard to health guidelines on alcohol could also possibly be useful, given the lack of international consensus on the topic.

Finally, the **EU Alcohol Strategy** has provided a positive contribution in that it has created a shared conceptual framework and research base on public policies to reduce alcohol harm, and guidance for Member States. The future of the Strategy (which expired in 2012) remains unclear however, and the IAS sees its continuation as critical in addressing the burden caused by alcohol in Europe.

#### *Disadvantages presented by EU competencies*

Whilst EU activity and prompting has probably had beneficial effects on Member States in which alcohol had not previously been identified or recognised as an important area of activity, it is not so easy to identify evidence of concrete, tangible benefits to the UK, which has had for many years a relatively highly developed alcohol policy. Rather, perhaps (as with tobacco) the UK could strive to achieve the position of an international leader on alcohol policy, sharing knowledge and expertise with other Member States on areas such as minimum unit pricing (MUP).

More generally, it is not clear that the EU has a useful role in disseminating/delivering alcohol health promotional material, given cultural/national differences that are presented by Member States.

**It is apparent that the big issues that relate to alcohol policy have less to do with specific EU health competences and with DG SANCO than with the single market, tax policy etc, which tend to undermine national policies such as alcohol taxes and MUP.** For example, **duty paid import allowances** were deliberately designed to undermine the tax regimes of higher alcohol tax countries such as the UK. More recently, the EC has submitted a [detailed opinion](#) to the Scottish Government outlining objections to the introduction of **MUP** on the basis that it will present a barrier to trade in the EU. It is a great concern that the EC is itself presenting a barrier to the implementation of a domestic public health policy the UK Prime Minister deems to be in the best national interest.

EU policies in other areas also have the potential to undermine health/alcohol policy, for example the recent [DEFRA consultation](#) to bring UK legislation into line with **EU nutrition**

**labelling.** This move has the potential to cause confusion regarding the terms used to describe 'low alcohol', which are currently regulated by the UK Food Regulations Act 1996, by adding a plethora of new terminology to describe low alcohol and other products, hence creating the possibility of misleading and thus dangerous claims being made (especially amongst drivers etc.).

Addressing these areas outlined above highlights the importance of adhering to the principle of subsidiarity with regards to alcohol policy, in that the EU must only intervene where UK national policy is insufficient and allow the UK Government the freedom to enact public health policies, such as minimum unit pricing for alcohol, that are deemed to be in the best national interest.

## Japan Tobacco International

This Response addresses one policy area covered by the Department of Health's (*DH*) Call for Evidence on the Government's Review of the Balance of Competences between the UK and the EU (the *Review*), namely EU competence on tobacco control. This policy area is an example of on-going and unjustified "competence creep" by the EU. The impact of this "creep" is felt far beyond tobacco, as the legal principles established apply to significant additional areas of competence.

The issue for consideration in the Review is not whether substantive measures, including tobacco control measures, are right or wrong, but whether either the EU or the Member States ought properly to have the competence to adopt those measures. JTI considers that tobacco control measures are primarily a national competence issue, a view that is consistent with the EU Treaties<sup>2</sup> and the Call for Evidence's description of EU competence in this area as "supporting".<sup>3</sup>

The evolution of EU tobacco control measures provides a clear example of "competence creep" by the EU. Despite a long standing prohibition on harmonising national public health laws and regulations, the EU has adopted a series of directives – harmonising legislation – in the area of tobacco control. These directives have been challenged before the Court of Justice of the European Union (the *European Court*) which has annulled some aspects, but upheld others on the basis that it was persuaded that an Internal Market objective was being met. This case-law has broadened EU competence, not only for tobacco legislation but also for other EU action.

The Lisbon Treaty has spelled out a specific exclusion on EU harmonisation of public health measures regarding tobacco. Nevertheless, the Commission has recently proposed an extensive revision to the Tobacco Products Directive (*TPD*) which purports to extend yet further the EU harmonisation of tobacco control laws (in reality with a direct public health objective), in manifest disregard for the limits of EU competence.

### **Appropriate and proportionate regulation of tobacco products is both necessary and right**

On the substance of tobacco regulation, JTI's view is clear: tobacco products carry risks to health, and JTI believes that:

- Minors should not smoke, and should not be able to obtain tobacco products. It is central to our Code of Conduct, our marketing practices, our operational policies and the way JTI does business; and
- Adult smokers should be appropriately informed about the health risks of smoking before they make the decision to smoke.

For these reasons, JTI supports legislative and regulatory measures on tobacco control which meet the principles of Better Regulation. Key elements of Better Regulation are that regulations should be made in accordance with a set of principles, including: necessity; proportionality; subsidiarity; transparency; accountability; accessibility; and simplicity, making full use of impact assessments and consultations as tools of good governance. In particular, any regulation must have a clear legal basis.<sup>4</sup>

### **"Competence creep" by the EU to regulate tobacco products**

Over two decades, the EU has increasingly imposed itself on Member States in the area of public health through binding and harmonising legislation on tobacco control. This has been despite the long standing presence in the Treaties of a general and express, exclusion of "any

*harmonisation of the laws and regulations designed to protect and improve public health*".<sup>5</sup> By definition, this exclusion should have precluded the adoption of Regulations and Directives in this area (being the instruments by which the EU harmonises national laws). This imposition cannot be adequately reconciled with the limits to the EU's powers to adopt health measures in general, and tobacco control measures in particular, as set out most recently in the Lisbon Treaty, which entered into force in 2009. The Treaty on the Functioning of the European Union (**TFEU**) spelled out that the EU's public health competence permits the EU to adopt "*measures which have as their direct objective the protection of public health **regarding tobacco** ..., **excluding any harmonisation of the laws and regulations of the Member States***".<sup>6</sup>

In contrast, *non-harmonising* measures whose direct objective is the protection of public health regarding tobacco could fall within the scope of the EU's competence. For example, the EU's current public awareness campaign "Ex-Smokers Are Unstoppable"<sup>7</sup> is a nonharmonising measure whose direct objective is the protection of public health regarding tobacco, and which falls within the EU's shared competence with Member States.

### **The evolution of EU directives on tobacco control**

The EU has, to date, regulated tobacco on the basis of its shared competence in the Internal Market domain (currently Article 114 of the TFEU). This is a "residual" legal basis and does not afford the EU a general power to regulate the internal market.<sup>8</sup> Provided the conditions for recourse to this legal base are fulfilled, the EU may consider public health protection as a decisive factor in the *choices* to be made (i.e. taking "*as a base a high level of [health] protection*"<sup>9</sup>). This Internal Market competence must be fulfilled by reference to the shortcomings of the Internal Market itself and a genuine objective for its improvement.

To date, tobacco control directives in the EU have proceeded in three broad waves:

- The first wave of regulation, in the late 1980s and early 1990s, concerned the introduction of tar and nicotine yield maxima and labelling requirements, health warning requirements (4% of the front and back of cigarette packs) and the prohibition of "snus";<sup>10</sup>
- The second wave concerned the prohibition of advertising of tobacco products. Tobacco advertising and sponsorship on television,<sup>11</sup> and more broadly in other media,<sup>12</sup> have been prohibited. The ban notably covers print media, radio and internet and extends to advertising and sponsorship with the aim, or direct or indirect effect, of promoting a tobacco product; and
- The third wave comprises the broader regulation of the TPD in 2001. The TPD notably revised downwards the tar, nicotine and carbon monoxide yields of cigarettes; expanded health warnings to cover at least 30% and 40% of the front and back of cigarette packs, respectively; prohibited descriptors that suggest that a particular product is less harmful than another; and required the disclosure of ingredients and toxicological data to the Member States.

The EU sought to justify each of these waves on the basis that the measures were necessary for the functioning of the Internal Market. The competence of the EU to adopt the second and third waves of regulation was challenged by Germany and various tobacco product manufacturers.<sup>13</sup> The challenge to the EU's first Tobacco Advertising Directive resulted in its annulment (as the European Court found that it did not genuinely contribute to the Internal Market). Subsequent challenges to the second Tobacco Advertising Directive and to the TPD were unsuccessful – the EU having persuaded the European Court that the measures adopted

were justified because they met the conditions for improving the functioning of the Internal Market.

This “competence creep” in the area of tobacco control is of concern to JTI and should be of concern to Member States. The EU has consistently sought – unjustifiably in JTI’s view – to adopt harmonising public health measures in the area of tobacco control on the basis of Internal Market pretexts. This has been despite the Treaty provisions excluding such harmonisation, and, more recently, notwithstanding the clear wording in Article 168(5) of the TFEU preventing the EU from adopting harmonising legislation on tobacco.

As the European Court has noted, if the conditions for the application of the Internal Market legal basis are not assessed strictly, then “*the powers of the [EU] legislature would be practically unlimited*”<sup>14</sup> as the mere presence of cross border economic activity could be sufficient to engage that competence. The development of EU directives on tobacco control, and the recent TPD proposal (examined below), demonstrate that the EU is continuing to try to go beyond the powers afforded to it under the Treaties.

### **The EU’s Proposal to adopt a revised TPD as a prime example of manifest disregard for the limits of EU competence**

The EU is now proposing to adopt a revised TPD (***Proposal***).<sup>15</sup> The main changes in the Proposal concern five areas, of which those identified in italics below are new areas entirely beyond the scope of the existing TPD:

- smokeless tobacco products, *novel tobacco products* and *non-tobacco products*;
- packaging and labelling requirements;
- ingredients disclosure and *additives regulation*;
- *cross-border distance sales*; and
- *traceability and security features*.

The Proposal also confers indefinite, ill-defined and wide-ranging new “delegated” and “implementing” legislative powers on the Commission, many of which concern core areas of tobacco policy. These powers would enable the Commission to adopt yet further public health motivated regulation without the proper oversight of Member States, the Council and European Parliament.

On analysis, it is clear that the Proposal not only expands significantly the scope of the TPD, but it imposes new, broader and far more restrictive prohibitions and requirements on tobacco (and certain non-tobacco) products than is currently the case.

JTI believes that the Proposal has as its direct objective the protection of public health (*not* the Internal Market), and that – as a purportedly harmonising measure – it is in breach of Article 168(5) of the TFEU. It lacks a proper legal basis, as well as being in breach of the principles of conferral, subsidiarity, proportionality and fundamental rights. JTI’s concerns regarding the Proposal are more fully set out in its submission made in response to the Irish Department of Health’s consultation on the Proposal, which JTI has provided to the DH, a copy of which is enclosed with this Response.

### **Conclusion**

Despite the Lisbon Treaty’s specific exclusion on EU harmonisation of public health measures regarding tobacco, the Commission is pressing ahead with the Proposal. This is a further example of the EU over-stepping the limits of its competence in relation to public health measures, and provides useful evidence for the Review process when assessing measures being promulgated by the EU in disregard of its powers. Other examples of concerns over “competence creep” have been noted by the UK Parliament including on public health: for

example, the House of Commons Scrutiny Committee's 50th Report in relation to the EU's *Health For Growth Programme 2014-20*;<sup>16</sup> the 31st Report in relation to direct taxation issues;<sup>17</sup> and the House of Lords' EU Select Committee's concerns in the field of the EU's nuclear package.<sup>18</sup>

If the Government is to “ensure that there is no further transfer of competence or powers [to the EU] over the course of the Parliament” (as stated by Foreign Secretary William Hague in the foreword to the Review), JTI believes that “competence creep” by the EU should be examined carefully.

JTI is committed to playing an important role in the development of an appropriate and proportionate regulatory regime for tobacco products which meet the principles of Better Regulation. We would welcome the opportunity to discuss these issues further.

1 Japan Tobacco International (**JTI**) is a member of the Japan Tobacco Group of Companies, a leading international tobacco product manufacturer. JTI has operations in more than 120 countries and about 25,000 employees. Since April 2007, Gallaher Limited, the UK-based tobacco products manufacturer, has also formed part of the Japan Tobacco Group. For more information, visit [www.jti.com](http://www.jti.com).

2 See Article 6 TFEU. It is not to say that EU law has no role to play if tobacco control measures (such as adopted to date or as proposed by the EU) were adopted by the UK or other Member States. All national measures that may affect, notably, the free movement of goods within the EU must be justified by overriding reasons of public interest and be necessary and proportionate to their aim (including that there are no less restrictive means of achieving the objective). They must not be a means of arbitrary discrimination or a disguised restriction on trade between the EU Member States.

3 Call for Evidence, page 6.

4 See, for example, Article 13(2) of the TEU; and the EU's Impact Assessment Guidelines (**IAG**), paragraph 5.2.

5 Article 129 of the EC Treaty.

6 Article 168(5) of the TFEU, emphasis added.

7 [http://ec.europa.eu/health/tobacco/ex\\_smokers\\_are\\_unstoppable/index\\_en.htm](http://ec.europa.eu/health/tobacco/ex_smokers_are_unstoppable/index_en.htm).

8 Case C-533/03 *Commission v Council (VAT)* [2006] ECR I-1025, paragraph 45; Case C-376/98 *Tobacco Advertising I* [2000] ECR I-8419, paragraph 83.

9 Article 114(3) TFEU.

10 Directives 89/622, 90/239 and 92/41.

11 Directive 89/552.

12 Directive 2003/33.

13 Cases C-376/98 *Tobacco Advertising I* [2000] ECR I-8419, C-491/01 *BAT* [2002] ECR I-9079 and C-380/03 *Tobacco Advertising II* [2006] ECR I-11573.

14 Case C-376/98 *Tobacco Advertising I* [2000] ECR I-08419 paragraph 107.

15 COM(2012) 788 final, 19 December 2012.

16 50th Report, published 30 December 2011. See in particular paragraphs 5.14-5.17 of the Report.

17 31st Report, published 18 February 2013. See in particular paragraph 5.4 of the Report.

18 37th Report, published 2006. See in particular paragraphs 74-76 of the Report.

## Liberal Democrat Parliamentary Party Policy Committee

### 1. Background to this submission

1.1 Having reviewed the Department of Health consultation document and the main areas of EU Competence identified in the document, the Liberal Democrat Parliamentary Committee for Health and Social Care (“The Committee”) wishes to submit the following evidence.

1.2 The Committee is made up of Parliamentarians and staff of the Liberal Democrats with expertise in the area of national health policy, social care policy, national and EU health legislation and regulations.

1.3 The contributors to this submission are: Baroness Judith Jolly, Lord Tim Clement Jones, Lord John Roper, Baroness Elizabeth Barker, Rebecca Taylor MEP, Ed Webber (Adviser, EU Affairs), Jemima Bland (Parliamentary Researcher), Tim Howard (Intern).

### 2. General points

2.1 The committee recognises that EU legislation in the Health sector is primarily intended to protect the single market rather than acting directly to promote the health or wellbeing of EU citizens. We recognise the positive value of this regulation as a whole in enabling the free market to operate.

2.2 The committee recognises the overall benefit to the UK of the non-statutory EU mechanisms for best practice or cooperation in the fields of pharmaceutical regulation and public health.

2.3 Further, the committee agrees that the EU provides the highly UK valuable access to funding, skills and other R&D resources, such as data sharing mechanisms and the FP7 health research programme.

2.4 The committee underlines the fact that where EU directives have been met with significant outcry in the UK health sector, such as for the EU working time directive and the clinical trials directive, revisions and opt-outs have been successfully secured by UK representatives in conjunction with those of other member states.

### 3. Pharmaceuticals, clinical trials and medical devices

3.1 We recognise that the EU has a regulatory role in medicines; in the implementation of clinical trials and in the authorisation of medicines for the market. This is to ensure safety and product efficacy standards across the EU, and a ‘level playing field’ for competition. We agree that there is a need to provide a degree of harmonisation across the EU, as medicines are free to be sold in every EU Member State, and trials often take place in a number of Member States.

#### 3.2 Clinical Trials

3.2.1 The recently proposed Clinical Trials Regulation is addressing the considerable concerns associated with the earlier 2001 Directive, and has been met by much enthusiasm by industry, academia and health charities. The earlier Directive was blamed for considerable bureaucracy

and delays for those wishing to conduct trials, and was linked to a reduction in medical research over the period of its implementation.

2.2.2 The three remaining major concerns are likely to be overcome before ratification. These are; the ambitious timelines for a decision by Member States concerned to approve trials, the tacit consent principle, which puts responsibility on Member States to scrutinise applications, and the role of ethics committees, which some Member States feel have not been written into the draft with enough clarity.

3.2.3 This demonstrates that EU directives can be modified when they cause problems, and that the UK's continued influence on this process is important.

3.2.4 We have remaining concerns about the level of bureaucracy associated with the ethics committees for clinical trials.

### 3.3 Medical research

3.3.1 The EU also provides member states access to 6.1 Billion Euros in funding for health research as part of the 7th Framework Programme for Research and Innovation (FP7). Horizon 2020, which is due to replace FP7 in 2014, is likely to have an even larger budget for health research. EU member states collectively spend approximately 10% of GDP on healthcare (€2730 per person annually) but spend only €40 per person annually on biomedical and health research. Of the €80bn Horizon 2020 budget, 11% will go to biomedical and health research. A large number of EU policy makers are pushing for a rebalancing of the EU's spending commitments, away from agricultural subsidies and towards funding for research and innovation. Research funding increased (slightly) in the 2014-20 EU budget. It is absolutely in the interests of the UK's health sector, including our leading research bodies, to retain access to this funding stream.

3.3.2 Medical research is an area in which the UK is a leading player. A disproportionate amount of EU health research funding comes to the UK. This is hugely important to the Russell Group universities and must be retained.

### 3.4 EU Standards for medicines

3.4.1 The EU Medicines Agency is based in Canary Wharf, approves drugs for marketing within the EU. The centralisation of this process is recognised by the committee as increasingly necessary. This is due to the complexity of biological trials, the growing need to base trials in several different countries.

3.4.2 Further, the question is not why we need an EU Medicines Agency, but rather why we need MHRA if it does the same role. NICE has a role as a rationing body, but MHRA duplicates some of the work done by the EU body.

### 3.5 Medical devices

3.5.1 An important area of regulation currently being discussed in Brussels, is the two Draft Regulations on Medical Devices and IVD Medical Devices. Similarly to Clinical Trials and Medicines, the committee agrees that this regulation is needed to ensure product/patient safety, and allow device makers to trade within all Member States under equal conditions.

3.5.2 The committee agrees that it would be in the interests of the UK to grant the EU greater competences for medical devices.

## 4. Public Health

4.1 The EU's jurisdiction on public health is based on the principle of 'complementary competence'. In practice, this means that the EU can only provide guidelines and best practice in this area, while legislation is left to national governments. Any legislation in this space is therefore led by the need to place basic public health standards at the centre of internal EU market harmonisation, even though this field remains largely in the hands of Member States. Tobacco directives are an example of this, since they deal with packaging and fraud but are not able to ban smoking in all public places.

#### 4.2 Health threats

4.2.1 On matters of cross-border health threats such as pandemics, the EU's role is limited to strengthening cooperation through evidence sharing and coordinating committees.

4.2.2 The EU can only provide best practise in this area. It was argued that due to the global nature of pandemics, cooperation should be on a global level – WHO.

#### 4.3 Food safety, nutrition and health claims

4.3.1 The 2006 Regulation on Nutrition and Health Claims made on Foods in the central text in this area. It seeks to ensure that goods traded across the EU, in this case food, is subject to basic public health standards. There have been some problems in the legislation's implementation, though these are being overcome gradually.

4.3.2 Where health claims (e.g. "Nutella: high in calcium") are made, the new regulations would require certain basic standards of fat, salt and sugar content to be met as well as the claim itself to be justified. The committee supports this objective and believes that it would be in the UK's interest for the EU to extend its powers to regulate health claims.

4.3.3 The maximum content of active ingredients in vitamin supplements is also currently being debated in the EU. The UK vitamins industry has objected to the potential regulation, as it would limit their ability to sell higher strength supplements, which are currently widely available in the UK. The regulation is drafted on the basis that the vitamins are only effective up to a certain concentration and the additional vitamin content has no effect.

4.3.4 EU Food labelling regulation has a positive effect for UK citizens and reduces costs for UK authorities.

4.3.5 National variations should be allowed in certain cases for food labelling regulation, to allow for different consumer preferences in different markets. The committee believes that where variations are in the UK 's national interest, UK representatives are already sufficiently empowered to argue for this differentiation in Brussels.

4.3.6 The committee recognises that where the EU prevents vitamin suppliers or other producers from making unsubstantiated claims, this is in the UK national interest and should be supported.

## 5. NHS Services and workforce

5.1.1 In general, the committee recognises that EU legislation on working time and minimum standards for certain careers are designed to ensure that Member States are comfortable accepting the freedom of movement of workers. Similarly when it comes to service quality, these directives ensure that basic health care can be accessed in any Member State, either for emergency reasons, or for those that choose to live abroad. We also enforce competition law, to ensure that companies can trade in each Member State in a fair and transparent market.

5.1.2 Some EU employment legislation has negative impacts for UK healthcare professionals. However, the committee believes that many of these negative impacts are related to choices made by UK authorities with regard to implementation of directives rather than the directives themselves. Employees in all sectors are currently able to opt-out of the EU working time directive.

## 5.2 Professional qualifications

5.2.1 The qualifications of healthcare professionals have been subject to minimum standards set by the EU since the 1970s. These minimum training requirements have gradually extended from doctors only to apply to pharmacists, nurses, midwives, vets and dentists. The EU is still reviewing some aspects of this including extension to specialists and language requirements. The EU minimum standards also enable cross-border background checks on medical professionals travelling between EU states.

5.2.2 In the UK, different language standards are currently asked of nationals depending on whether they come from outside or inside the EU. This is an irregularity in the interaction between UK internal regulation and EU regulation which is unfair and unbalanced. It is the responsibility of UK officials (and entirely within their remit) to correct this at the earliest possible opportunity.

5.2.3 Varying standards of medical teaching across the EU can lead to legitimate quality concerns, so the standardisation of professional qualifications is essential and life-saving work for UK citizens as for those of all member states.

5.2.4 Where background checks and verifications are bureaucratic or unreliable the process should be improved, and UK representatives in Brussels are empowered to influence these improvements.

5.2.5 Effective management of professional skills, including language skills, by the NHS, benefits patients and professionals and the highest standards in this area should be central to NHS management and culture.

## 5.3 Cross-border health care

5.3.1 Cross-border care for citizens of EU member states is facilitated by the EU on two premises: 1) that no EU national health service can refuse to reimburse a patient for their treatment on the basis that it happened outside the patient's native country within the EU; and 2) that no patient is allowed a free choice of countries in which to have treatment.

5.3.2 The committee notes that the EU is currently considering improvements to this regulation since there have recently been several cases where the NHS has been taken to the ECJ by patients because it has refused to reimburse treatment on grounds of 'undue delay'.

5.3.3 It is strongly in the interests of UK citizens to have free access to state healthcare providers across the EU. In the last 7 years, over 38m EU Health Insurance cards have been issued by UK authorities to UK citizens at home and abroad. There are currently over 260,000 UK citizens living and working in other EU member states who stand to benefit from the provisions for cross border healthcare put in place by the EU.

5.3.4 Health tourism is often cited as an issue by EU detractors, though little data is available on this and its impact is likely to be exaggerated. When data is available, the committee suggests that the NHS could require patients to show an ID before offering non-urgent treatment.

## 5.4 The Working Time Directive

5.4.1 The WTD has been criticised by the UK on the grounds that it limits the number of hours of training a doctor or nurse will be able to have before qualification. In particular, controversy rests on the fact that the EU considers 'on-call' time as working time. The UK has negotiated an opt-out of the working time directive, which can be signed by doctors and nurses.

5.4.2 The EC introduced the WTD in 1993 to provide a minimum amount of breaks, and limit the working week to 48 hours. The WTD wasn't adopted in the UK until 1998. Some temporary exemptions have been granted and junior doctors were opted out of the WTD *en masse* until 2004. The Jaeger Ruling of 2003 had major implications for healthcare as it changed the way on-call time should be calculated. The ECJ ruled that time spent on-call at hospital was to be regarded as working time. Even if they do opt-out, junior doctors cannot work longer than 56 hours under the New Deal.

5.4.3 There is a lack of clarity on the WTD and UK EU officials should aim to correct this and ensure that its implementation in the UK is in UK interests. We are not confident that this is currently the case.

## 6. 'E-Health'

6.1 This category includes telehealth, 'NHS IT' and automation of patient records would be impacted by data protection regulations set out by the EU to protect the confidentiality of personal data. Some UK health bodies have expressed concern about additional red tape which could impede research. UK MEPs are working to find solutions that ensure adequate data protection standards whilst ensuring the possibility of health innovation through new technologies.

6.2 With the rise in medical treatment taking place in other member states there is a universal need to improve IT connectivity. The Patients' Rights in Cross-Border Healthcare Directive sets up a voluntary network among member states' healthcare providers. The eHealth network will draw up guidelines for the use of electronic health systems and to improve the interoperability between eHealth systems across the EU.

6.3 The continued role of the EU in setting high standards for data protection are strongly in the interests of UK citizens and NHS patients.

6.4 Improved ICT connectivity across the EU is needed. EU-wide patient record portability is a good goal to set and one which it would be in the interests of UK citizens to achieve as soon as possible.

6.5 The committee notes that a closely related EU directive on e-commerce is currently being debated in Brussels which will impact the UK health sector.

## 7. EU Competition law

7.1.1 EU competition law currently applies to all private companies operating within the EU in order to protect the internal market. In the UK health sector, it is interpreted and applied by Monitor and the OFT/Competition commission alongside national legislation.

7.1.2 The committee agreed that balance of the EU's impact in the area of competition regulation is positive for the UK.

7.2.1 There are significant uncertainties about the application of EU competition law in the NHS following the Health and Social Care Bill 2012. These uncertainties will only be resolved by case law. This process should be closely overseen by the Department of Health and UK officials and MEPs in Brussels to ensure that the results are in the interests of patients in the UK.

7.2.2 The extent to which EU competition law will impact the UK health sector post-2012 depends on which entities are defined as undertakings. Monitor will address this question in the 'Fair Playing Field Review' which is currently ongoing.

7.2.3 Public goods, such as health and education, are exempt from competition law where they are classified 'Services of General Public Interest'. It is unclear to what extent this exemption will be relevant to the UK health sector.

## 8. Conclusion

8.1 The EU's competences in the area of health have a net positive effect on the citizens of the UK.

8.2 It is vital that the UK continues to play an active and influential role in shaping EU competences in health and social care.

8.3 The UK has a different market place with different standards and cultural practices to other EU member states. While the overall impact of the EU single market on UK interests is definitely positive, the UK must always retain the right and ability to resist or negotiate measures which are considered by UK voters to be in any way excessive or unnecessary.

8.4 Funding streams from the EU to the UK health sector, particularly in the area of medical research, are very significant indeed. Any reform of EU competences must recognise this and avoid endangering this lifeline for our universities. The committee also notes other European funding streams which the UK health sector benefits from, including the European Investment Bank (EUIB), which has part-funded hospitals in the UK.

8.5 It is important to note that there are many areas of EU competences to regulate which impact on the health and wellbeing of UK citizens but which are not addressed here. These include, for example, regulations on air or water quality.

8.6 The committee concluded that in all these issues discussed the main finding of the committee has been the degree of "EU Value-Added" for the UK health sector, rather than conflicting or obstructive competences or other powers.

8.8 There are three areas in which the committee recommends that the Department of Health seek greater clarity as soon as possible. These are: 1) The Working Time Directive; 2) the practices of Ethics committees in medical research and 3) the extent and costs of so-called 'Health tourism'.

## Marina Yannakoudakis MEP

Please find below some thoughts on the balance of competences for your call for evidence. I have focused my brief evidence on ongoing health dossiers which I am following in the parliament's environment committee.

### Clinical trials

The existing directive has been shown to be not fit for purpose even making it more difficult to conduct cross-border trials. The revision of the directive must ensure that the necessary checks-and-balances are in place while ensuring that the scrutiny process does not cause a delay in the approval of live-saving medications.

### Medical devices

There is a chance that another risk category will be set up, which will involve the European Medicines Agency. After visiting the EMA recently, I have concerns that the agency is trying to expand its competences.

### Tobacco directive

Plain packaging is likely to be passed, but also electric cigarettes will be affected. There is a danger that EU rules will interfere with Member States' competence over health.

### Labelling of foodstuffs

This is being discussed now. The question on country of origin labelling for processed meat might re-open the question of methods of killing animals. This will affect UK in terms of shechita and dhabaha slaughtering.

## Medical Research Council

1. The Medical Research Council (MRC) is one of the main agencies through which the UK Government supports biomedical and clinical research. It is dedicated to improving human health through the best scientific research. The MRC's work ranges from molecular level science to public health medicine and has led to pioneering discoveries in our understanding of the human body and the diseases which affect us all.

2. This evidence is submitted by the MRC and represents its independent views. It aims to address the areas of this consultation which are directly relevant to the work of the MRC. The MRC, as part of RCUK, will submit a full response to the Research and Development Review by the Department for Business, Innovation and Skills.

### MRC Response

3. Europe has some excellent research centres, universities, and world class infrastructures in the area of health research which have the potential to contribute significantly to the competitiveness of Europe, and in turn the UK. However, whilst this research sector is generally well funded, it operates in a heterogeneous and fragmented space. It is vital that substantial research investment within Europe continues, both at an EU and national level, in order to stimulate innovation and competitiveness, but also that steps are taken across the whole of Europe to harmonise the research environment and remove barriers to transnational research.

### Research Support

4. The European Framework Programmes for research funding play a vital role in supporting research and collaboration across Europe, particularly in the current economic climate, where national funding is increasingly difficult to obtain. It is important that activities continue to focus on areas of clear 'EU added value' and are not seen as a way to replace decreasing national activities across the EU. The UK is consistently among the most successful countries in terms of funding received from the Framework Programmes. Data from Framework Programme 7 (FP7) released in October 2012 shows that, in the Health theme of the Cooperation Pillar, the UK was the largest recipient of funding, receiving almost €588M, 17% of all available funding in this area. Overall, the UK had received 15% of FP7 funding, second only to Germany.

5. In addition to the direct funding support provided by the EU, actions taken at the European Community level can add significant value to actions taken by individual Member States. This is often the case for research in areas which require a large population base, for example research into rare diseases and large epidemiological studies, or when infrastructure is required of a scale or cost which could not be supported by any Member States individually. Key health-related infrastructure recently supported by Member States across the EU include ELIXIR, a sustainable infrastructure for biological information in Europe, and INSTRUCT, infrastructure for structural biology. Coordination of research programmes across Europe to address key societal challenges which could not be addressed by one country alone is also

welcomed, as such a joint approach to challenges enables Member States to maximise their use of resource for the advancement of science and to compete on a global scale in key research areas. It is difficult to imagine such collaborative efforts taking place without the coordination role of the Commission and joint ambitions towards a wider European Strategy.

### Legislation

6. Harmonisation of legislation across Europe in the area of health research is vital in order to reduce fragmentation and unnecessary delays or duplicative processes, which can often impede transnational research, and to ensure quality of conduct and protection of participants.

However, it is of utmost importance that European legislation and policy is proportionate and risk-based, avoiding administrative burden where possible. In all instances, clarity is also crucial: providing clear and detailed guidance in order to ensure successful consistent implementation across Member States. The importance of these points is clearly demonstrated by the Clinical Trials Directive, which was brought in to regulate clinical trials of investigational medicinal products in Europe. This Directive was widely considered to have acted as a disincentive to initiate studies, with key criticisms including divergent application across Member States leading to difficulties in performing multinational clinical trials, a significant increase in administrative burden, and a lack of differentiation in approach for well-known and completely new drugs. The Commission, seeking to address these issues, adopted the Clinical Trials Regulation in July 2012, which is broadly viewed as a positive step - the MRC endorsed the following joint statement (<http://www.acmedsci.ac.uk/p47prid118.html>) This issue highlights the importance of employing the correct legislative instrument, and the very real potential for inconsistent interpretation of European Directives at a national level without clear guidance regarding implementation.

7. Where European legislation is developed which does not principally concern research, it is vital that potential impacts on research are fully considered and understood so that, if necessary, the proposed legislation can be effectively modified, repealed or new legislation drafted to ensure that European research and innovation, and in turn European competitiveness, is not stifled. A highly-relevant example is the EU Data Protection Directive, currently undergoing scrutiny by the European Parliament, which has potentially serious implications for the use of patient data for health research purposes. It is crucial that the resulting legislation is able to balance data protection requirements with the need to retain sufficient flexibility for innovative research. (<http://www.acmedsci.ac.uk/p47prid107.html>).

8. Table 1 below provides further comments on a number of specific EU actions which impact on UK health research.

## **Medicinal products**

### Directive 2001/20/EC

The Clinical Trials Directive should have had a positive impact on research by harmonising legislation across Europe and ensuring quality of conduct. However, the Directive was widely considered to have acted as a disincentive to initiate studies in Europe (key criticisms included divergent application across member states, increase in admin burden, and lack of differentiation between high and low risk trials). The Commission adopted the Clinical Trials Regulation in July 2012 to address these issues, a step which was welcomed by MRC and other funders (<http://www.acmedsci.ac.uk/p47prid118.html>)

This issue highlights the importance of employing the correct legislative instrument and the very real potential for inconsistent interpretation of European Directives at a national level without clear guidance regarding implementation.

## **Health security**

### Decision no. 2119/98

Health security and cross-border health threats is an area where cooperation and collaboration at Community level is required and where EC facilitation can be valuable. This has a positive impact on research as it supports collaborative efforts across Member States.

## **Radiation**

### EU Physical Agents Directive

There were significant concerns that the original EU Physical Agents Directive 2004/40/EC would restrict the use of MRI for research and clinical diagnosis. In response to these concerns, the EC postponed implementation of the Directive and have since issued a revised Directive which includes an exemption for MRI. Workers using MRI remain protected by existing safety regulations. It is expected that this revised has avoided potentially negative impacts on research.

It is vital that potential impacts of European legislation on research activities are fully considered prior to adoption to avoid potential detrimental impacts.

### **Rare diseases**

Council recommendation and EC implementation

This is a key area where active collaboration and knowledge sharing across Member States is important as there are only a limited number of patients and limited expertise. Member States have competence but EU level

Table 1: Comments on specific EU actions which impact on health research.

report

facilitation and oversight is helpful

### **Health research**

Funding via Framework Programmes

The Funding Programmes play a vital role in supporting European research, particularly in supporting large-scale multinational projects which may not be able to be funded elsewhere. In addition to the direct funding, action at the European level, often through coordination by the Commission, can add significant value to action taken by individual Member States, for example in areas which require a large population base or when infrastructure is required of a scale or cost which could not be supported by any one Member State alone.

The UK is particularly successful in terms of receiving research funding from the Framework Programmes. In the health theme, the UK was the largest recipient of funding, receiving almost €588M, 17% of all available funding in this theme.

### **Data protection**

EC Proposal for a Regulation on the protection of individuals with regard to the processing of personal data and on the free movement of such data (COM(2012)0011)

This proposal has serious negative implications for the use of patient data for health research purposes.

It is crucial that the resulting legislation is able to balance data protection requirements with the need to retain sufficient flexibility for innovative research.

(<http://www.acmedsci.ac.uk/p47prid107.html>).

## National Grid

### **Context**

National Grid is an international electricity and gas company and one of the largest investor-owned energy companies in the world. Of relevance to the present context, we own and operate the high voltage electricity transmission system in England and Wales (and operate the transmission system in Scotland). Our interest in health issues arises from the issue of the non-ionising radiation (electric and magnetic fields) produced by our power lines (along with all other uses of electricity). As noted in the Call for Evidence, EU competence in this area is exercised through a Recommendation regarding public exposure, with a Directive on occupational exposure also in course of preparation. Additionally, an EU scientific committee SCENIHR publish reports covering the issue, and the successive research Frameworks have included funding for research.

### **Present position: legislation**

The Recommendation and the draft Directive are both based on well-regarded international guidelines (published by ICNIRP, the International Commission on Non-Ionising Radiation Protection). If there were no EU competence in this area, the UK would almost certainly have adopted similar guidelines for itself. So the strengths and weaknesses of the present position are not so much to do with the outcome achieved but with process issues.

### **Strengths**

In principle, National Grid supports making the controls that apply in different countries as similar as possible, and clearly this is more likely to be achieved across Europe through EU rather than national competence. Increasingly, transmission system operators operate networks in more than one country, and individual cross-border power lines are an essential and growing part of delivering the required energy outcomes across Europe, and both of these are facilitated if the constraints within which power lines have to be built (in this case, the exposure limits) are common. And, of course, citizens are likely to feel more comfortable if they know that the level of protection afforded them is common across Europe and not a function of which country they live in.

In practice, the Recommendation and draft Directive set only minimum standards and do not prevent member states adopting more rigorous standards. This is an understandable approach for Europe to adopt, but limits the advantages of standardisation. Similarly, the flexibility in the application of the guidelines means that their practical effect can end up rather different in different countries, even in countries that have nominally adopted the Recommendation without seeking to make it stricter.

Evidence: the European Network of Transmission System Operators – Electricity (ENTSO-E) has compiled the following summary of the situation regarding public exposure in relation to the

Recommendation across Europe:

| No limits          | EU Recommendation (or similar quantitative limits designed to prevent acute effects)   | More restrictive quantitative limits (either in addition to or instead of EU Recommendation; may apply only in restricted circumstances) | Additional protective policies not expressed as quantitative limits | Not known                          |
|--------------------|--|--|---|------------------------------------|
| Bosnia-Herzegovina | Bulgaria<br>Cyprus<br>Czech Republic<br>Germany<br>Estonia<br>Spain<br>Finland<br>France<br>Greece<br>Hungary<br>Ireland<br>Latvia<br>Portugal<br>Romania<br>Slovak Republic | Austria*<br>Belgium**<br>Switzerland<br>Italy<br>Croatia<br>Lithuania<br>Luxembourg***<br>Netherlands<br>Poland<br>Serbia<br>Slovenia    | Denmark<br>UK<br>Norway<br>Sweden                                   | Iceland<br>Montenegro<br>Macedonia |

\* for lines requiring EIA  
 \*\* restrictive measures are regional  
 \*\*\* not mandatory but still causes concern

**Weaknesses**

National Grid strongly believes that exposure limits (or any other health measures) should be scientifically based. In the UK, this is always likely to be the case. Such measures generally start with a recommendation emerging from a relatively dispassionate scientific review from the Health Protection Agency (HPA), possibly with some consultation, but with a minimum of lobbying. The scientific recommendation would then be considered and, probably, adopted by the relevant Minister, usually on its merits with a minimum of political considerations intruding. In the EU, the process allows for a more political approach and there is a need to ensure that the scientific basis and recommendations are not lost. (This can involve some effort in Europe on the part of, for example, DH and HSE.)

Thus, in summary in relation to the existing position:

- in practical terms, the outcome is likely to be similar with the competence residing in the EU as it would be in the UK, with no obvious advantage or disadvantage from the EU competence for the UK, industry or members of the public;
- there are benefits in principle from standardisation of health protection measures across Europe, but in practice these are quite limited; and
- the EU should seek to ensure that decisions taken in this area reflect the scientific analysis

**Present position: other EU actions**

The EU’s scientific committee SCENIHR publish reports periodically that review the scientific evidence on health issues. However, equivalent reports from WHO have a higher status, and within the UK, greater weight would be attached to reports from the HPA than from SCENIHR. EU research funding on non-ionising radiation has had, in our view, poor returns for the money expended. Too much of the available resource has been devoted to derivative activities such as risk assessment, management and communication, and too little to direct research into health

issues. By contrast, smaller UK research programmes have managed to fund more actual scientific research (and arguably of a higher quality).

### **Future changes**

With the Recommendation in place, and the Directive shortly to be, there is limited anticipated need for further action in this area.

When further action is needed, we are agnostic as to where it would best be originated: there are advantages in principle in EU competence, but practical advantages for UK competence, specifically with regard to the use of scientific evidence in decision-making.

If the EU competence were removed, the UK could readily effect the necessary health measures based on existing expertise at DH, HPA and HSE.

## National Heart Forum

### **How does the EU's competence in health affect you/your organisation?**

The National Heart Forum is a charitable alliance of professional and public interest organisations working to reduce the risk of avoidable non-communicable diseases by developing evidence-based public health policy and supporting its implementation through advocacy and information provision.

EU competence for regulation and policy-setting affects many of the public health challenges that concern our organisation; specifically, tobacco control, alcohol harm and diet-related ill health.

For over 20 years, we have worked with our members and with peer networks and organisations (including the European Heart Network and European Public Health Alliance) which operate at the EU level as stakeholders in EU policy-making processes. Our activities have included EU-funded pan-European projects with partner organisations on themes including child obesity and cardiovascular disease prevention.

We note that research and development, including the Framework Programme, will be handled separately in another review, and we will respond accordingly.

#### **A. Impact on the national interest**

##### **What evidence is there that EU action in health advantages or disadvantages:**

- **The UK national interest**
- **Business and industry**
- **Patients and citizens?**

The UK national interest, business interests and citizens' interests are all served by EU action where it has provided public health protections to the UK population which have reduced social and economic burdens of death and ill-health and reduced costs to the health services. An example is EU action on tobacco control which has supported UK efforts to reduce smoking rates. The overall costs of smoking to the UK public purse was estimated at £9 billion in 2010, and each percentage point reduction in smoking prevalence is estimated to lead to a net revenue gain of £240 million.<sup>1</sup>

EU action on trade and aid among other policy areas has direct and indirect global impacts on health as well as sustainable development and climate change. Therefore health supporting policies present a huge potential for health gain around the world. Because of the range of policies which impact on health, the EU's influence on public health is much greater than its impact on health through healthcare and we urge the Balance of Competences review to take this into account.

##### **What evidence is there to demonstrate the extent to which the EU's role in public health supports member state actions effectively and efficiently?**

Individual Member States can struggle to successfully regulate multi-national companies in the public interest, and there are instances where the 'corporate body' of the European Union has been effective in achieving this level of regulatory action. The EU Nutrition and Health Claims Regulation (EC 1924/2006) - and the supporting substantiation activity by the European Food Safety Authority - is an example of action that is beneficial to citizens in all EU Member States which would be beyond individual Member State capacity.

There is a clear consensus among health and consumer organisations and many food retailers that 'traffic light' nutritional labelling on front of pack can help people make better informed food

choices and can stimulate healthy reformulation to reduce levels of fat, sugars and salt. The Food Information to Consumers Regulation (EU FIC) allows Member States to introduce, albeit at on a voluntary basis, '*additional forms of expression and presentation*' – so balancing what can be achieved at EU level with some scope for Member States to 'experiment' with national labelling schemes.

There are mechanisms whereby the EU provides an opportunity for sharing policy evidence and experience between Member States. For example, the High Level Group on Nutrition and Physical Activity has acted as a focal point for sharing knowledge and for generating supportive actions between Member States on salt reduction in processed foods. While the UK has led progressive action on salt reduction policy with UK manufacturers and retailers in recent years, it has also benefited from any pressure that other Member States can exert on manufacturers who export to the UK market.

### **What evidence is there to demonstrate the extent to which health objectives are effectively and proportionately taken into account in wider EU policies?**

One example is the Tobacco Tax Directive which contains a number of references to the importance of health protection. The current Directive has been helpful in enabling the UK to continue its policy of reducing the affordability of tobacco through tax increases while also increasing the minimum excise tax other Member States have to levy and reducing the differential between manufactured and fine cut tobacco.

We note that the picture is mixed and that aspirations are not always matched by actions. For example, the 2011 Commission Communication on the Common Agricultural Policy (CAP) included public health as a priority and recognised the increasing focus on nutrition and sustainable consumption, as part of the larger societal issues that CAP must deliver on. However, the subsequent CAP legislative package did not, we would argue, go far enough in adequately addressing the radical changes that would need to be made in food production and consumption in order to mitigate and reduce the challenges of chronic diet-related disease, climate change and environmental impact, as well as feeding an increasing global population adequately, equitably and sustainably.

## **B. Future options and challenges**

### **How might the UK benefit from the EU taking more action in health?**

### **How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than the EU level?**

We believe that the UK and other EU Member States would benefit from more action to control alcohol harm, specifically the development of a new, robust EU Alcohol Strategy for 2013-2020, to ensure that the current progress by individual member states and the EU collectively can be built upon to effect greater change. The direct effects of alcohol on individual drinkers include illness, injury, mental ill health and premature death. In the UK, 26% of men and 17% of women drink at hazardous levels every week. In 2010, there were 8,790 alcohol-related deaths in the UK – double the rate in 1992.<sup>2</sup>

There are a number of ways that coordinated action at the EU level can support UK actions to reduce alcohol harm. These include:

- providing a platform for organisations active at European level to share approaches and develop joint actions to tackle alcohol related harm;
- establishing baseline, non-limiting standards on the marketing and promotion of alcohol, equivalent to those that already exist for tobacco control under EU regulation. The
- exposure of young people to alcohol advertising and marketing, particularly digital

- marketing, is a growing cross-border issue that cannot be solely addressed by individual
- member states and requires effective EU action;
- tackling the illicit trade in alcohol across Europe.

On tobacco control, we would echo the recommendation of our member organisation, Action on Smoking and Health (ASH), specifically:

*In the next review of the Tobacco Tax Directive to see changes which take into consideration more appropriately the need for 'a high level of health protection'. In particular, further increases in the minimum taxes to be levied and a further decrease in the differential between manufactured and fine cut tobacco, for the benefit of health as well as the working of the internal market.*

*The UK would benefit from the revision of the Tobacco Products Directive (TPD) currently underway which requires larger health warnings on the pack and that picture warnings be mandated. The proposal should, however, be revised to require all nicotine containing products to be authorized pursuant to Directive 2001/83/EC. The MHRA is currently examining how best to regulate nicotine containing products and ASH supports all such products being regulated by the MHRA. The current proposal for the revised TPD should allow the UK to implement standard packaging at national level, as set out in the DH consultation in 2012, and we strongly support this.*

#### **How could action be undertaken differently?**

The EU White Paper on Health in All Policies (HiAP) requires that the Commission and Member States ensure that health concerns are better integrated in all policies at Community, Member State and regional level. But health falls within a broad category of 'social impact' and there is a risk that a proposal with a broad range of social impacts fails to consider specifically potential health impacts. A study carried out by the National Heart Forum found that in 2005 and 2006, 73 out of the 137 impact assessments carried out by the Commission did not mention the word 'health'.<sup>3</sup> ***The constitutional obligation of EU institutions to ensure a high level of health in all EU policies, warrants that health should become a separate requirement for consideration in impact assessments.***

#### **Could action be taken at any other international level i.e. by the WHO?**

UK action on tobacco control has been supported by the WHO Framework Convention on Tobacco Control as the world's first health treaty which sets out a comprehensive set of obligations for tackling the harm caused by tobacco. It is notable that the EU negotiated the FCTC as a bloc.

Other important actions taken by WHO which benefit the UK and other Member States include:

- Surveillance of disease burdens and risk factors.
- Assessing effectiveness and cost-effectiveness of interventions (for low- and middle-income countries).
- Developing recommendations for action - e.g. controls on food and drink marketing to children.<sup>4</sup>
- Developing tools to support implementation of policies – e.g framework for implementing controls on marketing to children.<sup>5</sup>

**What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?**

Examples cited in this submission highlight the need for legislative action to address cross-border trade impacts on health such as tobacco promotion and to regulate the actions of multinational companies in areas such as food labelling which exceed Member State capacity. Many EU Directives, such as the Tobacco Tax Directive, 'enable' effective national legislative action to ensure a high level of health protection while not limiting that national action. EU recommendations and opinions can be helpful to Member States framing and prioritising national legislation or policy.

1 APPG Smoking and Health. Inquiry into the effectiveness and cost-effectiveness of tobacco control:

*Submission to the 2010 Spending Review and Public Health White Paper Consultation Process.* 2010.

2 ONS (2012). Alcohol-related deaths in the United Kingdom. 2010.

3 R Salay, P Lincoln. *The European Union and Health Impact Assessments: Are they an Unrecognised Statutory Obligation?* 2008. National Heart Forum. London.

4 WHO. Set of Recommendations on the Marketing of Foods and Non-alcoholic Beverages to Children. 2010.

WHO. Geneva.

5 WHO. A framework for implementing the set of recommendations on the marketing of foods and non-alcoholic beverages to children. 2012. WHO. Geneva.

## National Institute for Health and Care Excellence

Impact on the national interest

How does the EU's competence in health affect you/your organisation?

1. The areas of the EU's competence in health with a bearing on NICE's role or more directly relevant to NICE are as follows.
2. European legislation on medicines under the centralised procedure and EU directives on medical devices provide the broad regulatory framework enabling the market authorisation that is a necessary condition for these products to be eligible for evaluation under NICE's technology evaluation processes.
3. NICE is likely to benefit from any developments in the evidence base on medicines, medical devices and diagnostics, including those resulting from:
  - harmonisation of how clinical trials are carried out in the EU and pharmacovigilance over the safety and efficacy of medicines once they are on the market;
  - initiatives incentivising industry research and development on medicines for children and on rare diseases;
  - surveillance of the safety of medical devices once they are on the EU market;
  - EU investment in collaborative health research through the 7<sup>th</sup> framework programme for research and technological development.
4. NICE is a partner in the European network of organisations involved in health technology assessments, EUnetHTA, and benefits from opportunities to share information and expertise and disseminate best practice in health technology assessment (HTA).
5. Public health problems related to nutrition, tobacco, alcohol, and drugs cross national boundaries, so initiatives to tackle them at an EU and global level are essential in principle. EU public health initiatives (such as regulation of food labelling and EU-promoted voluntary initiatives on the nutritional quality of food; requirements on the manufacture, presentation and sale and marketing of tobacco; and regulations on the advertising and labelling of alcohol) create a broader supportive environment for public health measures in England and thus for NICE's public health guidance.
6. The EU's health in all policies (HIAP) approach, which recognises that health is determined to a large extent by factors outside the health area, is consistent with the government's public health policy in England and NICE's framework for public health guidance.

### **What evidence is there that EU action in health advantages or disadvantages the UK national interest, business and industry, patients and citizens?**

7. As indicated above, we believe that the EU actions under its health competence are generally supportive of NICE's functions and so bring some benefits to NHS patients and to communities affected by public health services and programmes. We have no quantitative evidence on these benefits.
8. We are not aware of evidence of disadvantages arising from EU action in health in the areas where NICE has responsibilities. For example, debates over the last few years

about encouraging or discouraging innovation, including uptake of NICE-recommended treatments, have not identified obstacles to progress arising from EU action.

#### Future options and challenges

- **How might the UK benefit from the EU taking more action in health?**
  - **How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?**
  - **How could action in this area be undertaken differently**
  - **How else could the UK implement its current obligations?**
  - **What future challenge/opportunities might we face in EU health competence and what impact might these have on the national interest?**
  - **What impact would any future enlargement of the EU have on health competence?**
9. The UK can benefit from improvements in the way existing EU actions are carried out – for example:
- Recent EU proposals for the introduction of a new regulatory framework for medical devices and in vitro diagnostic medical devices arising in part from deficiencies exposed by the recent scandals about silicone breast implants and metal-on-metal hip joint replacements.
  - The European Commission's proposed revision of the clinical trials directive. This aims to streamline the processes for approval of clinical trials, thus speeding up the initiation of clinical trials, but would also increase transparency, so ensuring that clinical trials with unfavourable results are made public, thereby avoiding 'publication bias'. For NICE, the transparency aspect is particularly important in that it consolidates our efforts to make recommendations on the use of medicines in the NHS based on all the evidence available from clinical trials. Importantly, this increased transparency will allow UK patients to gain from a better understanding of the benefits and risks of treatment.
  - The establishment of the permanent voluntary Health Technology Assessment network under article 15 of Directive 2011/24 provides the opportunity for the UK to share its expertise and learn from others through the development of coordinating infrastructures.
10. However, we have a concern that proposed amendments to a European Commission proposal on a new legal framework for data protection, which is now before the European Parliament, might have the effect of hindering important health and public health research.
11. The Commission's proposals<sup>28</sup>, as described in the 'recital' (or formal preamble to the articles of the regulation), include health purposes among public interest grounds justifying exceptions to a prohibition on processing sensitive personal data. These health purposes include 'public health and social protection and the management of health-care services, especially in order to ensure the quality and cost-effectiveness of the

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<sup>28</sup> See Proposal for a regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), European Commission, January 2012. [http://ec.europa.eu/justice/newsroom/data-protection/news/120125\\_en.htm](http://ec.europa.eu/justice/newsroom/data-protection/news/120125_en.htm)

procedures used for settling claims for benefits and services in the health insurance system, or for historical, statistical and scientific research purposes'. Personal data used for historical, statistical and scientific research purposes would include '[p]atient registries set up for improving diagnoses and differentiating between similar types of diseases and preparing studies for therapies'.

12. If accepted, an amendment from the Parliament's Committee on Civil Liberties, Justice and Home Affairs would remove 'historical, statistical and scientific research purposes' from the recital as justifications for use of personal data (amendment 27)<sup>29</sup>. The committee's view is that: 'Processing of sensitive data for historical, statistical and scientific research purposes is not as urgent or compelling as public health or social protection. Consequently, there is no need to introduce an exception which would put them on the same level as the other listed justifications.'
13. Consistent with this, the committee's amendments to article 81 of the framework on 'processing of personal data concerning health' have the effect of establishing much more stringent conditions than proposed by the Commission on use of personal data for historical, statistical or scientific research purposes. Use of personal data would be permitted only with the consent of the data subject (amendment 327); and member states' law could provide for exceptions to the requirement of consent for research, only with regard to research that serves an 'exceptionally high public interest, if that research cannot possibly be carried out otherwise' (amendment 328).

#### General

- **Is there evidence of any other impacts resulting from EU action in health that should be noted?**
  - **Are there any general points you wish to make which are not captured above?**
  - **Are there any published sources of information to which you would like to draw our attention for the purposes of this review?**
14. No comment.

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<sup>29</sup> See the draft report of the Committee on Civil Liberties, Justice and Home Affairs (16/01/13) at <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fNONSGML%2bCOMPARL%2bPE-501.927%2b04%2bDOC%2bPDF%2bV0%2f%2fEN>

## National Institute for Health and Care Excellence

NICE have been involved in discussions regarding the establishment of the permanent voluntary network through its participation in the EUnetHTA Joint Action Initiatives and membership of the Cross-Border Healthcare Expert Group to assist the Commission in preparation of the implementing acts under Art.15.3 of Directive 2011/24/EU. Throughout our participation in the Joint Actions, and when giving advice to the Commission, we have emphasised the need to develop systems that allow HTA organisations in Member States to consolidate the work they are already required to do within their healthcare systems. We have emphasised that, in our view, the priority for the permanent voluntary network does not lie in the production of HTA reports. Rather, it is much more beneficial to collaborate on activities that enhance the work already undertaken by HTA agencies by providing a coordinating structure that facilitates, for example, the following activities:

- information exchange
- capacity building, especially in countries that do not have well developed HTA systems
- development of templates for the submission of information required by HTA bodies
- development of initiatives that aim to consolidate the methodologies of HTA

## NHS Blood and Transplant

- *How does the EU's competence in health affect you/your organisation?*

### **A. Regulation.**

The major impact on the UK blood services over last 10 years has been as a result of the UK legislation arising from EU Directives on blood, tissues & cells, organs and clinical trials, together with amendments to the Medicines Directives to cover manufacture of Investigational Medicinal Products Advanced Therapy Medicinal Products. Much work was required initially across the services to achieve compliance with each of those requirements.

These Directives have been in place for varying lengths of time, from > 10 years for blood to a few months for organs. Therefore, the evidence available on benefits and disbenefits varies considerably. For example, there are no clear benefits yet for UK patients from the Organ Donation Directive as it is too soon to say what benefits might accrue from the new national reporting system launched in September 2012, and driven by the Directive.

### **Advantages of EU level regulation of blood, tissues and organs.**

- Sets agreed minimum standards internationally, facilitating movement of blood components, tissues, cells and organs across national boundaries to the benefit of patients.
- Some improvements in transfusion practice seen in hospitals are as a result of the Blood Directive e.g. improvement in traceability.
- Indirectly, the regulations have driven greater information-sharing across EU providers, which in turn improves practice eg the European Blood Alliance (EBA) was formed partly in response to the Blood Directive. This is an organisation comprising not-for-profit blood suppliers across Europe (not all in the EU). One of its functions is as a lobbying organisation to the Commission, but other benefits have accrued eg benchmarking on productivity, and the European Infectious Diseases Monitor, a regular conference call of members to alert one another to emerging infectious threats.
- The EU Directives have been the impetus for the establishment of national reporting systems for errors and serious complications of blood transfusion, tissues and most recently organ transplantation. The clinical benefits from such systems can take some years to be realised, but data from the Serious Hazards of Transfusion haemovigilance system have directly driven blood safety initiatives eg for prevention of Transfusion-Related Acute Lung Injury and bacterial contamination of platelets.
- The Directives set minimum standards for all countries. If the UK is able to achieve higher standards than in the Directives, we may have a competitive advantage eg in tissue exportation (although vCJD currently prevents this)
- Regulation and independent oversight by Competent Authorities has increased quality and consistency and reduced errors eg by reducing manual interventions and transcription. This in turn increases user and public confidence in our services and improves patient outcomes.
- In areas where there was no national regulation eg tissues, the Directive was a major driver in achieving national consistency.

### **Disadvantages of EU-wide legislation**

- Transposition of the Directives into UK law, and then interpretation of the law by regulators provides two opportunities to ‘gold-plate’ the requirements, with increasing costs but without the need to demonstrate cost-effectiveness. Three examples illustrate this:

A. The UK haemovigilance scheme SHOT was established in 1995 in anticipation of the EU Blood Directives. Initially voluntary and led by health care professionals, it became a required standard for laboratory accreditation and had a very high degree of participation from hospitals. Once the Directives were in place, the UK also established the SABRE reporting system for blood incidents, run through the MHRA. This created complexity for reporting hospitals, as well as requiring additional resource. SHOT and SABRE now produce a joint report; the added value for patients of SABRE reporting remains to be proven.

B. Licencing of organ retrieval and transplant units was not mandated in the EU Organ Donation Directive, but is required by HTA.

C. Similarly, there is a requirement in England under the Human Tissue Act for licensing of premises providing tissues for research. This includes operating theatres if tissues from deceased donors are taken during retrieval of organs for donation. This is not required in Scotland, which has its own legislation, yet also based on the same Tissues and Cells Directive. This illustrates the issue of different degrees of stringency in interpretation of EU Directives when they are drafted into national legislation.

- The EU Blood Directive contains technical appendices, and one result of this is that achieving changes in technical requirements in response to new evidence or threats is slow. Even when we had ‘rapid’ derogation of donor selection criteria to maintain supplies in response to the swine flu threat, this took some months (swine flu began April 2009, change in EU law 4 November 2009).
- Any permanent changes need agreement between all countries, followed by a change in EU law, followed by change in UK law. The only change so far enacted at EU level has been removal of the upper limit of platelet pH, which has so far not been translated into UK law.
- Inadvertent restrictions in the wording of Directives cannot be rapidly rectified eg in the EU Blood Directive, donation testing is not included as an alternative to 28-day donor deferral for travellers returning from West Nile Virus endemic areas. Such deferrals threatened blood supplies to meet contingency requirements during the Diamond Jubilee and Olympics. Achieving a UK derogation to permit this involved many months of negotiation at EU level, the MHRA and two different health ministers. Many countries in the EU now wish the wording in the Directive to be altered to allow this alternative to be made permanent, but it is not clear when this can be achieved.
- EU countries do not start on a level playing field with regard to transfusion and transplant practice. Therefore it is difficult to obtain consensus on standards which some countries will struggle to meet initially.

- *What evidence is there that EU action in health advantages or disadvantages:*
  - o *The UK national interest*

The UK was already engaged in promoting transfusion and transplantation best practice and putting resource into this before the Directives. Blood Services required quality systems since the early 1990s, against a background of HIV and HCV transmission, and the removal of Crown Immunity from NHS premises. The major disadvantage of the Directives is that each has

required much resource to implement, and there are ongoing resource implications eg in trying to influence changes across the EU.

The UK has a record of implementing EU regulation to an extremely rigorous standard, which is sometimes perceived to be in contrast to the approach taken in other member states. This could put UK organisations at a disadvantage (see below).

## **B. Product Liability.**

The EU Directive on Product Liability 1985 was transposed into UK law as the Consumer Protection Act 1987. In the civil action brought against the National Blood Authority by patients infected with hepatitis C in 2001, it was conceded (even prior to the judgement) that blood could be regarded as a product under the Act. This resulted in some outcomes that are good for patients:

- Blood Services provide material explaining transfusion risks and, more importantly, alternatives to transfusion. There is now also consensus that documented consent for transfusion is required.

- Blood Services are now obliged to investigate all new technologies which might improve blood safety (there is no obligation to implement every one)

- Blood Services have developed a safety framework to guide standardised decision making

- Patients who are harmed by a transfusion no longer have to prove negligence, so they can be compensated without going to court.

However, there are less favourable implications of blood being regarded as a product:

- it opens the door to organs being considered as products under CPA. This has not yet been tested in court, but could drive risk averse behaviour, and thus deprive patients of life saving transplants

### *o Business and industry*

The tissues sector potentially benefits from a more level playing field regarding quality and safety standards, but it is not clear that the costs of obtaining regulatory approval and authorisation to operate are the same across member states, giving advantage to some operators in other EU countries.

- The Directives facilitate exchange of blood, stem cells, tissue and organs. This is introducing more competition for UK businesses from other EU providers. Production of EU standards facilitates competition, which in transfusion is not desirable as it destabilises the relationship built up over years between a nation's donors, its blood service and its hospitals. For example, emergence of a commercial blood provider in an EU member state took donors and hospital contracts away from the not-for-profit national provider. When the commercial supplier withdrew the service, the national provider had to again start to supply hospitals at short notice.

### *o Patients and citizens*

Patients are likely to benefit from the improved Quality Systems in hospitals and from new suppliers from an EU wide supply chain, for example novel cell based treatments which are not yet available in this country can be imported for named patients.

- *Please consider what evidence there is to demonstrate;*
  - o the extent to which the EU's role in public health supports member state actions effectively and efficiently*

Many of the comments above in relation to transfusion apply here. An additional point is that member states need the freedom to set local policies based on their own population epidemiology. This is relevant for the selection of blood donors, where too specific requirements can impair flexibility. As well as the West Nile Virus example discussed above, other donor selection policies are not optimal if the details are specified transnationally eg relating to men who have had sex with men.

*o the opportunities and costs for the delivery of health and social care in the UK that flow from wider EU competences and policies such as the free movement of workers or the single market generally.*

The ease with which young scientists from across the EU can contribute to UK health research is welcomed. The corollary is that it can be cumbersome to recruit a specific individual from outside the EU to a key post.

The situation with medical staff is more complex. While the UK might endeavour to balance medical school places with eventual demand for doctors, this is not yet achieved across the EU. Therefore, there is a risk of an imbalance between UK graduates and those from other EU countries in competing for UK post-graduate training places.

*o the extent to which EU competence and policies intended to allow EU citizens to access healthcare across the EU are effective and proportionate*

This can create imbalance in organ provision/transplantation, if citizens from one country can be transplanted in another without reciprocal provision of organs.

*o the extent to which health objectives are effectively and proportionately taken into account in wider EU policies.*

### **Any impacts of Working Time Directive here**

### **Future options and challenges**

- *How might the UK benefit from the EU taking more action in health?*

A pro-active role in monitoring and communicating with members regarding emerging infections relevant for transfusion/transplantation would be useful. This role, however, is being well fulfilled by the European Blood Alliance Emerging Infectious Disease monitoring group.

EU-wide registries eg in organ transplantation would help answer questions on rare issues.

- *How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?*

The issue with the EU Blood Directive is the inclusion of Technical Appendices, which set out in detail the standards that are to be met. These are not systematically supported by a transparent evidence base. For example, EU changed the haemoglobin thresholds for blood donors, without taking into account different population norms, and without specific evidence. Proposed changes now have to be evidence-based, which is welcome, but have to be agreed at EU level. This is neither speedy nor easy. Taking responsibility for setting detailed blood transfusion specifications nationally rather than at EU level will mean that these can be made appropriate for the UK, and be up to date and evidence based. New evidence can be reviewed more promptly and translated into revised guidelines / standards. This will ultimately have benefits for the safety of donor and recipient and security of the blood supply, as the UK requirements will be taken into account when considering revisions. This would also be true for tissues, cells and organs.

- *How could action in this area be undertaken differently e.g.*
  - *Are there ways of improving EU legislation in health, e.g. revision of existing legislation, better ways of developing future proposals, or greater adherence to the principle of subsidiarity and proportionality?*

Possibly through even more rigorous consultation and listening to national issues around implementation impacts – for example revision of Medical Device Directives.

The issue of medical devices remains problematical for Blood Services. The CE marking system permits devices to be licenced for use that meet laboratory requirements for biocompatibility but which have never been tested in patients. This can be true even of new technologies eg prion filters, methylene blue treatment of plasma. This means that, in order to provide clinicians and patients with evidence for the safety of blood components treated by new devices, Blood Services have to fund and sponsor safety trials themselves.

At the same time, proposals regarding in vitro diagnostics would require organisations to CE mark reagents used only in house. This will be hugely costly for the NHS, yet no evidence has been presented to suggest that the current system causes any problems for patients.

- *Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest?*

(1). Greater acceptance by regulators of data generated in another country.

(2) Member states are required to provide haemovigilance data to the EU. To date, there has been minimal feedback/education to close the audit loop. EU should demonstrate the added value of central data provision.

- *Could action be taken at any other international level i.e. by the WHO?*

The Council of Europe already has a process set up to set transfusion guidelines for a wider area in Europe than the EU. Currently their guidelines are not legislative in most EU countries,

although they have been adopted by Australia [Note: this is not a typo, it is Australia]. However there is beginning to be more cooperation between EU and CoE, and the standards in the CoE guide may eventually be adopted as an Annex of the EU Directive. Involvement with this organisation and these guidelines has the advantage for the UK of being part of a wide network which facilitates sharing of best practice, with translation of those guidelines which are appropriate to the UK into UK national guidelines.

We do not see a specific role for WHO in this area, as there are such differences in the needs of the developed and developing world.

In the area of tissue banking and cell therapies, the production, or adoption of harmonised European Standards, covering at least safety and quality such as those produced by the CoE, JACIE and EATB under the legislation in areas would help ensure a more level playing field and prevent unfair competition. These should cover at least standards for safety and quality systems.

- *What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?*

Do transfusion guidelines need to be enshrined in law? Probably yes to ensure that minimum standards which ensure safety of donor and recipient are attained; probably no for the technical detail.

- *How else could the UK implement its current obligations?*

By setting its own national standards, based on international best practice and research evidence.

- *What future challenges/opportunities might we face in EU health competence and what impact might these have on the national interest?*

There may be future challenges in terms of the economic ability of some member states to afford to implement changes to legislation. There will certainly be pressure to not make change unless there is a clear evidence base.

- *What impact would any future enlargement of the EU have on health competence?*

Increased complexity and time in making consensus decisions.

## **General**

- *Is there evidence of any other impacts resulting from EU action in health that should be noted?*

The creation of EU funding for health research is a highly welcome step. This permits conduct of collaborative studies/clinical trials of such a size and/or in a timeframe that simply would not be possible in a single country.

## NHS European Office

We have based our response on the questions asked in the public call for evidence. We have not responded to every question, but rather have concentrated on where we feel we can add most value. This response also covers issues of relevance to the reviews of other government departments. We are happy for the response to be used in these reviews.

### **Impact on the national interest**

#### **• How does the EU's competence in health affect you/your organisation?**

The NHS European Office was established with the specific remit to represent the NHS in England to EU decision-makers and to monitor EU developments in health policy of importance to the NHS. The EU's competence in health therefore affects our work directly. For example, we are currently working to influence revisions to several important pieces of EU legislation in the area of health in the interest of the NHS, including:

- Clinical trials
- Medical devices and *in vitro* diagnostic medical devices
- Tobacco products

However, the EU health interest runs much wider than the EU health competence, and several other areas of EU competence also directly affect the NHS, such as EU law on health & safety at work, internal market, competition, environment and energy. Our Office engages with developments in these areas; for example, we have engaged with the revisions of EU directives on:

- Public procurement
- Data protection
- Mutual recognition of professional qualifications
- Working time

Our Office also has a role in working closely with the UK government in advance of an agreed piece of EU legislation being implemented into UK law, ensuring that any exemptions or areas of national responsibility are utilised appropriately, and that any new duties on the NHS arising from EU law are correctly administered. For example, the EU Directive on patients' rights in cross-border healthcare must be implemented into UK law by October 2013 during a period of significant change in the NHS. We have been working with DH colleagues to ensure that new NHS Clinical Commissioning Groups are made aware of their responsibilities under the new Directive and that they are not too onerous in their scope.

#### **• What evidence is there that EU action in health advantages or disadvantages:**

##### **o The UK national interest**

The UK is the largest EU Member State beneficiary of **EU funding into health research**. Throughout the first six years of the EU's current seven year Framework Programme for research (FP7), the UK received over €570m in EU funding, over 17% of the whole EU contribution and €30m more than Germany, the second highest beneficiary. There is no doubt that this funding and the further collaborations that have grown out of it, have helped cement the UK as one of the leading clinical research centres in the world, attracting clinicians and researchers to the NHS and enabling the development of numerous clinical and non-clinical health related advances.

While we are aware of numerous EU research projects specifically involving NHS organisations, there are also similar UK success stories across the full range of EU funding programmes,

enabling UK public and private actors to research, develop and deploy innovations on a wider scale.

For the period 2014 - 2020, EU research and innovation funding will be organised through the Horizon 2020 programme. Horizon 2020 will have a budget that exceeds that of FP7 and commit around €8-9bn specifically to health-related research. The expectation is that the UK will again be at the forefront of utilising this research funding and we are working to ensure the NHS is aware of, and engaged in, the new EU funding landscape.

o ***Patients and citizens***

EU action in health can prove an important safeguard for patients and citizens. For example, the main intention of the existing **EU Clinical Trials Directive** was to improve the safety and quality of clinical trials across Europe. This has largely been achieved, however as the European Commission's 2012 proposal for a new Regulation on clinical trials makes clear, this has come at the expense of the ability to undertake a high number of trials - depriving patients of new medical discoveries.

**EU rules regulating the authorisation and the placing on the market of new medicinal products for human use** also play an important role in terms of guaranteeing safeguards for patients and citizens. Furthermore, once a medicinal product has been authorised and placed on the market, its safety is monitored throughout its entire lifespan to ensure that, in the event of adverse reactions that present an unacceptable level of risk under normal conditions of use, it is rapidly withdrawn from the market. New EU rules aimed at strengthening existing legislation on pharmacovigilance have been agreed recently to ensure greater protection of public health. Similarly, **EU Directives on medical devices**, which regulate the placing on the market of medical devices, are currently being revised to ensure a greater level of protection and safety for patients and consumers.

• ***Please consider what evidence there is to demonstrate;***

o ***the extent to which the EU's role in public health supports member state actions effectively and efficiently***

There is widespread acceptance that public health challenges cannot solely be met within national borders. It is therefore important that the EU helps coordinate and support Member States where most appropriate. For example, in the area of **organ donation and transplantation** EU action can bring significant added value. In 2011, 30,000 organs were transplanted in the EU, many of which were shipped across borders. The role of the EU in facilitating the cross-border exchange of information about organs and their donors is therefore an effective way of supporting the UK's health system in treating patients in need.

Similarly, EU action in the field of rare diseases brings particular added value given the low prevalence of these diseases and the need to concentrate expertise and knowledge to foster progress in the diagnosis and treatment of these conditions.

o ***the opportunities and costs for the delivery of health and social care in the UK that flow from wider EU competences and policies such as the free movement of workers or the single market generally***

The fundamental principles governing the EU's single market - free movement of goods, services, and citizens - increasingly apply to the delivery of health and social care in the UK and to the NHS.

For example:

- the NHS has benefited significantly from the free movement of workers, many of whom have entered the UK health sector under the **EU Mutual Recognition of Professional Qualifications Directive**. Currently, more than 9% of the doctors on the General Medical

Council's register qualified in other parts of the EEA. In 2010, the GMC granted registration to over 2,900 doctors under the provisions of the Directive.

We strongly support the principles of mutual recognition and free movement, but we believe these mustn't be at the expense of safety and quality of healthcare. This is why in the context of the revision of the existing Directive, our office has pressed for a more balanced approach between facilitating the movement of professionals and maintaining sufficient quality and safety standards by checking the competence and suitability of health professionals who qualified abroad.

- the **European Working Time Directive** has had a significant impact on the health sector. Through a combination of more staff, greater team working and changing working patterns, the NHS has implemented the 48-hour working week for the vast majority of staff. In spite of these changes, some services continue to face challenges, notably smaller or isolated hospitals that do not lend themselves easily to solutions implemented in other parts of the NHS. Maternity and paediatric services have also experienced problems as they are staffed by specially trained doctors who need to be in the hospital to respond to emergencies.

The narrow interpretation by the European Court of Justice of the rules, notably around "on-call" time and "compensatory rest", has impacted adversely on staffing levels, costs and time available for patient care. Hospitals have had to significantly rearrange working patterns to avoid situations such as cancellation of clinics and outpatient or inpatient procedure lists at short notice.

While it is essential for workers in the healthcare sector to have adequate rest, both for their own safety and that of their patients, we are convinced that the Working Time Directive needs updating and allow for more flexibility in local implementation.

- The **EU Directive on patients' rights in cross-border healthcare**, agreed in March 2011, seeks to clarify the right of patients to receive healthcare in other EEA member states and to be reimbursed by their healthcare system.

The Directive, when implemented, is expected to provide more clarity to NHS commissioners on how to deal with requests from patients willing to receive healthcare in another EU member state.

Future trends in the area of cross-border healthcare are difficult to predict due to the very limited information on current levels of cross-border healthcare in Europe. In the short term, it will take time for the Directive to bed in, for the rules to be understood and for the message to get out to the public. It is however possible that over time the number of outgoing and/or incoming patients could increase.

Our briefing "*Patient choice beyond borders: implications of the EU Directive on crossborder healthcare for NHS commissioners and providers*", which can be downloaded from our website, provides additional views on the potential implications of the Directive.

- As public bodies, NHS organisations are subject to **EU public procurement rules**, which govern the way in which public bodies purchase goods, services and works, and seek to guarantee equal access to and fair competition for public contracts within the EU market. NHS organisations often perceive the current rules as very onerous, both in terms of cost and the

level of administration. There is also a lack of legal clarity on their application which results in an increasing number of NHS bodies requesting legal advice in this area.

o ***the extent to which EU competence and policies intended to allow EU citizens to access healthcare across the EU are effective and proportionate***

It is important to note that EU law regulating cross-border access to healthcare in the EEA has arisen through various rulings in the European Court of Justice, reflecting the natural movement of citizens across borders. EU competence in this area has therefore largely followed the patient, rather than the other way round, resulting in an evolving system of administrative duties.

As mentioned earlier, the EU Directive on patients' rights in cross-border healthcare has yet to be implemented into UK law meaning it is too early to draw conclusions on its impact and proportionality.

o ***the extent to which health objectives are effectively and proportionately taken into account in wider EU policies***

While EU Impact Assessments across the range of legislative proposals often directly address the foreseen impact on public health, we believe this is a rather narrow approach that does not reflect the potential impact on health systems as a whole. This is a particular concern in the current climate where health systems are facing serious financial and demographic challenges.

### **Future options and challenges**

• ***How might the UK benefit from the EU taking more action in health?***

We believe better coordination in certain areas at EU level can bring benefits for the UK. One example would be increasing the accessibility to and understanding of the results of the many EU funded projects, which would be of significant interest at both national and local level in our health system. This would not require an increase in the EU's health competence, but rather better coordination of the areas for which it already has responsibility.

• ***How could action in this area be undertaken differently e.g.***

o ***Are there ways of improving EU legislation in health, e.g. revision of existing legislation, better ways of developing future proposals, or greater adherence to the principle of subsidiarity and proportionality?***

Several pieces of EU legislation in the area of health are currently being revised – both periodically and in response to specific criticisms - and will have important implications for the NHS. To fully understand these implications it is essential that the UK Houses of Parliament operate proper means of scrutiny of the full range of EU proposals, giving domestic MPs a chance to understand and discuss the issues in parallel with the developing European Union legislative process. Such a form of scrutiny would go some way to ensuring the UK has a clear view on its negotiating strategy in Brussels, including when the UK needs to work with other Member States and Members of the European Parliament on a specific issue.

Another important aspect is the clarity of the impact assessment, both at the level of the associated EU document and as drafted by the UK government. The role of the impact assessment is crucial in determining the full implications of an EU proposal for the UK and the level of response which actors in the UK should place on it. One suggested means of improving the impact assessment process could be to widen the scope of organisations consulted during its drafting. This is particularly important in the English health landscape going forward, where several new national organisations will hold system responsibility.

o ***Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest?***

The economic value of health and social care is now increasingly understood at national member state level. Despite this the specific health competence at EU level is not always reflected in the approaches of the other European Commission Directorates General (DG). We would like to see more coordination at EU level between the respective DGs in the Commission in ensuring the health aspects of a policy have been taken into account in the formulation of their work programmes.

An example of where such cross-EU coordination is benefitting the national interest is in Research and Innovation work. The European Innovation Partnership on Active and Healthy Ageing, initiated in October 2010 to tackle the common challenge of an ageing population in Europe, brings together public and private stakeholders to develop innovations which can improve the quality of life of older people, whilst simultaneously creating market opportunities for businesses. The concept developed from cross-DG discussions and reflects well the model necessary to leverage the most benefit from EU and national actors in an area of increasing importance.

o ***What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?***

Given the breadth of measures covered it is difficult to comment on the merits of each of them individually. Nevertheless, our responses to other questions of this consultation provide information on the merits of some EU initiatives.

• ***What future challenge/opportunities might we face in EU health competence and what impact might these have on the national interest?***

Health systems across Europe are facing common challenges associated with the demographic change and the increase in healthcare demand. These challenges will last well beyond 2020 and Member States and the EU Institutions should be reflecting now on how best to respond - collectively and individually – to this challenge in the long term.

This discussion should respect the national competence for the resourcing, planning and running of a Member State's own health system, and focus on supporting the development, spread and adoption of innovations, systems and ideas in health and social care delivery which can be applied across Europe.

It is possible that the reach of the EU's health competence will seek to extend in the future, reflecting the increased movement of citizens and services across borders and the commonality of the above mentioned demographic challenge. This would bring with it the challenge of ensuring that any extension is appropriate and structured in such a way to bring benefits to our healthcare sector.

**General**

• ***Are there any published sources of information to which you would like to draw our attention for the purposes of this review?***

We have covered a range of EU issues relevant to the NHS but this response is not exhaustive. Our website [www.nhsconfed.org/europe](http://www.nhsconfed.org/europe) is a helpful source of information to complement this response. We would be happy to discuss anything in this response in more detail.

## NHS Partners Network

The NHS Partners Network is the trade association representing the widest range of independent sector providers of NHS services ranging through acute, diagnostic, primary and community care. Our members are drawn from both the “for profit” and “not for profit” sectors and include large international hospital groups and small specialist providers. All are committed to working in partnership with the NHS and to the values set out in the NHS Constitution. Our members deliver care ranging from primary to acute elective provision as well as out of hours and home-based services. NHSPN is one of the networks of the NHS Confederation – the independent membership body for the full range of organisations that make up the modern NHS.

### General comments

The NHSPN The NHS Partners Network (NHSPN) is pleased to respond to the Department of Health's call for evidence on the Review of the Balance of Competences: Health. We recognise the rationale and purpose behind the Review and look forward to further engagement and discussions with the Department of Health in due course. Despite health policy being a matter for individual Member States, we recognise that the EU has an important role to play in issues related to public health and healthcare. In this response, we intend to outline some key areas of interest and concerns related to the EU and health and provide evidence where appropriate. In line with the request from the Department of Health, we will not attempt to improve or amend the wording or specific areas of legislation, but instead keep our comments relatively high level and balanced.

At this juncture, we would also like to point out that a number of EU issues affecting the independent health sector may be more suited in the Reviews for other Government Departments such as the Department for Business, Innovation and Skills, Home Office and Department for Work and Pensions. We do not intend to duplicate our comments and so will tailor our responses where appropriate.

1. The NHSPN is supportive in theory of point 13.2 of the call for evidence, which outlines the EU Directive related to the recognition of professional qualifications. It is crucial that the EU continues to act under an Internal Market treaty base to enable the free movement of workers within the EU, including healthcare professionals. Many sectors and employees within the healthcare industry benefit enormously from this Directive.

However, we are concerned that the 'listed professions' for health professionals within this Directive are too narrow and therefore not always conducive to the needs of the independent health sector. For example, whilst it is sensible that the minimum training for doctors, dentists, nurses, midwives and pharmacists are harmonised to enable automatic recognition of their professional qualifications throughout the EEA, we would strongly encourage the Directive to recognise other classes of professions. For instance, the recognition of the biomedical scientist qualifications across borders would greatly benefit independent sector providers who would welcome the opportunity to train or move staff across within and different EU Member States, where a company might have subsidiary international operations.

2. The EU has shared competence with Member States on employment policy, which impacts the whole UK economy including the health sector. In the context of health, the Working Time Directive has implications for delivering the health service. We do not intend to comment on the wider debates surrounding the operational implications of this Directive to medical professionals. Instead, we would like to highlight to an area we believe is not currently covered by this Directive.

For instance, despite overall restrictions of doctors' working hours, it is unclear what implications this has on consultants who undertake private health work outside their NHS remit. While there is no evidence that the current position is in any way detrimental to patient safety in the independent sector, the lack of clarity may not be helpful and we would welcome further engagement or information on this issue.

3. The Cross - Border Healthcare Directive clarifies patients' rights to access safe and good quality treatment across EU borders, and be reimbursed for it. We recognise the enormous benefits this brings to patients if they are subject to the same conditions that apply to accessing treatment at home. However, we are concerned that the Directive in its current form does not provide sufficient information about reimbursements or the process for reimbursements for mainland European patients who are accessing independent sector healthcare under the 'choose and book' system in the United Kingdom. We would welcome further information and engagement on this issue.

## North of England EU Health Partnership

The North of England EU Health Partnership (NEEHP) is an expansion of the North West Health Brussels Office, operating since 2004 in the North of England. NEEHP assists organisations to explore opportunities and impacts of European Union (EU) policy, legislation and funding that may influence health, and which may provide opportunities to health services and organisations responsible for public health, in the North of England. It aims to:

- Act as a **Health Advocate** to position and influence within Brussels, ensuring that **EU policies and opportunities add value** to health related organisations across the North.
- Act as a **conduit for two-way knowledge transfer** to promote and disseminate **innovative healthcare practice** and research between EU member state peers and organisations across the North of England.
- Provide **early warning** and act as a **knowledge broker** to support Northern organisations in **EU funding applications**.

We welcome the Department of Health call for evidence on health and detail our response, drawing on our position and experience as an organisation. Our comments represent the views of our organisation and members.

### 1. Overview

#### ***How does the EU's competence in health affect you/your organisation?***

NEEHP's role is to act as a knowledge broker and advocate between the EU and the North of England. EU legislation and policy that has a direct effect on the health community in the North of England is of interest and importance to us. The organisation is based on the premise that EU policy should be influenced by current evidence and best practice and should be incorporated and supported by our health partners. We support public and voluntary sectors organisations in EU funding applications, allowing them to access necessary and vital funding streams to innovate and initiate high quality research and development.

For our organisation to be successful we need to appreciate EU competence on specific health topics and be able to support the implementation of directives within our member organisations.

It must be appreciated that many of the EU competences relating in any way to health are closely associated with the Single Market, and the manner in which this affects services related to health (e.g. competences relating to pharmaceutical products, medical devices, offering of health services across borders, and even legislation to limit market activity in blood products, tissues and organs, etc.). We believe it would difficult to alter competence in these areas while remaining within the Single Market.

#### ***What evidence is there that EU action in health advantages or disadvantages:***

##### ***The UK national interest?***

##### ***Business and industry?***

##### ***Patients and citizens?***

As an organisation that supports partnership working between the EU and the North of England we see the direct benefits of EU action in health as;

18. Improving health outcomes by supporting work to address key health challenges: cancer, heart disease, obesity, social inequity within the region and the effects of alcohol.
19. Increasing collaboration across the region and between regions and member states
20. Enabling high quality research
21. Capacity building of individual organisations

***Please consider what evidence there is to demonstrate;***

***a. The extent to which the EU's role in public health supports member state actions effectively and efficiently***

The EU's competence on health and health topics allows policy and practice within the UK to be guided by best practice and internationally recognised standards. In the UK this has a direct impact on health and health related policies linked to the wider determinants of health, e.g. diet and nutrition, transport, employment.

***b. The opportunities and costs for the delivery of health and social care in the UK that flow from wider EU competences and policies such as the free movement of workers or the single market generally.***

Free movement of services: the patients' rights in cross border healthcare directive will be transposed into UK law by 25 October 2013. This Directive clarifies existing case law in the field and is not predicted to substantially alter UK patient flows. Opportunities for tertiary care health trusts may arise through the creation of specialist reference networks, which aim to connect centres across Europe to share knowledge and expertise in diagnosing and treating complex clinical cases.

Free movement of workers: the free movement of regulated health professionals, under appropriate conditions, can help ameliorate specific health workforce shortages in the UK. The EC estimates that there are shortages in 35 specific health-related professions in the UK, including medical practitioners, specialist nurses, midwife and therapists. Estimates for 2014 are that the average number of entry-level posts for specialty training will be around 6511. Unless training posts are revised accordingly, there might be a shortage of GP and medical specialists of more than 6,000.<sup>30</sup> Less than a decade ago, when there was a serious shortage of junior doctors in UK, hospitals came to rely on doctors trained in other EU member states.

Currently, the UK actively participates in a current joint action on forecasting health workforce needs, which may assist with improved health workforce planning in respect of professional mobility.

***c. The extent to which EU competence and policies intended to allow EU citizens to access healthcare across the EU are effective and proportionate***

The Commission's original proposal for the third community programme in health – Health for Growth programme<sup>31</sup> – illustrates an increasing tendency for EU action to be focussed on matters related to healthcare organisation and delivery. This can potentially extend beyond the current EU competence in health, which is primarily concerned with public health issues (health promotion and health protection in particular) and legislation stemming from completion of the internal market. However, concerted UK national action was effective in reorienting the Health for Growth proposal towards public health.

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<sup>30</sup> Commission Staff Working Document on an Action Plan for the EU Health Workforce  
[http://ec.europa.eu/dgs/health\\_consumer/docs/swd\\_ap\\_eu\\_healthcare\\_workforce\\_en.pdf](http://ec.europa.eu/dgs/health_consumer/docs/swd_ap_eu_healthcare_workforce_en.pdf)

<sup>31</sup> Regulation establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020 [http://ec.europa.eu/health/programme/docs/prop\\_prog2014\\_en.pdf](http://ec.europa.eu/health/programme/docs/prop_prog2014_en.pdf)

The Europe 2020 strategy<sup>32</sup> presents a framework for boosting growth in the Union during the current decade. As such the strategy is focussed on smart investment and job creation plans, with health viewed as a cross-cutting priority in the strategy. The strategic priorities of the key flagship initiative related to health under strategy – the pilot European Active and Healthy Innovation partnership<sup>33</sup> - demonstrates how the focus of Europe 2020 has led to framing the EU's health competence under economic parameters, neglecting areas such as health promotion that are more in line with the treaty obligation for health.

***d. The extent to which health objectives are effectively and proportionately taken into account in wider EU policies***

The UK presidency of the European Union in 2005 pioneered the consideration of health inequalities as a policy priority at the EU level. Following this, the Finnish Presidency of 2006 launched Health in All Policies (HiAP) as one of its key priority areas for its Presidency programme. The European Commission's impact assessment process compels EC directorates to take health into consideration within the consideration of all policies. However, the delay to which the recently adopted EC proposal for a revision of the tobacco and related products directive was subject in the EC inter-service consultation raises a number of worrying questions regarding how seriously the HiAP principle is applied to EU legislation.

The present framework for Cohesion Policy [2007-2013] earmarks €5 billion for health infrastructure investment. Moreover, the European Social Fund deals directly with a number of key social determinants of health, such as labour market mobility, social inclusion etc. In the UK, use of the Structural Funds for health improvement has been traditionally low, despite the significant potential for investment in projects designed to address the social determinants of health.

The Commission proposal for structural funds for the next programming period includes a priority on reducing health inequalities, whilst the potential to harness the Structural Funds remains feasible in all thematic areas of concentration. The challenge is for the UK to apply systematically a health equity lens, building on the Marmot review, to integrate the consideration of the potential positive impacts of health over the long term that these significant investments can make, for example, through application of sustainable active labour market policies and accessibility strategies for vulnerable groups.

To their credit the EC has financed several important projects on these topics – EUREGIO III, Health Gain, Equity Action - and continues<sup>34</sup> to stress the importance and relevance of health to Cohesion Policy. However, the responsibility lies with Member States and regions to implement these funds in an equitable manner.

The Common Agricultural Policy (CAP) has contributed to maintenance of good health across Europe (including in the UK) by ensuring security of food supplies, and by protecting and supporting rural economies. However, there is a strong case for further reforms of CAP to be agreed, in the interests of health promotion<sup>35 36</sup>, for example by removing subsidy from

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<sup>32</sup> Europe 2020 Strategy <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:2020:FIN:EN:PDF>

<sup>33</sup> EC Communication - Taking forward the Strategic Implementation Plan of the European Innovation Partnership on Active and Healthy Ageing: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52012DC0083:EN:NOT>

<sup>34</sup> Lloyd-Williams F, O'Flaherty M, Mwatsama M, Birt C, Ireland R and Capewell S (2008) **Estimating the cardiovascular mortality burden attributable to the European Common Agricultural Policy on dietary saturated fats**. Bull World Health Organ vol 86 issue 535-541

<sup>35</sup>CA Birt, M Mwatsama, M O'Flaherty, S Capewell, R Ireland. (2008) **Improving health through reform of European agricultural** European Journal of Public Health vol 18 issue Supp 1 pp 128

production of saturated fat-rich foods in favour of subsidising instead healthy alternatives, such as fruit and vegetables.

## **General**

### ***Is there evidence of any other impacts resulting from EU action in health that should be noted?***

Benchmarking between EU member states, both in terms of health outcomes and health expenditure, has been a significant driver for policy change in the UK leading to increasing investment in, for example, comprehensive cancer care. Whilst this process can be potentially sensitive for competent authorities involved, the practice of benchmarking services and outcomes can be invaluable for stimulating positive change. In addition, voluntary targets agreed upon at the EU level can also be a useful tool for improving service delivery, such as with the Digital Agenda target for the digitisation of patients health records by 2015.<sup>37</sup>

Comparing UK services in this area with EU counterparts and engaging in shared learning can lead to significant improvements and the avoidance of replicating costly errors previously made elsewhere in the EU. The North West of England has benefited from several EU-funded projects along these lines; an example is the very successful Healthy Stadia project, which was led by a North West organisation, with sports-related partners (such as UEFA) as partners, and which developed systems for health promotion aimed at populations using sports stadia.

The UK should consider closely the implications for health presented via the European Semester, through which the EC issues country specific recommendations on public budgets, including national healthcare budgets. Consideration should be given to any effect this may have in the future on developed administrations.

**The following subsections detail our response to specific topic areas:**

## **2. Medicinal products**

### ***How might the UK benefit from the EU taking more action in health?***

NEEHP recognises that regulation and strong legislation of medicinal products at a European level is required, as part of a single market, to ensure that consistent high standards are met for all medications, including herbal medicines, for all EU member states. Strong regulation will assist in preventing sales and smuggling of counterfeit medicines across borders. In particular NEEHP acknowledges the importance of schemes such as pharmacovigilance across the EU, which provides a process for rare side effects to be identified more readily. In addition, other projects such as the provision of incentives to industry to research rare conditions (orphan drugs) would not be possible without coordination at a European level.

A European-wide regulatory agency (EMA) is the best way to regulate medicinal products. However in order for the EMA to be able to fully evaluate medicinal products, all clinical trial data should be made available to them. The current best estimate is that half of all the clinical trials that have been conducted and completed have never been published in academic

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<sup>36</sup> <http://ec.europa.eu/digital-agenda/en/pillar-vii-ict-enabled-benefits-eu-society/action-75-give-europeans-secure-online-access-their>

journals<sup>38</sup> and some are not made available to regulators and advisory groups e.g. NICE. The UK government spent £500 million stockpiling Tamiflu (oseltamivir) for pandemic flu, however, Roche is currently withholding clinical trial data<sup>39</sup> and so its true benefits and risks are unable to be assessed. Stronger legislation and regulation may be required at UK and EU levels to ensure that all clinical trial data made available in order to ensure that regulatory and advisory organisations are able to make an appropriate evidence-based decisions.

***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

NEEHP believes that legislation and regulation on medicinal products is more effectively coordinated from the EU level to ensure cross government involvement and that country-level action would not be adequate to regulate the industry. In particular, as the pharmaceutical industry accounts for 8% of the UK manufacturing sector and is also largely profitable in other EU countries, it has the potential to be highly influential over health policy. Therefore, legislating at EU level may reduce the risk of pharmaceutical lobbying in other EU countries where regulation is less stringent.

***How could action in this area be undertaken differently?***

The Clinical Trials Directive has led to a stringent process that leads many researchers to conduct their research outside of the EU<sup>40</sup>. Studies conducted in non-European populations may have different health profiles to UK populations and therefore studies may be less generalisable to the UK. This may lead to patients receiving drugs that are less effective than thought in studies or having additional side effects that have not been noted in non-European populations. Work is currently being undertaken on the Clinical Trials Directive but concerted effort should be made to ensure that legislation will not stifle innovation, while still ensuring rigorous regulation is in place to ensure that trials are conducted in an ethical manner. There are a number of possible means that the EU might add to legislation currently planned, to enable clinical trials (and other population-based research) to be planned and implemented with greater ease and speed than is currently the case; for example, ethics approval in principle could be agreed at EU level (rather than in each member state individually), with the details of implementation (such as patient information) to be agreed locally.

***Could action be taken at any other international level i.e. by the WHO?***

Legislation and regulation is required within medicinal products and therefore it is more appropriate for EU to lead the process, rather than any advisory organisation. However, access to trial data is relevant to all organisations, in particular with the WHO coming under scrutiny regarding advice on Tamiflu, and therefore should work in partnership to develop stronger legislation and regulation on access to clinical trial data.

***What future challenge/opportunities might we face in EU health competence and what impact might these have on the national interest?***

The future voluntary Health Technology Network proposed via the implementing acts of the patients' rights in cross border health care directive<sup>41</sup> should be monitored closely to ensure that

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<sup>9</sup> NHS NIHR. Dissemination and publication of research findings: an updated review of related biases, Health Technology Assessment programme, <http://www.hta.ac.uk/fullmono/mon1408.pdf>

<sup>10</sup> <http://www.bmj.com/tamiflu>

<sup>11</sup> Has the European Clinical Trials Directive been a success? <http://www.bmj.com/content/340/bmj.c1862>

<sup>41</sup> Cross border health directive <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF>

the UK's well functioning process is continued and not detrimentally affected by the outcomes of the proposed network. In particular, the modalities for stakeholder engagement at the EU level must be open, transparent and fully accountable.

The current proposal to update the 'Medicinal products for human use: transparency of measures regulating the prices and their inclusion in the scope of public health insurance systems directive'<sup>42</sup> may present challenges if provisions favouring the competitiveness of the pharmaceutical industry [such as shorter time limits for pricing decisions] are adopted in the final text. Overall, increasing the transparency of pricing set across Europe by EU member states is a preferential outcome as it will increase the potential for procurers to negotiate more competitive prices.

### **3. Medical devices**

#### ***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

The UK would not benefit from the EU taking less action on this issue, as stringent legislation and regulation at an EU level is required to maintain the internal market. The internal market in medical devices benefits UK companies and the UK economy and therefore should be continued.

#### ***How could action in this area be undertaken differently?***

As discussed in the consultation document, the EU legislation is being revised due to recent controversy. The EU directive on devices is required to allow them to be licensed, bought and sold across the internal market. However, it is therefore important for this industry to be well regulated. Recent investigations from the BMJ found that regulation within this industry was poor and that patient's lives were being put at risk due to the lack of regulation<sup>43</sup>. Therefore, additional action with stronger legislation and regulation is required to ensure that the medical device industry is practising to a high standard and providing good quality medical devices to the UK population.

#### ***Could action be taken at any other international level i.e. by the WHO?***

Legislative and regulatory action is required and therefore action should be taken at EU level and not from other organisations such as WHO.

#### ***What future challenge/opportunities might we face in EU health competence and what impact might these have on the national interest?***

Of potential concern is the possible divergence and contradiction that may arise as a result of having two separate legislative instruments in this area: the in vitro medical devices and the medical devices directive. MHRA has recently concluded a public consultation on the revision of EU medical devices legislation in order to consider the views of healthcare professionals, patients, industry, academics, and the interested public on the draft new European legislation on medical devices. The views of this consultation should provide further guidance as to how to maximise the UK interest in this field.

## **Public health**

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<sup>42</sup> <http://www.europarl.europa.eu/oeil/popups/summary.do?id=1194220&t=e&l=en>

<sup>43</sup> How safe are metal-on-metal hip implants? <http://www.bmj.com/content/344/bmj.e1410>

#### **4. Organs, blood, tissues and cells**

##### ***How might the UK benefit from the EU taking more action in health?***

NEEHP supports adherence to the Blood, Tissue, Cells and Organs Directive for all Member States of the EU. We welcome the transposition of the BTCO directive into policy for all member countries in line with the current position within the UK. Consistent implementation would enable greater quality assurance of all BTCO to a high standard. We believe it is vital that all BTCO products are traceable from donor to recipient. This is particularly relevant given the increasing level of shared health related activities and products across countries. With the increasing potential for competition for blood products, we share the view of the European Blood Alliance<sup>44</sup> that improved regulation is required. Shared competence would facilitate this and support inter-country activities including the sharing of best practice and collaboration on research.

##### ***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

Although the UK law and policy relating to BTCO is of a high standard and in parts greater than that required by EU legislation, removal of competence to a supporting status would effectively allow member states to formulate their own policies, putting patient health and safety at risk. This is particularly pertinent given the increasing movement of people for healthcare within the EU from the UK. NEEHP do not support less action from the EU in this subject area.

##### ***Could action be taken at any other international level i.e. by the WHO?***

The WHO Blood Transfusion Safety Programme conducted a consultation on haemovigilance in conjunction with International Haemovigilance Network and the International Society of Blood Transfusion in 2012<sup>45</sup>. 50 countries were invited including EU member states. This level of coordination, for example the Global Database on Blood Safety is of vital importance to the global health community and any alterations or revisions to policies should be reflected in subsequent EU legislation. This coordination and technical input needs further facilitation at EU level and NEEHP believe it should exist in conjunction with the current level of EU competence in this area.

##### ***What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?***

The EC communication on the action plan on Organ Donation and Transplantation (2009-2015): strengthening cooperation between Member States<sup>46</sup> is an example of where non-legislative and legislative items, such as the Directives on the minimum standards of quality and safety of human organs intended for transplantation, can work symbiotically to produce effective results.

Council conclusions are a useful non-legislative instrument for highlighting future priorities and identifying improvements to current policies. For example, the recent European Council conclusions of the Cypriot Presidency<sup>47</sup> highlight the benefit of this measure. The conclusions suggesting improvements to this policy by include organ transplantation within the scope of EU

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<sup>44</sup> World Health Organisation Global consultation on haemovigilance

<http://www.who.int/bloodsafety/ConceptPaperWHOGlobalConsultationHaemovigilance.pdf>

<sup>45</sup> Follea G, de Wit J, Raiger P European Blood Alliance (EBA) and EuroNet TMS: What Challenges for the transfusion of tomorrow? *Transfus Clin Biol* 2011 18(2) 106-14

<sup>46</sup> [http://ec.europa.eu/health/ph\\_threats/human\\_substance/oc\\_organs/docs/organs\\_action\\_en.pdf](http://ec.europa.eu/health/ph_threats/human_substance/oc_organs/docs/organs_action_en.pdf)

<sup>47</sup> [http://www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/lisa/134095.pdf](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lisa/134095.pdf)

initiatives against trafficking of human beings in line with recommendations of the World Health Organisation and the Council of Europe.

## 5. Nutrition and food labelling

### *How might the UK benefit from the EU taking more action in health?*

One of the main benefits for the UK existing as a member state of the EU is the free market, which enables food production companies to trade freely in Europe. With this internal market, other EU countries can freely import food products to the UK. It is important that quality of foods brought into the UK are well regulated to ensure that nutritional components are clearly marked and foods are produced and transferred safely to prevent transmission of infectious agents (e.g. E. Coli). Strong legislation must be in place to ensure that food brought into the UK is safe and of a high quality.

Obesity is on the increase in the UK and is reaching epidemic levels. There are a number of interventions that should be considered, both at UK and EU level to reduce obesity levels in the UK:

- Food traffic light systems are in place in the UK to provide a simple tool to assist consumers to choose healthy options, although these are currently voluntary. Evidence shows that traffic light food labelling is effective and cost effective<sup>48,49</sup>; this system of labelling should be pursued when future revision of the labelling directive is considered, as this was ruled out in 2011,
- Taxing junk food has been shown to be effective and cost-effective<sup>5</sup>;
- Restriction of trans fats (as recently been implemented through legislation in some European countries) has been shown to reduce transfat consumption<sup>50</sup>; reducing consumption of industrial TFAs by even 1% of total energy intake would be predicted to prevent 11,000 heart attacks and 7000 deaths annually in England alone<sup>51</sup>;
- Reductions in salt in food reduces blood pressure and prevents cardiovascular disease. Voluntary labelling on food regarding salt would lead to a 15% relative reduction in salt intake whereas legislative action to ensure a reduction of salt in processed food with appropriate labeling would lead to a 30% relative reduction in salt intake<sup>52</sup>

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<sup>48</sup> G Sacks, J L Veerman, M Moodie and B Swinburn. 'Traffic-light' nutrition labelling and 'junk-food' tax: a modelled comparison of cost-effectiveness for obesity prevention. *International Journal of Obesity* (2011) 35, 1001–1009

<sup>49</sup> FSA. Citizens' forums on food: Front of Pack (FoP) Nutrition Labelling  
<http://tna.europarchive.org/20100910172942/http://www.food.gov.uk/multimedia/pdfs/citforumfop.pdf>

<sup>50</sup> Angell SY, Silver LD, Goldstein GP, Johnson CM, Deitcher DR, Frieden TR, et al. Cholesterol control beyond the clinic: New York City's trans fat restriction. *Ann Intern Med* 2009;151:129-34

<sup>51</sup> Mozaffarian D, Katan MB, Ascherio A, Stampfer MJ, Willett WC. Trans fatty acids and cardiovascular disease. *N Engl J Med* 2006;354:1601-13

<sup>52</sup> WHO. 2002. The world health report 2002 - Reducing Risks, Promoting Healthy Life [online]. Available from <http://www.who.int/whr/2002/en/>

NEEHP would welcome further legislation at EU and UK levels in these areas to assist the population to reduce obesity levels in the UK, and reduce the burden on our health services.

***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

In the modern world it is becoming increasingly difficult, if not impossible, to control epidemics of either communicable or non-communicable diseases within the boundaries of any relatively small European country. For example, the problem of obesity will require action at every possible level. Obesity is not simply a UK problem and therefore increasing legislation at EU level is welcomed. This is particularly important due to the free movement of individuals throughout the EU with access to healthcare, and so it is vital the UK takes an interest in the health of other EU member states. More action is also required at the national level to ensure that action is being taken to address obesity. NEEHP welcomes the Public Health Responsibility Deals and the involvement of industry in aiming to reduce the obesity epidemic. However, there is concern that more could be done by legislating, than by allowing industry, whose profits depend on the population buying their foods, to decide on how they will improve the health of the population<sup>53</sup>.

***Could action be taken at any other international level i.e. by the WHO?***

As this is a global epidemic, action is needed in partnership across the EU and with other international bodies. This will encourage a strong evidence base to be built, thereby enabling strong guidance to be developed and legislation to be taken at EU and country levels.

***Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest?***

As already stated above, there is a clearly demonstrable need to reform the CAP so as to ensure that subsidies are used to promote production and consumption of foods that will promote healthy nutrition, and to remove such subsidies from production of unhealthy foods (such as those which are saturated fat-rich).

***How could action in this area be undertaken differently e.g. Are there ways of improving EU legislation in health, e.g. revision of existing legislation, better ways of developing future proposals, or greater adherence to the principle of subsidiarity and proportionality?***

The Commission should release without delay the proposed setting of nutrient profiles foreseen under Regulation 1924/2006 on nutrition and health claims made on foods and envisaged in the 2013 Commission Work Programme [4<sup>th</sup> quarter]. Nutrient profiles will provide the criteria which foods and/or categories of foods must respect in order to bear claims. The profiles will, primarily, be based on the levels of nutrients intake of which in the overall diet are shown to have incidence on health and in particular on obesity and non communicable chronic diseases.

## **6. Tobacco**

***How might the UK benefit from the EU taking more action in health?***

NEEHP welcomes the EUs directives on advertising and sponsorship of tobacco products. UK citizens travel to other EU states and therefore, it is important that these directives on

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<sup>53</sup> Hastings G. Why corporate power is a public health priority. *BMJ* 2012;345:e5124

advertising and sponsorship are maintained in order to prevent initiation of smoking in younger people. The recommendation on smokefree places is disappointing and stronger legislation should be encouraged within the EU to protect vulnerable populations living in the EU and UK citizens during travel<sup>54</sup>.

Counterfeit and smuggled cigarettes are thought to hold 8-18% of the tobacco market in the UK, with one in six cigarettes smoked being illicit. This poses a large problem for the UK as this is thought to cost taxpayers £3 billion per year in lost revenue<sup>55</sup>. In addition, illicit cigarettes are more commonly used by younger people and those in lower socioeconomic groups due to lower costs. Therefore illicit tobacco may increase health inequalities and continue to encourage young people to start smoking. There are therefore a number of concerns regarding the health in, and economy of, the UK. In 2007/08, counterfeit products made up 82% of large seizures of UK brands. The bulk of counterfeit cigarettes are manufactured in China and, to a lesser extent, Eastern Europe. These are typically shipped in bulk directly to the UK by sea, or re-routed via other EU ports. It is vital that the government, working with the EU, strengthens legislation and regulation of tobacco in order to protect the health and economy of the UK, including by bringing tobacco taxes in all EU member states into line, by increasing taxation levels in countries with low rates.

Health warnings on packages makes smoking less attractive<sup>56</sup>. Health warnings should continue to be shown on all cigarette packs, including all cigarettes sold within all EU Member States.

In addition, strong legislation at UK and EU levels should be implemented to introduce plain packaging on cigarette packages. Plain packages has been shown to reduce the appeal of tobacco products, increase the effectiveness of health warnings and reduce initiation of non-smokers, in particular young smokers<sup>57</sup>.

### ***Could action be taken at any other international level i.e. by the WHO?***

The EU and the UK are separate parties to the WHO Framework Convention on Tobacco Control,<sup>58</sup> which is an effective method of working in respect of the relevant balance of competences between the UK and EU.

### ***What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?***

The Commission should continue in full cooperation with Member States its efforts to combat cigarette smuggling, address the illicit and counterfeit tobacco trade.

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<sup>54</sup> Daniel F. Mackay, Scott M. Nelson, Sally J. Haw, Jill P. Pell. Impact of Scotland's Smoke-Free Legislation on Pregnancy Complications: Retrospective Cohort Study. PLoS Med. 2012;9(3):e1001175.

<sup>55</sup> North of England: Tackling Illicit Tobacco for Better Health. 2009. North of England (NoE) 'Tackling Illicit Tobacco for Better Health' Programme Action Plan (2009-2012).

<sup>56</sup> Hammond, D, et al., "Impact of the graphic Canadian warning labels on adult smoking behavior," Tobacco Control 12(4): 391-395, December 2003

<sup>57</sup> Moodie C, Stead M, Bauld L, McNeill A, Angus K, Hinds K, Kwan I, Thomas J, Hastings G, O'Mara-Eves A. Plain Tobacco Packaging: A Systematic Review. 2011. [http://www.plainpacksprotect.co.uk/assets/pdf/plain\\_tobacco\\_packaging\\_systematic\\_review.pdf](http://www.plainpacksprotect.co.uk/assets/pdf/plain_tobacco_packaging_systematic_review.pdf)

<sup>58</sup> [http://www.who.int/fctc/signatories\\_parties/en/index.html](http://www.who.int/fctc/signatories_parties/en/index.html)

## 7. Alcohol

### ***How might the UK benefit from the EU taking more action in health?***

It is vital that the future progress reports and evaluations of the EU Alcohol strategy are shared with member states. NEEHP support the revision and extension of an EU alcohol strategy and EU support to implement policy in member states. Competence in this area would continue to ensure that policies are derived from best available evidence and reflect effective interventions to reduce the impact of alcohol on health. The UK will benefit from ongoing research and evidence collated from member states to guide country level policies to tackle a key public health priority. NEEHP supports stronger legislation on advertising and promoting of alcohol products and believes this should be led by the EU and linked to implementation of the EU alcohol strategy.

EU funding from the Seventh Framework Programme for research FP7 supported our members' project AMPHORA (Alcohol Measures for Public Health Research Alliance). This work, collaborating with 35 partners across the North West, enabled creation of the European Alcohol Policy Research Alliance, evaluation of cost effectiveness of policy measures, and the conduct of longitudinal studies on alcohol policy and pricing. All of these activities have contributed to the development of alcohol reduction policies within the UK, translating science into policy. NEEHP supports opportunities for continued funding of such projects to enable further collaboration and successful health outcomes.

### ***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

NEEHP acknowledges that public health priorities and outcomes related to alcohol may be country specific. As price and availability are key determinants of consumption we would want to ensure that any proposal, if suggested in the future in a manner compliant with EU law, for harmonisation of alcohol duties across the EU does not hinder the ability of individual Member States to set higher alcohol duties designed to tackle the harmful consumption of certain products, especially amongst young people.

### ***Could action be taken at any other international level i.e. by the WHO?***

NEEHP believes that the global alcohol strategy supported by WHO should co-exist with the EU Alcohol strategy, and that both should provide recommendations for Member States to implement, relevant to alcohol reduction strategies. EU action should take into account and implement feasible elements from the WHO Europe Action Plan to reduce the harmful use of alcohol 2012-2020.<sup>59</sup>

### ***Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest?***

The EU should be encouraged by Member States to take more effective measures through internal market legislation to address the harmful use of alcohol, for example with targeted taxation policies. In light of this, the EU should also allow Member States such as the UK to implement Minimum Unit Pricing for alcohol in order to meet priority health objectives.

### ***What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?***

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<sup>59</sup> [http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0006/147732/RC61\\_wd13E\\_Alcohol\\_111372\\_ver2012.pdf](http://www.euro.who.int/__data/assets/pdf_file/0006/147732/RC61_wd13E_Alcohol_111372_ver2012.pdf)

The EU alcohol strategy expired in 2012 and as yet, despite a joint call from the UK, Ireland and Sweden, the Commission is reluctant to propose a follow up strategy for 2013-2020. NEEHP support the UK in its call for a renewed strategy and one which will focus upon internal market levers at the disposal of the EU to address marketing, labelling and pricing issues. It is regrettable that the EC has yet to consent to renewing the strategy.

## **8. Health security**

### ***How might the UK benefit from the EU taking more action in health?***

NEEHP supports the proposition to extend the EU competence to cover cross-border threats other than communicable disease. It is vital that a mechanism exists to share health intelligence on threats to human health and security within EU states. Particular benefits of such an approach can be seen from the Europe wide response related to recent health threats, e.g. pandemic influenza 2009 and E.Coli 0104:H4 outbreaks in 2011, in Germany. A joint response from the Health Protection Agency and international partner organisations (e.g. Koch Institute in Germany) is vital in outbreak responses with a wide impact on the health of UK citizens and citizens of other EU countries. The supervisory role of European Centre for Disease Control (ECDC) and internal mechanisms of the EU has enabled this to be facilitated and should be continued.

### ***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

Less action from the EU would result in a lowering of standards and of security for all states. NEEHP does not support a change in the level of competence in this area. Cross country mechanisms for collaboration and cooperation would be impaired if competence is reduced. This could pose a high level of risks to UK citizens. NEEHP supports the ability for Member States to implement actions in extreme cases of need related to emergency situations, and any change in EU competence needs to ensure this vital capacity remains.

Possible improvements in this area would arise from altering the mandate of the European Centre for Disease Control to include the surveillance and monitoring of non-communicable diseases. This would allow for comprehensive data collection on a whole range of key mortality and morbidity indicators that can be used to design effectively and to shape evidence based policy, both in individual Member States, as well as at the EU level.

### ***Could action be taken at any other international level i.e. by the WHO?***

Attention should be paid to the risk that duplication of function between EC apparatus and the WHO might cause confusion in this field; such duplication should be avoided.

## **10. Public health programmes**

### ***How might the UK benefit from the EU taking more action in health?***

NEEHP supports the continuation of support for the EU Public Health Programme. The benefits of the programme have been key to the success of our organisation and have enabled our members to work to improve health outcomes within the North of England. Continued funding for voluntary sector organisations, health service organisations, and academic institutions to work in collaboration on health research and development related to health determinants, thus

supporting HIAP, health security and health information is key to the success of this programme. NEEHP strongly supports and advocates for all of our member organisations involved in the previous rounds of the PH programme, and believes that it provides direct benefits to individuals and organisations across North of England. Collaboration and partnerships are encouraged and fostered by this approach.

Examples of the benefits within our member's projects are:

Club health project, tackling the issues of high risk behaviour related to sexually transmitted infections and substance misuse in nightlife settings. This project was developed following a previous EU funded project; 'Recreational culture as a tool to prevent risk behaviours'.

Healthy nightlife toolbox: disseminating evidence of interventions to reduce harm from alcohol and drug use among young people, supporting the EU drugs action plan.

EUREGIO III: learning lessons from health investments and enabling knowledge exchange as well as building strategic links and networks between stakeholders.

EURO-URHIS and EURO-URHIS 2: projects to develop systems of urban health indicators, both led by academic institutions in North West England.

Healthystadia: 3 year co-financed project which used the setting of sports stadia as a locus for health improvement strategies.

***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

NEEHP does not support less action in this area of health. Reduction in competence and therefore loss of opportunities for innovation and collaboration within member states and across member states would impact heavily on our organisation and our members. This could potentially result in a loss of momentum of current projects and partnerships built successfully, and impact on health determinants, health security and health information.

**How could action in this area be undertaken differently e.g. Are there ways of improving EU legislation in health, e.g. revision of existing legislation, better ways of developing future proposals, or greater adherence to the principle of subsidiarity and proportionality?**

The principle of subsidiarity could be better taken into account in the development and implementation of the Programme through enhanced consultation with competent authorities at the sub-national level, which can be conducted in full cooperation with the Member State level.

Priorities should be linked to medium-long term public health goals, with the over-arching objective of reducing health inequalities between and within EU member states. The 2009 Court of Auditors report highlighted methods for improving the Programme which have been subsequently taken into account. However, the report criticised unfairly the Programme on the basis of its minimal impact on individual health. The Programme is most effective when engaging with competent authorities at the national and sub-national level, whom, as the report states, valued the possibilities for collaborative working offered by the Programme.

Future priorities should be orientated towards the needs and objectives of competent bodies and should assist them in implementing existing research or policy requirements from EU legislation. In this respect, joint actions have been a very successful mechanism for Member States.

The number of discrete projects has reduced in recent years, which decreases the possibility for research bodies and civil society organisations to participate in the programme. Short scale

projects charged with more immediate outcomes [e.g. production of guidelines] should have a significant and distinct role in the programme in relation to broader medium/long term priorities.

***Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest?***

The Public Health Programme is the only dedicated public health funding programme at the EU level and the UK has been consistently one of the Member States recipients to make most use of the Programme. Therefore, it is highly important to support and value the opportunities presented by this Programme.

Potentially most other funding structures at the EU level are applicable to health concerns if the Health in All Policies principle is applied. However, too often little attention in UK is paid to other funding programmes and to the possibilities they offer to UK organisations to harness the funding offered for health improvement.

The Public Health Programme could be improved by gearing it towards taking the outcomes and findings from other EU funding programmes, e.g. to FP7 and its successor, and by implementing this in practice at both national and local levels in the EU. This will require an enhanced role of the Executive Agency for Health and Consumers, which could assist with aligning programmes related to health, thus avoiding duplication of topics across work programmes. It is fair to add that the Commission is currently trying to achieve such coordination of funding streams.

***Could action be taken at any other international level i.e. by the WHO?***

The WHO is not primarily a funding organisation and so it is not appropriate to consider them as an alternative. However WHO guidelines and recommendations should feed into the design and implementation of the programme's work plan as part of the broader consultation with experts.

## 11. Rare diseases

### ***How might the UK benefit from the EU taking more action in health?***

A move from recommendation to shared competence would encourage member states to prioritise rare diseases in line with the EU Public Health Programme recommendation. NEEHP believes that EU competence should encourage collaboration for research across member states. The UK national policies and implementation plans for rare diseases should be shared with other member states.

The RARE DISEASE PLATFORM is a Seventh Framework Research Programme (FP7) funded project, which has created a set of tools for collaboration in the field of rare diseases. Current competence at EU level was crucial in enabling this project to succeed; this included identifying key stakeholders and partners, information sharing on OrphanXchange and developing platforms for dissemination of information.

### ***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

NEEHP believes that less action would be detrimental. Rare diseases are few in numbers, with low incidence and prevalence and shared learning and collaboration opportunities within the PH Programme would be limited and dissolved if further EU action was reduced.

### ***Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest?***

The use of EU structures and resources in this field is both appropriate and logical. Careful attention should be paid to the presence and influence of external lobby groups to ensure transparency and accountability exists within decision making in this field.

## **NHS and the provision of services to patients.**

## 12. Implications of employment policy

### ***How might the UK benefit from the EU taking more action in health?***

The European Working Time Directive was introduced as part of a safety initiative as evidence suggests that long working hours and overtime can adversely impact on health of doctors, and impact of safety<sup>60</sup>. A number of concerns have been raised by junior doctors regarding the quality of their training, in particular: limited training opportunities, including surgery and continuing medical education; and lack of continuity due to shift work patterns<sup>61</sup>. However, the Government's independent review, The Temple Report, found that high quality training could be provided within a 48 hour week, but that services and training may have to be delivered differently in order to meet training needs. The EWTD was introduced to promote safety and this should be paramount in the NHS. There are clear requirements to ensure that doctors' training needs are being met, and these should be incorporated into hospital human resources plans.

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<sup>60</sup> A Spurgeon, J M Harrington, C L Cooper. Health and safety problems associated with long working hours: a review of the current position. *Occup Environ Med* 1997;**54**:367-375

<sup>61</sup> Medical Education England. 2010. Impact of the European Working Time Directive on the Quality of Training: Literature Review. [www.mee.nhs.uk/pdf/LiteratureReviewFINAL.pdf](http://www.mee.nhs.uk/pdf/LiteratureReviewFINAL.pdf)

### **13. Implications of free movement of persons: healthcare professionals**

***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

Prior to last Government increasing the number of junior doctors, the UK relied on medically trained professionals from member states to work in the UK and ensure hospital systems did not collapse. However, we are now training enough doctors. As doctors in training in the UK have been subsidised by the UK government, the UK should reap the benefits and ensure that these doctors are prioritised with regard to training numbers and jobs. The UK government needs to take a stronger role in promoting this. However, it is also important that where gaps in human resource exist, that these can be filled by doctors from other EU member states. There needs to be a fail safe approach to ensure that doctors trained in other EU Member States have adequate language skills to enable them to work competently in the UK. This should be considered and agreed at EU level; however, to ensure this should be a priority for the UK government, in association with the General Medical Council

### **14. Implications of free movement of persons: coordination of healthcare provision**

**14.1. The free movement of persons will be considered by a separate balance of competences review to be led by the Home Office and the Department for Work and Pensions in the second semester (spring 2013). We would welcome evidence from the health sector about the impact of this EU competence through this call for evidence.**

***How might the UK benefit from the EU taking more action in health?***

NEEHP supports the current regulations related to healthcare provision within the EU and within member states. Further consideration related to the EU legislation and member states obligations to provide healthcare is needed and this should be coordinated at EU level.

### **15. Implications of free movement of services: cross-border healthcare**

***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

NEEHP supports the cross border healthcare directive and believes that increased competency in health at EU level is required in order for Member States to be supported and guided adequately as to how best to implement policies related to cross border healthcare provision. This is vital in order to protect UK citizens and to ensure that health care provided is delivered to high standards so as to meet agreed European recommendations.

The directive is not expected to have a large material effect on patient flows to and from the UK. Reimbursement levels, set at home country rates, limit the extent to which patients could travel realistically to the UK for free health care from lesser developed member states.

Moreover, the directive does not introduce new responsibilities for the UK to implement, instead it clarifies existing case law but with mutually agreed parameters that all member states and the European Parliament have endorsed.

Of particular interest for the UK are the implementing acts which introduce measures such as a voluntary network on HTA; an eHealth network; European reference networks and an ePrescriptions framework. These measures can be a welcome opportunity to further the interoperability of services across the EU, in particular with recognition of prescriptions issued in one

Member State for dispensing in any other Member State, which should contribute significantly to improved patient safety.

Others Areas:

### **Chronic Diseases / Non-Communicable Disease**

*How might the UK benefit from the EU taking more action in health?*

The EC, in cooperation with member states, has begun to prioritise the issue of the rising burden of chronic disease in the Union by undertaking a reflection process in the European Council, which is set to conclude in 2013.

The UK can benefit by encouraging the EU to take further action on innovative health promotion strategies for the prevention of the major chronic illnesses. This approach can leverage existing EU resources with the cooperation of member states to tackle common societal challenges, such as childhood obesity, in a collaborative manner. The redesign of DG SANCO to incorporate Chronic Disease more firmly into its organigram should be welcomed and could lead to more focused efforts in this field. However, efforts should be focussed on primary prevention and health promotion in the first instance, in order to engender long-term and meaningful change for society.

The UK should be wary of external lobbying (for example, from pharmaceutical industry interests) under the umbrella term of chronic disease management; this would tend to push for the inclusion of a wide range of conditions, thus decreasing the focus and impact of the EU efforts. It would also be likely to lead to increased emphasis on treatment and care in the short term, which will not lead to the significant long term societal changes needed to deal with the growing burden of chronic disease.

*Could action be taken at any other international level i.e. by the WHO?*

This area is an example of where effective collaborative working between international bodies, the EU and member states respectively can yield positive results. The EU should be encouraged to integrate the recommendations and approaches contained within the WHO Health2020 strategy across of its policy domain but especially regarding the prevention of non-communicable/chronic diseases. Consideration should also be given to the UN declaration on non-communicable diseases of September 2011.

*What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?*

Non-legislative items such as the reflection process and its' subsequent activities (for example the future joint action on chronic disease and healthy ageing) are highly valuable and should be encouraged and maintained. The value lies in bringing competent authorities and their counterparts together from across Europe to address common problems and to find appropriate solutions for their respective populations.

Legislative items primarily are related to internal market legislation, such as advertising, marketing, labelling etc., and should be harnessed in tandem with effective non-legislative items to improve population health as top line priority.

Non-legislative measures should not be seen as a substitute for legislative measures such as directives and regulations. Without effective hard law from the EU level, where it has the competency to act, the non-legislative items will be ineffective and lead only to the exchange of practice and opinions with minimal effect upon population health.

## **eHealth**

### **How might the UK benefit from the EU taking more action in health?**

E-Health is one of the EU lead market initiatives<sup>62</sup> and as such has been earmarked as one of the sectors in which the EU as trading block can become a global leader in the field. eHealth policies offer significant opportunities for health systems and for quality of care at the patient level. Sustainable investments are possible at the EU level through multiple funding instruments, joint procurement programmes and collaborative working between member states on matters of mutual concern (such as the digitisation of medical records, holistic patient records, implementing tele-care / telemedicine), and also with industry in effective and mutually beneficial partnerships. This approach can see innovative technology clusters which are emerging domestically particularly, in the growing field of mHealth, access a wider market.

## **Statistics**

### **How might the UK benefit from the EU taking more action in health?**

The European Community Health Indicators projects, and others that have contributed and are contributing to the development of an EU health information system, have proved to be extremely useful and valuable initiatives. These information systems will considerably contribute and facilitate the planning and evaluation of better-targeted health-related services in future, at national level, as well as at regional and urban levels. These developments should be implemented, sustained and developed, as they promise considerable benefits to member states and to improved health of their citizens. The new EU health information systems have been developed so as to supplement, rather than to duplicate, existing WHO systems, and this principle should be sustained.

## **Research**

### **How might the UK benefit from the EU taking more action in health?**

The current proposal for the next multi-annual financial framework for the EU 2014-2020, envisages a 50% increase in the funding for the EU research budget. This would see approximately €11 billion allocated to health, wellbeing and life sciences research. In 2011, the UK had the second highest number of applicants retained in FP7 proposals,<sup>63</sup> illustrating the strong research infrastructure and capacity that the UK has. There is significant potential to increase the participation and success rates of EU research funding in the UK and to leverage these funds as matched funding to existing national sources of funding for priority topics such as dementia research.

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<sup>62</sup> <http://ec.europa.eu/enterprise/policies/innovation/policy/lead-market-initiative/>

<sup>63</sup> [http://ec.europa.eu/research/evaluations/pdf/archive/fp7\\_monitoring\\_reports/fifth\\_fp7\\_monitoring\\_report.pdf](http://ec.europa.eu/research/evaluations/pdf/archive/fp7_monitoring_reports/fifth_fp7_monitoring_report.pdf)

## North West London Hospitals NHS Trust

Issues encountered with EU patients:

- 1) In most cases, it is difficult to establish that they are here in the UK for settled purposes.
  - they normally come with their passport/ID. no movement of assets, transfer of funds, etc.
  - lots of these cases stay with their friends and relatives so no tenancy agreement in their name
  - many are working on cash basis therefore no proof that they are working, no bank statements, etc
  
- 2) Maturely pregnant ladies who come to the UK to join their partner
  - again, difficult to establish that they are here to stay as no paperwork to support this.
  - not married therefore we cannot go under the partner's documents
  
- 3) Encountered some cases where EU patients initially come for emergency cases then stay on to get further treatment for pre-existing conditions.
  
- 4) Pensioners coming for settle purposes without S1 and getting pension credit etc.

## Nursing and Midwifery Council

- 1 The Nursing and Midwifery Council (NMC) is the regulator for nursing and midwifery in the UK. We exist to safeguard the health and wellbeing of the public. We set standards of education, training, conduct and performance for nurses and midwives, and hold the register of those who have qualified and meet those standards. We have clear and transparent processes to investigate and deal with nurses and midwives who fall short of our standards.
- 2 The UK is a net importer of healthcare professionals, both from Europe and internationally. There are approximately 16,188 nurses and midwives from the EU registered with the NMC. These professionals provide a vital and skilled resource and the NMC appreciates the positive contribution that nurses and midwives from EU member states make to the provision of healthcare in the UK.
- 3 It should be pointed out however that the free movement of professionals and the existing regime for the recognition of professionals' qualifications has raised a number of challenges to public protection. We believe that the EU's competence in relation to the free movement of healthcare workers must be balanced in favour of patient and public safety whilst at the same time facilitate the freedom of movement of healthcare workers.
- 4 While competent authorities should strive to ensure that their recognition processes are fair and transparent, it should always be remembered that the primary responsibility of healthcare regulators such as the NMC is to protect patients and ensure high standards of care.
- 5 We have consistently raised a number of clear public protection related issues, which we have highlighted through our registration and recognition processes. These include the inability of regulators to be able to test the English language competence of nurses and midwives at the recognition stage, and the inadequacy of the EU wide minimum training standards for general nurses and midwives in relation to contemporary practice and methods of healthcare delivery. Effective language and communication skills are integral to the safe practice of all healthcare professionals, regardless of the post they take up. We therefore strongly believe that language testing of EU trained nurses and midwives as part of the recognition procedure is clearly in the interests of patient safety.
- 6 We welcome the ongoing review of Directive 2005/36/EC *on the Recognition of Professional Qualifications* which includes initiatives for sharing information between health regulators across the European Union.
- 7 We believe that public protection should be at the core of any changes to European Union legislation relating to the free movement of healthcare professionals.

### **Resourcing Implications**

- 8 We recognise that we have an obligation under EU law to process applications to the register. It should be pointed out however that any changes to EU legislation and the introduction of new processes for recognition are likely to have a financial impact on the NMC, which in turn will impact on the registration fees for nurses and midwives. This should be borne in mind when considering changes to the recognition procedures as part of the current review of the recognition of professional qualifications directive.

## Optical Confederation

1. Thank you for consulting the Optical Confederation on the Review of the Balance of Competencies specifically related to Health.
2. The Optical Confederation represents the 12,000 optometrists, the 6,000 dispensing opticians and 7,000 optical businesses in the UK who provide high quality and accessible eye care services to the whole population. The Confederation is a coalition of the five optical representative bodies: the Association of British Dispensing Opticians (ABDO); the Association of Contact Lens Manufacturers (ACLM); the Association of Optometrists (AOP); the Federation of Manufacturing Opticians (FMO) and the Federation of Opticians (FODO). As a Confederation, we work with others to improve eye health for the public good.
3. As a member of the European Council of Optometry and Optics (ECOO)<sup>1</sup>, the Optical Confederation is well accustomed to working with the European Union Institutions (EUIs). For example, we regularly share the views of our members through ECOO in response to consultations launched by the EUIs, thereby ensuring that the optical and optometric position of the UK is understood and taken into account<sup>2</sup>
4. Since 2008 we have been a proactive member of Vision 2020 UK and the cross-sector UK Vision Strategy (a Vision 2020 UK initiative led by the Royal National Institute for Blind People and involving all four UK Governments).<sup>3</sup> The UK Vision Strategy was developed in response to the World Health Assembly Vision 2020 resolution to reduce avoidable blindness by the year 2020.<sup>4</sup>
5. As far as the scope of this review is concerned, we are of the firm opinion that the EU has and will continue to have an “important role” to play in issues concerning public health and healthcare” (page 4).

As outlined below, EU action in healthcare has been a catalyst to

- facilitate the growth and expansion of high-calibre optical professionals which in turn has improved access to affordable eye care across the UK and Europe
- improve our regulatory adherence with other Member States and
- to improve safety standards for the public and patients.

6. The number of people in the UK alone with partial sight or blindness is projected to increase by 155 per cent to nearly 4 million people by 2050. Furthermore, 100 people start to lose their sight every day and at least 50 per cent of this is preventable.<sup>5</sup>

The UK Government has recently recognised eye health and the prevention of avoidable sight loss as a national public health priority in the form of a preventable sight loss indicator in England. We would like to see a similar indicator replicated at the European level, however progress is hampered by the current balance of competencies with public health and healthcare deemed a ‘supporting competence’. Such an indicator would provide valuable and comparative data on the number of people across the EU with partial sight or blindness and assist Member States in assessing their progress towards tackling the currently unacceptably high levels of visual impairment across the EU.

We would therefore encourage the Department of Health to consider re-categorising public health (and healthcare) as a shared competence in accordance with Articles 3, 4 and 6 of the Treaty of the Functioning of the European Union (TFEU). This would be particularly beneficial to both patients and the public at both the UK and EU level, especially with regard to ophthalmic public health.

7. It is against this background that we provide more detailed responses below to the consultation questions which we believe are of relevance to our sector.

8. We are very happy for this response to be made publicly available.

### **Impact on the national interest**

#### **How does the EU's competence in health affect you/your organisation?**

As previously mentioned, the EU's competence in health provides a platform to share best practice between Member States and drive better patient care outcomes. This cross country collaboration also provides UK optics and optometry with an opportunity to expand into new markets and for leading EU professionals to add value to UK eye care.

The EU Directive on Recognition of Professional Qualifications has, for example, provided our professions with the impetus, under the leadership of ECOO, to take a leading and proactive role in the harmonisation of a broad and varied landscape of qualifications for the benefit of EU citizens. This has resulted in the development of the European Diploma of Optometry (EDO) and the ongoing development of a European Qualification in Optics (EQO). This will clearly facilitate further the free movement and development of high-calibre optometrists and opticians throughout Europe.<sup>6</sup>

By way of another illustration, the EU Medical Devices Directives affects our sector by covering the manufacture of a wide range of products, including ophthalmic appliances, contact lenses and solutions, instruments and equipment. We very much welcomed the Medicines and Healthcare products Regulatory Agency (MHRA) recent proposal to include non-corrective contact lenses in the definition of 'medical device' under European law. Such changes will provide improved protection for patients and the public when using these devices.<sup>7</sup>

Given the impact of EU legislation on our sector, of which we can provide further examples upon request, we foresee a natural progression to the rebalancing of competencies with a re-categorisation of public health (and healthcare) as a 'shared competence' in accordance with Articles 3, 4 and 6 of the Treaty of the Functioning of the European Union (TFEU).

#### **What evidence is there that EU action in health advantages or disadvantages on the UK national interest?**

EU action in health brings economies of scale to health care and promotes competition, these factors can be used to improve access to care, quality of care and contain costs.

#### **What evidence is there that EU action in health advantages or disadvantages on business and industry?**

The Single Market of the EU has brought advantages to our sector from a supply perspective with better trade and productivity.

Also, EU action in health helps our sector by

- ameliorating safety standards across Europe
- harmonising regulatory requirements and reducing inappropriate, unnecessary burdens and barriers, which can often drive up the costs of healthcare
- bringing economies of scale to our activities.

## **What evidence is there that EU action in health advantages or disadvantages on patients and citizens?**

Except for the free movement of persons and professionals, EU action is not relevant as the health of patients and citizens are regulated at a national level.

Cross border healthcare has a minor but noteworthy impact on optics and optometry. <sup>4</sup>

As patients regularly travel increasingly around Europe, access for treatment can be time critical for certain ophthalmic needs and it is only right that patients should have unhindered access to care. We would welcome clarity from the Department of Health about patient access to NHS services and specifically in our case to General Ophthalmic Services, under the cross border healthcare arrangements (pages 22-23).

### **Please consider what evidence there is to demonstrate:**

#### **- the extent to which the EU's role in public health supports member state actions affectively and efficiently?**

The EU has a clear role to play in supporting Member States to introduce written eye health warnings on tobacco products within the two year timescale, for the first time raising awareness among consumers of the risk of blindness from smoking. This eye health warning for smokers is one of 14 new health warnings adopted by the European Commission (pages 13-14).

#### **- the opportunities and costs for the delivery of health and social care in the UK that flow from wider EU competencies and policies such as the free movement of workers or the single market generally**

As already mentioned, the EU Directive on Recognition of Professional Qualifications has provided our professions with the impetus, under the leadership of ECOO, to take a leading and proactive role in the harmonisation of a broad and varied landscape of qualifications for the benefit of patients and EU citizens. This will further the free movement and establishment of optometrists and opticians throughout Europe and also clarify the distinction between free movement of workers and healthcare professionals. <sup>8</sup>

#### **- the extent to which EU competence and policies intended to allow EU citizens to access healthcare across the EU are effective and proportionate?**

Yes, we believe they are currently effective and proportionate.

We would welcome clarity from the Department of Health about patient access to NHS services under the cross border healthcare arrangements particularly in areas of ophthalmic intervention, which are time critical.

#### **- the extent to which health objectives are effectively and proportionately taken into account in wider EU policies**

We feel that there is a greater leadership role for the EU to play in highlighting the public health and prevention contributions to the European economy, including the harmonisation of health standards (for example, vision standards for drivers), outcomes, active ageing of the workforce and equality for visually impaired citizens.

### **Future options and challenges**

**How might the UK benefit from the EU taking more action in health?**

As mentioned above, the UK could benefit from the sharing of more knowledge, best practice and statistical data through eHealth (page 23), e.g. with the introduction of an ophthalmic public health indicator at EU level to measure preventable sight loss across Member States. This would help our sector to adapt to the emerging challenges of an ageing population.

Given the impact of EU legislation already outlined above on our sector, we would recommend the Department of Health rebalance competencies in this particular area with a re-categorisation of public health (and healthcare) as a 'shared competence' in accordance with Articles 3, 4 and 6 of the Treaty of the Functioning of the European Union (TFEU).

**How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?**

No comment.

**How could action in this area be undertaken differently, e.g.**

**- Are there ways of improving EU legislation in health, e.g. revision of existing legislation, better ways of developing future proposals, or greater adherence to the principle of subsidiarity and proportionality?**

We very much welcome the proposed revisions of the Medical Devices Directives, in particular the MHRA's support for the inclusion of non-corrective contact lenses in the definition of 'medical device' under European law. Such changes will provide greater protection for patients and the public and eliminate any gaps in interpretation by individual Member States.<sup>9</sup>

**- Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest?**

No comment.

**- Could action be taken at any other international level, i.e. by the WHO?**

Any action taken at the international level should only complement and reinforce, rather than replace, any action at the EU and UK level.

**- What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?**

No comment.

**How else could the UK implement its current obligations?**

Since 1993 EC legislation has placed responsibilities on employers whose employees regularly use Visual Display Units (VDUs) as part of their work. These regulations include the requirement of an employer to pay for a full eye examination. Uptake by employers in the UK is relatively poor and employees are generally unaware of this requirement. To improve UK implementation, we feel that all parties would benefit from clear guidance from the HSE that encourages employers to inform VDU users of their entitlement to, and the benefits from, regular eye examinations.

There is a need for more consistency on drivers' vision. In our view the UK is not implementing the EU Driving Licence Directives to best effect.<sup>10</sup> The distance number plate test is not an accurate method to assess whether drivers meet these tougher measures as it does not check a person's peripheral (side) vision. The Optical Confederation continues to call on the UK Government to introduce vision screening for all drivers to ensure they meet these requirements. This will also reassure drivers that they have safe vision to drive and that they meet the legal eyesight requirements.

**What future challenge/opportunities might we face in EU health competence and what impact might these have on the national interest?**

As the ageing population develops, it will be important to address the issue of an ageing workforce and associated challenges, such as those on workforce productivity. From an ophthalmic perspective action should centre on ensuring that all employees have adequate vision to remain in the workforce for longer, while at the same time ensuring equality of opportunity for visually impaired citizens.

**What impact would any future enlargement of the EU have on health competence?**

We do not foresee any significant impact of future EU enlargement on health competences.

**General**

We have no further comments.

1 The European Council of Optometry and Optics (ECOO) is the European umbrella organisation which represents the interests of more than 75,000 optometrists and opticians from 27 European countries. More details are available here: <http://www.ecoo.info/>

2 A list of recent consultations submitted by ECOO can be found here:

<http://www.ecoo.info/projects-and-eu-affairs/consultations/> (Last accessed: February 2013)

3 Members of the Optical Confederation were involved in the development of the strategy with a view improving the eye health of the nation, a key aim of the strategy.

4 <http://www.who.int/blindness/partnerships/vision2020/en/index.html> (Last accessed: February 2013)

5 Access Economics (2009) Future sight loss UK (1): The economic impact of partial sight and blindness in the UK adult population

6 ECOO response to the European Commission Public Consultation on the Professional Qualifications Directive can be read here: <http://www.ecoo.info/wp-content/uploads/2012/11/ECOO-response-to-RPQ-consultation.pdf>

7 The Optical Confederation's response to the MHRA consultation on the revision of European Legislation on Medical Devices can be read here:

<http://www.opticalconfederation.org.uk/downloads/consultations/FINAL-Response-to-MHRA-Consultation-on-the-Revision-of-European-Legislation-on-Medical-Devices.pdf>

8 ECOO response to the European Commission Public Consultation on the Professional Qualifications Directive can be read here: <http://www.ecoo.info/wp-content/uploads/2012/11/ECOO-response-to-RPQ-consultation.pdf>

9 The Optical Confederation's response to the MHRA consultation on the revision of European Legislation on Medical Devices can be read here:

<http://www.opticalconfederation.org.uk/downloads/consultations/FINAL-Response-to-MHRA-Consultation-on-the-Revision-of-European-Legislation-on-Medical-Devices.pdf>

10 Directive 91/439/EEC and 2006/126/EC

## Oxford University Hospitals NHS Trust

As an Overseas Visitors Manager in a very large NHS Trust, the total confusion regarding the eligibility of EEA Nationals moving to the UK to free (secondary) Healthcare is of major concern to me.

Each year, there is an (unbudgeted) cost involved in treating EEA nationals who have moved to the UK.

Because the regulations are unclear and difficult (impossible?) to apply, many Trusts will take the stance that all EEA Nationals, regardless of:

The time they have been in the UK

Their deemed “self-sufficiency”;

Their CSI

Their exercising of treaty rights,  
are eligible for free treatment.

Most EEA nationals are completely unaware of the regulations relating to the above.

Many have no idea what an EHIC is!

More/better information throughout the EEA for travellers, not just those intending to reside in the UK, would help.

There appears to be no easy solution to the problem as long as Health care is free in some countries, but not others.

Perhaps if every EEA national intending to reside in the UK had to produce either:

A valid EHIC or

Health Insurance (valid for 12 months from date of arrival), and the clause giving exemption if the “family member is economically active” was removed, the situation would be clearer. However, I am sure that proposal probably raises other issues and would require a major change to existing EEA agreements.

Below are a couple of examples of recent situations which have caused uncertainty. In both cases the patients were exempted from charges.

Example 1:

Polish girl

Arrives in UK, claims to be coming to live permanently

Baby is due within next 3 months

Not working, Not a student

Seems to be supported by friends – but we have no proof

May have come here just to have the baby

The Guidance states:

*Women from the EEA/Switzerland who are visiting the UK are covered for all maternity care, including antenatal and postnatal care, providing the reason for their visit was not specifically to give birth or receive maternity treatment, in which case they should have been referred here using an S2. However, for pragmatic reasons, a valid EHIC can be accepted instead of an S2 at the discretion of the relevant NHS body.*

Therefore if she has a valid EHIC this can be used.

DoH advice is:

*If she doesn't have a valid EHIC then because she is within the first 3 months of her visit, and she has an initial right to reside here during that period, she could be exempt if she can prove her intention is to reside here, she doesn't have to be exercising treaty rights in that period.*

*After 3 months the "Easement Clause" applies, and we can't charge for treatment*

What proof can she give me that her intention is to reside here?

Verbal assurance is all she can provide

I have to accept this, we provide free treatment, and she goes back to Poland after the birth!

Example 2:

German National is moving to the UK to live with her partner who is a UK permanent resident

As an EEA person she has a "route to settlement".

She has an initial right to reside for 3 months, and can exercise Treaty Rights because she can be deemed "self-sufficient" – her partner will be supporting her.

It is assumed that she qualifies for free NHS care from the moment she arrives but, because she is an economically inactive person (not employed) she would need to have "comprehensive sickness insurance" (CSI) for her residence to be lawful.

Acceptable CSI is a valid German EHIC

It was assumed that as her partner is economically active here, this lady would not need CSI.

But information from the European Operational Policy Enquiries unit would seem to indicate otherwise:

*Durable (unmarried) partners of EEA nationals can assert a right of residence under the Regulations, however as they are extended family members rather than direct family members, this right of residence only comes into effect when the person has obtained a document confirming this right from the UK Border Agency. Therefore, if the EEA national in question is the durable partner of another EEA national, they would need to obtain a document from the UK Border Agency confirming a right of residence in this capacity in order to have a right of residence in the UK beyond the initial 3 month period.*

Full statement

**From:** European Operational Policy Enquiries

**RE:** Comprehensive Sickness Insurance (CSI).

If an EEA national wishes to rely on being self-sufficient (including where this is on the basis of being maintained by their spouse/partner), they will need to meet the conditions for that category of Treaty rights.

This includes (1) having sufficient resources to prevent themselves and any family members from becoming a burden on the social assistance system of the UK and (2) holding CSI for themselves and any family members. (It should be noted that “family members” includes persons who are reliant on the EEA national for their right of residence in the UK)

CSI can be evidenced by producing;

A valid EHIC issued by another EEA member state

A valid S1, S2 or S3 card (where applicable), or

A policy document demonstrating that the person has comprehensive private medical insurance (this does not include cash-back plans or travel insurance)

If an EEA national does not have any of the above forms of sickness insurance, they will not be exercising Treaty rights as a self-sufficient person and will therefore not have a right of residence on this basis.

An EEA national who is exercising Treaty rights as a self-sufficient person must hold CSI for any period during which they are relying on a right of residence on that basis, and would be required to evidence that they had held CSI for this period in any application for a document confirming a right of residence. Once a person has acquired permanent residence, they are no longer required to be a “qualified person” by exercising Treaty rights and therefore are not required to hold CSI after that point.

UK resident partner

Civil partners of EEA nationals are direct family members and as such have an automatic right of residence under the Regulations and will have a right to reside where the EEA national is exercising Treaty rights or has acquired permanent residence under the Regulations.

Durable (unmarried) partners of EEA nationals can assert a right of residence under the Regulations, however as they are extended family members rather than direct family members, this right of residence only comes into effect when the person has obtained a document confirming this right from the UK Border Agency. Therefore, if the EEA national in question is the durable partner of another EEA national, they would need to obtain a document from the UK Border Agency confirming a right of residence in this capacity in order to have a right of residence in the UK beyond the initial 3 month period.

## Planet of the Vapes

### **How does the EU's competence in health affect you/your organisation?**

Planet of the Vapes (PotV) is a UK based limited company which provides a community for vapers (users of ecigarettes) both nationally and internationally. It provides a forum, a wiki and a marketplace, enabling members and vendors to come together for chat, support and advice across all issues impacting vaping. At the time of writing, it has over 1,400 active members including 97 vendors and 15 modified device makers. Furthermore, it has strong social media following, specifically through Facebook and Twitter. By current standards it – and its members – will be directly and negatively affected by the proposed EU legislation into further tobacco control, specifically the Tobacco Products Directive (TPD), and potentially those directives covering medicine and medicinal devices. **It is PotV's argument that the EU is incompetent and ill-informed in dealing with this matter, as it directly contradicts stated government policy, and the UK's national interest economically and socially.** In summary, the proposed legislation would prevent all the businesses mentioned above from operating legally, making several hundred employees redundant, and potentially several thousand more across the sector nationally. Furthermore, it has been estimated that 600,000 people have given up smoking as a direct result of vaping. Based on research undertaken by PotV, the majority of these people would revert to smoking, with the resultant negative impact on health and social care. The remainder would be likely to continue vaping through utilising the black market which would surely spring up in the vacuum. This goes against the published government aims of reducing smoking across the population, as well as of reducing crime. In responding to this call for evidence, PotV will be referring specifically to the proposed legislation on vaping, but from this will extrapolate the competence or otherwise of the EU in matters of public health.

### **What evidence is there that EU action in health advantages or disadvantages:**

#### **The UK national interest**

A healthy population is in the UK's national interest, and smoking has been shown to account for over 81,000 deaths in the UK in 2009 alone (ASH, 2011). Government policy reflects this concern, and it has launched initiatives such as Stoptober and the Smoking Health Harm campaign, with the stated aims of reducing the number of British smokers. Furthermore, organisations such as NICE have included the use of ecigarettes in their guidelines as part of the Tobacco Harm Reduction programme. The proposed revisions to the EU Tobacco Products Directive exactly oppose these policies, by severely restricting the use of ecigarettes, which have been shown in numerous surveys to be one of the best means of encouraging smokers to quit, with success rates of up to 70% (Siegel, M.B., Tanwar, K.L., & Wood, K.S., 2011), compared with conventional NRT rates of a maximum of 12% (West R, Owen L, 2012). Research undertaken by PotV has indicated that if restricted in the proposed ways, 77% of vapers would revert to smoking cigarettes (2013). The Electronic Cigarette Consumer Association in the UK (ECCAUK) estimates that there are at least 600,000 vapers in the UK at the current time. If the ratio of vapers who would start smoking again were applied to this figure, then **462,000 people would return to smoking as a direct result of this legislation.** The UK is a democracy, and the population expect that decisions will be taken fairly and democratically, with due consideration of the facts, without bending to pressure from certain powerful groups. If it appears that the government is not fulfilling these expectations, there will be reduction in trust in both the national and European parliaments. This could lead to an increase in popularity of fringe political single-issue groups, which could have a far-reaching negative effect on the UK national interest. So far, the EU's approach to ecigarettes has been one-sided and undemocratic. This is evidenced in the TPD public hearing on 25th February 2013, at which all

bar one of the expects were from big pharmaceutical companies with a vested interest in preventing the rise of a free market in ecigarettes. The other voice was that of a tobacco corporation representative, who was ridiculed and not given a fair hearing. There was no consideration given to the voice of ordinary vapers, nor to the companies which would be directly affected by the directive. **The EU has therefore shown itself to be incompetent in considering evidence in an unbiased and professional manner.**

**Professor John Britton, who leads the Tobacco Advisory Group for the Royal College of Physicians, believes nicotine itself to be no more or less harmful than caffeine** (BBC, 11 February 2013), and that the real danger of cigarettes comes from the other chemicals within them. Caffeine in itself is lethal at high doses. It is estimated that 500mg of caffeine in one day can trigger serious health problems (Chad J. Reissig, Eric C. Strain, Roland R. Griffiths, 2008) yet there are some products in which one can alone contains 500mg, which are perfectly legal. Ecigarettes are not necessarily even closely connected with tobacco: of those surveyed by PotV, only 16% favoured tobacco flavoured liquid over other flavours, and half of respondents did not refer to their vaping devices as ecigarettes (2013). Furthermore, a company in Minnesota successfully challenged its state tobacco tax laws in 2012 by proving that its nicotine was derived from plant sources other than tobacco leaf (greensmartliving.com). If the EU were to apply its decisions fairly, it would ban cigarettes and relabel caffeine as a medicine with all of the restrictions on coffee and chocolate that it is proposing to place on ecigarettes. The approach which the EU is proposing is potentially unlawful, and implementation would lead to several legal challenges: deciding to limit nicotine absorption by only one of the many legal methods is both questionable as a human rights issue and a matter of unfair competition.

### **Business and industry**

The British ecigarette industry is a fledgling industry which is experiencing considerable growth. In Q1 of 2011, the industry was considered to be worth over £10m per annum. By Q4 of 2012, this figure had doubled, with several firms declaring annual earnings of over £1m (ECCAUK, 2012). PotV has 97 vendors as members, and there are hundreds more who are not. All of these businesses are SMEs, a group which the government has specifically targeted and praised as being beneficial to the UK's economic growth. Furthermore, all of these companies pay taxes within the UK. Most employ staff and many have storefronts which are helping to support local high streets.

The TPD would stop this economic activity immediately. **The EU's interference would prevent the UK markets from operating freely, and would be promoting monopoly by big pharmaceutical companies.** All of the ecigarette businesses would be forced to close, as they would no longer be able to supply the products their customers require. Thousands of employees would be made redundant, having a significant impact on already dismal unemployment rates. This would put further stress on the economy and lead to more people claiming benefits. Additional health service costs would be incurred, with half a million people reverting to smoking. Prescription and GP costs would increase as the remaining vapers turned to their surgeries for life-long repeat prescriptions, as vaping is seen as a lifestyle choice rather than an NRT in the traditional sense. Of those surveyed by PotV, over half stated they knew of no-one who had stopped vaping (2013).

The PotV survey suggests that 61% of current vapers would try to obtain nicotine liquid through alternative means before they started smoking again (2013). This would send all sales outside of the EU and establish a black market, thus criminalising a section of society. Not only would this have a negative impact on the UK economy by removing tax revenues, it would also put further burden on the criminal justice system as perpetrators were prosecuted.

### **Patients and citizens**

The effects of smoking are well known and summarised above. If the EU's proposals are implemented almost half a million vapers will return to smoking. This will not only have a negative impact on patients' health, but will also serve to normalise smoking, breaking the hard work of several decades within the UK and across all political parties.

As indicated above, 61% of respondents to the PotV survey stated they would attempt to obtain nicotine from the black market. The EU would therefore push potentially 366,000 vapers into criminal activities, putting them in touch with criminal gangs with all the moral and social issues this would entail, and would lower the quality of products making them more dangerous to public health.

### **Does the EU's role in public health support UK actions?**

**The EU's role in public health, so far as it relates to tobacco control, negates UK actions.**

It does this by:

- Undermining government policy
- Sending almost 500,000 vapers back to smoking
- Normalising smoking
- Reducing freedom of choice in determining how to stop smoking
- Ignoring, misrepresenting or misunderstanding the facts about vaping

### **Future options and challenges**

#### **How might the UK benefit from the EU taking less action in health?**

Refusing to support the TPD would enable the UK to:

- Continue to offer smokers the freedom of choice in when and how to stop smoking
- Keep one of the most successful NRTs on the open market, thus improving the chances for smokers to stop smoking permanently and keep almost half a million vapers from returning to smoking
- Support UK SMEs

#### **How could action in this area be undertaken differently?**

More research, particularly longitudinal studies, needs to be conducted on the effects of ecigarettes, both in and of themselves and in comparison with other substances, particularly cigarettes and other materials which could be considered hazardous (such as caffeine). This research should be carried out in conjunction with those in the industry and those who use the devices.

The government should help support those organisations, such as the Electronic Cigarette Industry Trade Association (ECITA), which are attempting to improve standards of quality across the industry, and provide help and guidance to companies both already in the industry and which are considering entering it. More regulation would also be welcome on the quality of import coming in from countries such as China, whose standards can vary widely.

Further work needs to be undertaken in educating the general public about ecigarettes in a rational and unbiased manner. This would be particularly helpful across the NHS, to ensure that health practitioners have all the facts and can advise their patients accordingly.

### **General**

#### **Is there evidence of any other impacts resulting from EU action in health that should be noted?**

In 1992, the EU banned snus, a tobacco product that is placed under the lip, on the basis that it had a causal link with mouth cancer. The only country still allowed to produce it is Sweden, who

entered the EU in 1994. The EU has resisted challenges to the ban despite a considerable amount of scientific evidence showing the health benefits in using snus to reduce smoking prevalence: 'the proportion of male smokers [in Sweden] fell dramatically from 40% in 1976 to just 15% in 2002. Almost a third of ex-smokers used Snus when quitting, and those who did were about 50% more likely to succeed' and Sweden now has the lowest number of tobacco related diseases within the EU. 'Anti-smoking organisations...played a major role [in upholding the ban], some of them funded by pharmaceutical companies worried that their share of the lucrative smoking cessation market was under threat. **These were the same companies regarded as "stakeholders" by the European commission, and who continue to be consulted regularly over EU tobacco regulation.**' (Guardian, 2012) This is the same approach that has been displayed in the TPD review.

### Other general points

The NHS is the largest health organisation in the world. Health policies and health provision and the way this is funded and organised varies substantially through the EU: the major and more credible source of expertise is the NHS.

Public health, including the use of tobacco, is a social matter and is largely dependent upon the prevailing culture in each country, and often in regions within those countries. For the EU to think that it can determine an overarching strategy which suits all countries equally is palpably impossible. The EU was created to enable free trade between member states and provide a degree of commonality in key areas, such as human rights and trade laws. It was not designed to dictate the daily life of member states' citizens at this level.

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## Examples of European Economic Area Citizens Accessing NHS Treatment

### October 2010

#### Patient from Bulgaria Accessing Haematology Treatment

- Mr I was suffering from a rare blood disorder, PNH paroxysmal nocturnal haemoglobinuria which required the very expensive treatment for PNH. This is a monoclonal antibody called eculizumab. This is supplied by NHS specialist commissioning via two specialist centres at Kings and Leeds. Provided by home infusion to the patient by home nursing service organised centrally. This patient had already been seen at the Leeds outreach clinic at Southampton in March 2010, when not eligible for NHS and attended there again in October 2010.
- drug was not available free of charge in Bulgaria in October 2010.
- This is lifelong treatment at an estimated cost of £50,000 per year.
- In October 2010 Leeds Teaching Hospital and Kings were the only establishments in the UK who could administer this drug, they had a satellite in the Southampton area, which was ideal for Mr I as he had an aunt residing in Gosport, Hampshire, who he stayed with when visiting the UK.
- Mr I was referred by the Gosport General Practitioner, who informed PHT in his letter that Mr I was entitled to his treatment at the Trust.
- On investigation PHT discovered that Mr I had initially come to the UK to be a self employed worker, but this was not possible due to his ill health.
- Mr I had not provided Leeds teaching hospital with the proof that he had severed all ties with Bulgaria in order to take up the NHS exemption of being a permanent resident in the UK to enable him to access NHS free of charge.
- Mr I wanted to use the student exemption which would entitle him to access the NHS free of charge and had enrolled in a language course at St Vincent College, Gosport, a local technical college.
- PHT confirmed with the college that Mr I's course was only a part time course and did not allow him to qualify for this exemption. He had also been returning to Bulgaria on a regular basis to look after the company he had registered in Bulgaria and for medical treatment.
- Mr I did apply to the UKBA to try to obtain student status in the UK, but this was refused.

#### Patient from Romania Accessing Rheumatology Treatment

- Mrs T arrived from Romania in October 2010 as a self employed cleaner for a company
- This patient required to be prescribed expensive Rheumatology medication - , which she was self funding in Romania, but if a full time resident of the United Kingdom she could access this free of charge.
- The patient did fulfil the criteria and is still being treated at Portsmouth Hospitals NHS Trust.

- We have since learnt the patient is constantly returning to Romania and her treatment is being affected by this, the Trust will now have to investigate if she can be classed as a resident of the UK.

### **Maternity Patients from Poland**

- When the UK was allowing maternity patients to receive a benefit to buy equipment for their baby – midwives were asked to complete the form to allow them to receive this benefit and for them to return to Poland and other Eastern European countries before having their children.

## PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP (PwC) is one of the UK and Europe's largest professional services firms.

PwC UK provides an extensive range of support to clients in all areas of public and private sector in the UK, including internal and external audit services, tax advice and consultancy support.

The work we do with our clients gives us an insight into the wide range of challenges and opportunities facing them and the regulatory and economic environment that they operate in. This response has been prepared on the basis of our work with both public and private sector organisations in the Health sector. We recognise that the Government will, no doubt, receive a significant number of responses to their review so we have kept our response brief and focused on the issues that we believe are most pertinent to the review. These are:

- Medicines and Medical Device Testing
- Pricing
- Research and Development
- Data and integration
- Employment and Working Time Directive
- Competition
- Clinical Trials
- Common Standards for Training

### *Medicines and Medical Device Testing*

The role of the EU with regards to the approval of medicines and medical devices has been largely positive and we believe it has led to a much more efficient and streamlined process – which is obviously welcome.

The role of the EU in biosimilars has also been positive and they have led the way in developing a pragmatic approach to supporting the development of these drugs, which are much cheaper than the original biopharmaceutical products.

In both areas there are clear benefits to patients and citizens in reducing the costs of drugs available and in improving the speed with which drugs are approved and available. Practice in the EU however, can be at odds, with the US, where the relevant agencies can reach different conclusions about the safety of drugs and medical devices and this can bring uncertainty into an area where many, particularly patients, are looking for assurances around the quality and safety of medicines and medical devices. One example is the recent health scare around the use of Poly Implant Prosthese (PIP) breast implants. The use of these implants was halted by a moratorium by the Food and Drug Administration (FDA) in the USA in 2000, but continued to be widely used in Europe until 2010.

We would not wish to suggest that all EU activities should conform with US processes, in many cases, as with biosimilars, we believe that the EU approach brings great benefits, but we encourage the EU to continue work on an international scale to seek to secure international consistency and to have regard to developments in other territories that might lead to different standards or approval and acceptance of medicines and devices.

### *Pricing*

Pricing of medicines vary significantly across the EU which can lead to high levels of parallel imports. Over recent years when the Pound has fallen in value against the Euro this means that at various points UK medicine prices have been within the lowest ranges of prices across the EU, which could potentially lead to shortages of key medicines within the UK as they find their way into other European markets. Pricing of medicines is a very complex area, impacted by many factors, including preferences for branded versus generic drugs. Pricing consistency would be very welcome, but very difficult to achieve. However, action by the EU to limit or control the practice of parallel imports could provide important protection from drug shortages in the UK health sector.

#### *Research and Development*

Across the member states of the EU there are different tax treaties relating to investment in research and development. This can impact on pharmaceutical companies' practices around where it locates its research and development and manufacturing activities – decisions taken to gain maximum benefits from these different tax regimes. Such practices can lead to 'skewing' of certain activities and the associated employment opportunities in those activities in member states. On a wider perspective we believe the EU State Aid Law can have a similar impact on R&D activities in the EU compared to the US where the NIH is able to apply much greater freedom to the funding of research and innovation in medicines and medical devices. This can result in the migration of scientists to the US where there are greater R&D opportunities, impacting on the ability of UK and based companies to recruit highly skilled staff. Action to ensure a more level playing field around funding and tax treatment for research and development activities, both across the EU and International could address these issues, and support a greater retention of skilled individuals in the UK.

#### *Data and Integration*

In the UK, the Office of Life Science's Strategy has opened up the availability and use of data within the health sector. Availability of similar data across EU member states could facilitate a much improved understanding of health outcomes which could support more innovation in the development of new products, particularly around difficult to treat conditions.

We also believe that wider availability and greater consistency of data could support improved integration within the health care system – integration, which we believe, is fundamental to a successful health care system with multiple providers.

The Oyster Card in the UK has proved that the existence of multiple providers is not a barrier to provision of service, where there is effective integration of systems and data flows. The introduction of EU wide interoperability standards for common data and systems could facilitate EU wide integration, delivering significant benefits for patients and citizens, particularly those that might move more frequently across EU member states.

#### *Employment and Working Time Directive*

The nature of services provided in the UK's Public Health sector is such that it requires modern and flexible employment policies in order to provide high quality patient care. However, we believe that much of the employment framework within which the sector operates is rigid and prevents innovation and local choice in employment practices in healthcare providers.

Under UK regulations Foundation Trusts (FTs) do have some freedoms that enable them to alter the terms and conditions of employment of their employees. However, our experience suggests that few exercise these freedoms as the local employment market for many positions in health care organisations is highly competitive and many potential employees do not differentiate between FTs and non-FTs. So in areas where both types of providers operate many staff will choose to work for a non-FT provider, if they believe the terms and conditions of employment are more advantageous for them.

The existing restrictions are not however, the result of the Working Time Directive, but of UK policy and we believe that there needs to be great freedom for all local health care providers, in order for them to be able to determine the terms and conditions of employment that would be most appropriate to meet their local needs and circumstances.

With specific regard to the Working Time Directive we would again urge for flexibility in how the regulations are applied. We absolutely support the need to manage the hours that junior doctors work, but rigid application of rules, we believe, can mean that the patient care can suffer as their care is passed from one doctor to another. The consistency of care and sense of 'ownership' over patients can be lost as a result.

### *Competition*

At present clinical care is exempt from EU rules on competition. Whilst we understand the need to ensure high quality standards of patient care, we believe that opening up the health care provider market to more competition could bring significant added benefits to patients and citizens through:

- improving quality and driving down prices
- stimulating greater innovation
- introducing new providers to the market and removing existing barriers / disincentives to new entrants
- driving more efficient, effective and economic business practices within existing health care providers.

We do not believe that introducing competition into the market would destabilise existing providers, one of the arguments most often cited against increasing competition. Effective information flows can facilitate an integrated health care system which comprises many different providers. We also believe that regulations governing procurement and competition can be perceived to act as a barrier to market activity. Why, for example, are there so few cross border hospital groups? We would encourage the EU to consider what role they could play in helping to drive greater innovation and best practice in market competition across the EU through its policies and mechanisms.

### *Clinical Trials*

We believe that the current regulations surrounding the conducting on clinical trials could be simplified, in particular, to remove the need to go through numerous local and national Ethical Committees. A system which oversaw regulated and approved local Ethical Committees, all operating to a consistent and high standard, could mean that approval would only need to be gained from one Committee in order to provide assurance to all other areas that a trial had been conducted properly and that the results were reliable and safe. Current arrangements run the risk of stifling innovation because of the burden of cost and effort required to gain the necessary approvals.

### *Common Standards for Training*

We believe that the EU could do more to foster consistently high standards of training across member states, creating common standards for all. This would support the free movement of people across EU member states and help address staffing shortages in key skills, whilst at the same time raising professional standards, leading to improved patient care.

## Proprietary Association of Great Britain

The Proprietary Association of Great Britain, PAGB, is the UK trade association for over the counter medicines and food supplements. We represent the major manufacturers of these products in the UK, many of whom are multinationals with experience of regulatory structures world-wide.

### **Impact on the national interest**

#### ***How does the EU's competence in health affect you/your organisation?***

The harmonisation of medicine and food law has both positive and negative aspects. Whilst the single market and harmonised trade are vital to the UK economy, the complex range of cultures across the EU means the single market must somehow embrace immense diversity and all too often this is reduced to the lowest common denominator.

#### ***What evidence is there that EU action in health advantages or disadvantages:***

- ***The UK national interest***

The complexity of the EU lends itself to multiple layers of regulation which can be restrictive and limit innovation and flexibility. The need for conformity within the greater whole of the single market can be viewed as a disadvantage for small to medium sized enterprises (SMEs).

- ***Business and industry***
- ***Patients and citizens***

The huge single market for the free movement of goods and services is generally viewed as advantageous and as increasing choice.

#### ***Please consider what evidence there is to demonstrate; o the extent to which the EU's role in public health supports member state actions effectively and efficiently***

- ***the opportunities and costs for the delivery of health and social care in the UK that flow from wider EU competences and policies such as the free movement of workers or the single market generally***
- ***the extent to which EU competence and policies intended to allow EU citizens to access healthcare across the EU are effective and proportionate***
- ***the extent to which health objectives are effectively and proportionately taken into account in wider EU policies***

The healthcare systems across the EU are so widely varied that it is difficult to see how the EU can exert much influence on them. It should be national governments who determine health policies and programmes that are appropriate to their own populations and to control aspects such as management and budgets accordingly.

### **Future options and challenges**

- ***How might the UK benefit from the EU taking more action in health?***

The EU is taking the lead in harmonising the regulation of OTC medicines and medical devices; however it should also take the lead in the issues of prevention and self-care, both of which are lacking in the health programmes and communications of many member states.

#### ***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

***How could action in this area be undertaken differently e.g.***

***Are there ways of improving EU legislation in health, e.g. revision of existing legislation, better ways of developing future proposals, or greater adherence to the principle of subsidiarity and proportionality?***

Where rules are not harmonised, the EU relies on mutual recognition to facilitate the market but very often this fails to work. Taking tryptophan as an example, sale of this amino acid is restricted by dose and purity within the UK, but it is freely available in other EU member states at higher doses. These higher dose products cannot be sold within the UK because the UK considers it to be a health risk, despite much evidence to the contrary.

There are other instances where mutual recognition cannot be used where Member States have public health concerns about a food. The substance melatonin, which is freely available in a number of member states and has two authorised health claims against it, is considered medicinal in the UK and therefore mutual recognition cannot be used to open up the market.

***Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest***

The EU is not present to deliver anything in the national interest; it is there to deliver on a federal level across the EU.

The EU aspires to better regulation principles however; all too often it gets bogged down in endless negotiations and compromises, especially where it tries to protect consumers from misunderstanding specific issues. This could be due to the wide diversity of cultural issues across the EU; what a consumer in one country may accept or understand from a medicine or food label, a consumer in another country would view very differently. Placing this within the control of national governments and putting more emphasis on mutual recognition would allow greater diversity and innovation in national markets, which in turn could provide greater flexibility in the wider trade arena.

***Could action be taken at any other international level i.e. by the WHO?***

The WHO works on a global level which is not necessarily appropriate for a national level. As already noted above, the vast diversity of the EU already impacts on the UK's ability to fit regulation to the needs of its population.

***What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?***

- ***How else could the UK implement its current obligations?***
- ***What future challenge/opportunities might we face in EU health competence and what impact might these have on the national interest?***
- ***What impact would any future enlargement of the EU have on health competence?***

Future enlargement will add to the complexity of an already unwieldy conglomeration of states, many of which are at vastly different stages of development.

**General**

- ***Is there evidence of any other impacts resulting from EU action in health that should be noted?***
- ***Are there any general points you wish to make which are not captured above?***

EU law has built up so gradually over so many years it is impossible to say what the protection of patients, consumers and business would be without it. If it were to be removed tomorrow what exactly would it be replaced with? It is likely that national law would mirror, as closely as possible, that which already exists to allow the continuance of free trade.

The blunt instrument of Regulation that applies as a blanket across the EU without the possibility of national variation is not necessarily appropriate for all legislation. The use of Directives provides the flexibility for interpretation to be applied at national level.

There are also cultural and geographic issues to consider; some problems arise due to Member States' different approaches to law. Many follow the Napoleonic tradition of codification, whereas the UK has a common law tradition. These differences of approach result in inconsistencies in interpretation across the EU. In addition, the UK's traditional use of principle based legislation does not sit well with the EU's highly prescriptive view. The UK has had one of the broadest markets in the EU for both over the counter medicines and food supplements largely because of its use of principle based legislation.

## Provision Trade Federation

PTF's members are companies of all sizes involved in supplying bacon and ham; canned foods; and dairy products of all kinds, including milk powders, cheese, butter, yogurt and other dairy desserts. Our members include importers and exporters of these products, as well as processors, and many supply the major retailers. PTF supports free trade.

PTF attended the FSA/DEFRA workshop on the BoC review on 7 February and the DoH workshop on 5 February. Both workshops were extremely helpful, highlighting the aims and importance of the review, and encouraging stakeholders to think through the issues.

This is a vast subject. There are many points that could be raised and arguments for and against each. On balance, PTF supports about 90% of the output document from the FSA/DEFRA event. The positive aspects of EU competence include the harmonisation of legislation; the single EU voice on global issues; and the EU acting as a driver for learning/collaboration, and sharing data, to the benefit of all. The negatives requiring change include that there is a need for EU procedures to be more open and transparent; legislation can be too prescriptive, discouraging innovation; and frequently there are different interpretations of legislation between Member States and different approaches to, and level of, enforcement in each Member State.

Our detailed comments, responding to the questions in the consultation document of relevance to PTF, are below.

- **What evidence is there that EU action to create the single market for food has been advantageous or disadvantageous for the UK?**

A harmonisation of legislation and removal of trade barriers allows for free movement of goods and makes trading between Member States easier. The harmonisation of hygiene legislation, for instance, makes it easier to source with confidence, knowing that the legislation ought to be consistent across all Member States.

However, there is not always a level playing field, with differing interpretation and enforcement of legislation across Member States. One example is the partial sow stall ban which came into force across the EU at the start of 2013. It was vital that all Member States implemented these animal welfare requirements before the deadline in order to avoid unfair competition between countries where pig producers complied with the requirements and those where some of the producers did not comply. Yet even after the deadline, there was still a significant level of non-compliance with only 5 Member States fully compliant and 8 Member States less than 70% compliant. The Commission did nothing to ensure compliance before it was too late. It now intends to launch infringement proceedings against non-complying Member States but this will be slow and cumbersome. If all Member States had implemented and enforced this legislation adequately, this would not have been necessary.

- **What evidence is there that the national interest in terms of trade is best served by action at EU level, national level or by action being taken at a different level, eg in Codex Alimentarius?**

Currently, the majority of food law in the UK implements EU legislation. This allows for harmonisation between Member States but creates problems when national legislation would have been preferable. For example, for foods that are traditional in one Member State, such as British territorial cheeses and bacon in the UK, the Member State concerned should be allowed to set compositional standards at national level so that consumer expectations, and their 'local'

understanding of the product, can be taken into account. The fat and moisture limits for territorial cheeses, currently specified in the Food Labelling Regulations 1996 (FLR), are an example. These limits, which have been specified in UK law for over 30 years, help to protect the quality and characteristics of these traditional UK cheeses. In implementing EU Regulation 1169/2011 on food information to consumers (FIC) into UK law, and revoking the FLR, these national rules will be lost. However, the UK industry is fighting to retain them because there is a fear that, without them, standards will decline due to economic pressure. The protection of these cheeses is of particular concern to the UK market but will be a low priority for other Member States. In situations such as this, legislation should be set at national level.

- **Has EU action in food law provided the right balance between protecting the consumer and protecting the interests and reputation of UK businesses?**

EU legislation rightly protects consumers' health, protects them from being misled and from sub-standard products. However, there is sometimes a feeling that EU action is disproportionate and ignores the interests and reputation of UK businesses.

One example is the new rule under the EU FIC which requires added water to be declared in the name of the food for meat and fish products having the appearance of a cut, joint, slice, portion or carcase of meat, if the added water makes up more than 5% of the weight of the finished product. The objective of this requirement was to protect the consumer from unfair and misleading practices with regard to the addition of significant amounts of water which they would not expect in such foods. In fact, with respect to bacon, the opposite is the case because the UK will lose the 10% limit which currently applies in national legislation and prevents the over-watering of bacon.

The UK legislation specifying a 10% limit for uncooked cured meat such as bacon has applied since the 1984 Regulations on meat products and spreadable fish products came into force. The discussions at that time had acknowledged the need for 10% water in uncooked cured meats in order to dissolve sufficient curing salts. Replacing the 10% limit with a 5% limit will mean that the labels for 98% of bacon sold in the UK will need to be changed to declare 'added water' in the name of the food, because they will contain more than 5% added water.

However, there will no longer be an effective limit preventing over-watering. As such, this additional labelling burden on UK bacon suppliers offers little, if any, benefit to consumers.

- **What evidence is there that the principle of science-based food legislation at the European level has served the national interest well? Are there any concerns about the principle and its application? Are there any examples of where it was not followed?**

It is right that EU policies and decisions should be based on the best available scientific evidence and this is in line with the FSA policy in the UK. However, there are occasions on which the principle is followed too slavishly. For example, EFSA's evaluation of health claims has been overly strict, adopting an approach more appropriate for medicines than food. As a consequence, there are so many claims that are no longer permitted that investment in new product development has been stifled because companies cannot guarantee they will be able to inform consumers about the benefits of their products.

The probiotics category is a good example because, to date, EFSA has not approved any claims in relation to probiotic cultures and, as a consequence, the term 'probiotic', an implied health claim according to EU guidance, is no longer permitted. This is despite the fact that the WHO has recognised the role of probiotics and scientific experts recognise the contribution probiotics can make to human health. Companies active in this area have a long history of probiotic research and development and are confident in the science behind their products.

However, they are now unable to communicate the benefits of their products to consumers in an easily understandable manner, and research and investment in this sector will become pointless. Consumers whose health could have been improved or maintained by probiotics will be denied an informed choice and may suffer as a consequence. They will be forced to refer to less reliable sources of information such as the internet and the media, and may lose confidence in the category as a whole.

- **How might the UK benefit from the EU taking more or less action on food law in the future?**

The food legislation that currently exists in the EU is extensive and wide-ranging to the point that it creates burdens for businesses because it is so difficult to keep pace with the stream of new rules.

The new EU FIC is comprehensive and requires significantly more on the label than previously. Even more labelling is on the horizon under this legislation, for example on origin of foodstuffs and ingredients. This is subject to impact assessments, which, in themselves, are of questionable accuracy. Too much unnecessary food labelling is counter-productive because it can lead to labels which are confusing and difficult to read. It can also contribute to food waste when errors or omissions on labels lead to recalls and withdrawals. This is particularly galling when the error or omission relates to information which is not required for food safety purposes.

The food hygiene legislation is thorough, focusing on a HACCP approach by which the onus is on the food business operator to analyse the hazards in their business and seek to control them. As such, there should be no need for further prescriptive legislation in this area.

A moratorium on new legislation should be considered except where there is a real food safety need for more rules. The focus should now be on enforcing the legislation that currently exists.

- **Could action be undertaken differently e.g. are there ways of improving EU food law?**

The development of EU law must be more open and transparent, particularly to allow all sectors affected to have an input at an earlier stage. The current approach is rather haphazard with a drip-feed release of papers to some parties but not to others. It is vital that there is a proper discussion of proposals, by all affected parties, while there is still time to influence them. Currently, this is not that case and it is difficult to get involved in the legislative process at an early stage.

With 27 Member States, it is often difficult to reach an acceptable agreement, and compromise legislation ends up being imposed on Member States, sometimes with very little, if any, consultation. We were particularly alarmed at the procedure adopted to secure an agreement between all parties on the EU FIC at second reading. A series of trilogue meetings were held between European Council, Commission and European Parliament representatives. Compromise proposals agreed behind closed doors at these trilogue meetings contained some new requirements (including the new rules on added water above) which had not been subject to consultation and have since caused significant problems for the food industry.

Although there are a number of concerns that need to be addressed, on balance we believe that the UK benefits from membership of the EU because it facilitates trade.

## Rebecca Taylor MEP

The following submission has been prepared on behalf of Rebecca Taylor MEP in order to clarify the state of play with regards to health in the current framework of EU legislation and the broader EU dialogue.

The recommended questions set out in the 'Call for Evidence' are answered briefly below. However, Ms Taylor considered it more appropriate to give a summary of sectors. They are set out in this format:

- A. Regulation: Pharmaceuticals, clinical trials and medical devices,
- B. Public Health measures
- C. Services and workforce

You will find these after the 'Call for Evidence' questions.

### **Impact on the national interest**

- *How does the EU's competence in health affect you/your organisation?*

As an MEP, health specialist, and UK citizen from Yorkshire, I seek to create legislation which has a positive impact on health across the EU, whilst maintaining a focus on the interests of the UK. The questions below are answered from this perspective.

- *What evidence is there that EU action in health advantages or disadvantages:*

- o *The UK national interest*
- o *Business and industry*
- o *Patients and citizens*

As an EU Member State with a thriving life science and medical research sector, the UK benefits substantially from the single market in health products (especially pharmaceuticals and medical devices), and from the EU's focus on innovation. This benefits EU business, which in turn benefits the UK national interest.

Most health-interested MEPs try to keep legislation patient-focussed, through dialogue with patients groups, proportionate risk-based policies and increased transparency. UK patients and citizens have access to cutting-edge technology and medicines, whilst gaining from a high level of consumer and health protection.

- *Please consider what evidence there is to demonstrate;*

- o *the extent to which the EU's role in public health supports member state actions effectively and efficiently*

To a large extent, the EU's role in public health is complimentary to Member State action, as Member States remain responsible for the organisation, funding and delivery of healthcare. The European Commission and its agencies serve as hub for communication, sharing best practice and addressing health risks through warning mechanisms. The recent horse meat scandal has shown how effective communication and warning mechanisms are needed when problems occur within the single market.

*o the opportunities and costs for the delivery of health and social care in the UK that flow from wider EU competences and policies such as the free movement of workers or the single market generally*

The free movement of citizens and workers provides opportunities for Member States, in meeting gaps in their healthcare labour market, including people with specialist medical skills. More details on this question can be found in Section C below.

*o the extent to which EU competence and policies intended to allow EU citizens to access healthcare across the EU are effective and proportionate*

The principals guiding these policies were established by the Kohl and Decker ECJ judgements of 1998. Please see more details in Section C below

*o the extent to which health objectives are effectively and proportionately taken into account in wider EU policies*

The EU health objectives, for the moment, are limited to ensuring that the smooth functioning of the internal market maintains a degree of health and consumer protection. The organisation, funding and delivery of health care is still the responsibility of Member States, with the EU providing some guidelines, for example the European guidelines on cancer screening, and action plans, for example the EU e-health action plan. In this sense, EU policies are wholly appropriate.

## **Future options and challenges**

- *How might the UK benefit from the EU taking more action in health?*

Answered together with the question below.

- *How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?*

The EU is not in a place to take on the role of Member States in the provision of services, nor would it want to. The principle of subsidiarity is recognised by all, and in the field of health-care, where proximity to the patient is hugely important, this is especially appropriate. Gaps in health and consumer protection will almost certainly become apparent over the coming years (as they have recently with the horse meat scandal) and coordinated action at EU level will probably be needed, though there is unlikely to be a large shift in the direction of the Commission in the near future.

- *How could action in this area be undertaken differently e.g.*

*o Are there ways of improving EU legislation in health, e.g. revision of existing legislation, better ways of developing future proposals, or greater adherence to the principle of subsidiarity and proportionality?*

The Commission and the majority of MEPs recognise and adhere to the principles of subsidiarity and proportionality in their work. The Council of the European Union is particularly adept at drawing attention to these principles when negotiating with the other institutions.

Health legislation negotiated within the European Union over the past two years has, for the large part, been revisions and updates of existing legislation.

*o Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest?*

The existing EU competences deliver, on-the-whole, a very beneficial settlement for the UK.

*o Could action be taken at any other international level i.e. by the WHO?*

The EU often uses WHO actions and principles as the basis of its own health legislation. The WHO still has a role in European public health. For example, legislation is currently being negotiated on how the EU deals with pandemics and other cross border health threats; This cannot be done without reliance on the WHO.

*o What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?*

This is a question for which hundreds of pages could be written. Further details are given in the text following the formal questions.

Nevertheless, a good example to draw attention to would be Clinical Trials;

Clinical trials legislative measures are needed as in order to generate enough patient safety and efficacy data to produce new medicines, researchers need to conduct trials across many different EU Member States, and outside of the EU.

These countries often differ greatly in their views on ethics, on safety and in the organisation of their health systems. They also need to communicate to establish trust in each other's oversight and ability to communicate safety concerns.

Legislation is needed to allow these multi country trials to take place; to generate new and better medicines, to create jobs, and to create a network where safety concerns are communicated and addressed effectively.

The current proposal and ongoing negotiations on a new Regulation on Clinical Trials is a good illustration of how EU legislation can work well to address these issues. It is also an example of where a purely national approach would not be advantageous for the UK, as the UK life science and medical research industry already conducts many multi country trials and having to deal with 27 clinical trials regimes would be more costly and take more time than the more streamlined and harmonised EU clinical trials system, as proposed in the new regulation.

*• How else could the UK implement its current obligations?*

The effectiveness of EU legislation is the key to the success of the single market. This means that the Court of Justice must be effective in enforcing legislation. If the UK would like to revise its existing commitments it can seek agreement with its partners in the Council to initiate revisions of legislation.

In the future, the UK can try to avoid gold plating legislation, and can try to adequately fund the enforcement of existing legislation so that more trust can be built in the EU framework as a whole.

*• What future challenge/opportunities might we face in EU health competence and what impact might these have on the national interest?*

Broadly speaking, if current legislation is monitored and enforced inadequately, leading to health risks, we might see the need for new legislation, or better funding of existing legislation.

*• What impact would any future enlargement of the EU have on health competence?*

Enlargement in the near future is likely to be confined to a few small states in the Balkans and perhaps Iceland, meaning that the overall make-up of the EU is unlikely to fundamentally change.

## EU Competences Review: Health Policy

### OVERVIEW

Although some aspects of EU legislation in the area of health are controversial, the overall package of legislation, recommendations, research funding and mechanisms for collaboration and the exchange of best practice and evidence, are beneficial to the UK.

First of all, it is important to understand that EU competence in health is for the most part complementary, i.e. it complements national policy and encourages cooperation where beneficial e.g. cross border health threats like pandemic flu. The relevant treaty article (TEU article 168) is clear that the organisation, delivery and funding of healthcare remain national matters.

EU legislation in the Health sector is linked to the single market rather than acting directly to promote the health or wellbeing of EU citizens, although obviously good regulation of pharmaceuticals and medical devices is a way of protecting citizen's health and well-being. The non-legislative initiatives in the health field such as the European cancer screening guidelines are justified on the basis of improving European public health.

Where EU legislation has been met with significant outcry in the UK health sector, such as for the EU working time directive and the clinical trials directive, revisions and opt-outs have been secured by the UK. Currently, several legislative initiatives are underway including revisions of the clinical trials directive and the medical devices directive, and these are being followed closely by UK MEPs with an interest in health.

The EU also provides member states access to 6.1 Billion Euros in funding for health research as part of the 7th Framework Programme for Research and Innovation (FP7). Horizon 2020, which is due to replace FP7 in 2014, is likely to have an even larger budget for health research. A large number of EU policy makers, including MEPs and national governments are pushing for a rebalancing of the EU's spending commitments, away from agricultural subsidies and towards more funding for research and innovation.

#### A. Regulation: Pharmaceuticals, clinical trials and medical devices

The EU has a regulatory role in medicines; including the authorisation procedures for clinical trials, medicines and medical devices. This is to ensure the same level of quality, safety and efficacy across the EU. There is also a need to provide a degree of harmonisation across the EU, as medicines authorised through the "centralised procedure" (a single EU wide marketing authorisation issued by the European Medicines Agency) can be marketed in every EU Member State, and nowadays most clinical trials take place in a number of Member States in order to recruit enough patients to generate sufficient data.

The proposed Clinical Trials Regulation is addressing the considerable concerns associated with the earlier 2001 Directive. The Draft Regulation looks likely to amend many of the flaws of the previous Directive, and has been met with much enthusiasm by industry, academia,

regulators and medical research charities. The earlier Directive was transposed (implemented at national level by each individual Member State) in ways which created much bureaucracy and delays for those wishing to conduct trials. The Draft Regulation aims to provide a more uniform and streamlined approach. This has also been welcomed by Member States.

The proposed new regulation has elicited three main areas of concern, which are likely to be overcome, namely; the ambitious timelines within which Member State authorities will have to approve applications to undertake clinical trials, the tacit consent principle, which puts responsibility on Member States to scrutinise applications within the time limits laid out, and the role of ethics committees, which some Member States feel have not been written with enough clarity, although it is important to note here that the European Commission is adamant that the proposal is and will remain in line with the requirements of the Helsinki declaration (<http://www.wma.net/en/30publications/10policies/b3/>)

The European Medicines Agency (EMA), based in Canary Wharf, approves pharmaceuticals for marketing within the EU through a centralised procedure that involves the national medicines agencies. The centralised procedure is now required for most new medicines (see: [http://www.ema.europa.eu/ema/index.jsp?curl=pages/about\\_us/general/general\\_content\\_000109.jsp](http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000109.jsp)), although some are still authorised (at least initially) only at national level and then later on in further countries through a process of mutual recognition ("decentralised procedure").

The other key area of regulation currently being discussed, and a vital internal market consideration, is the proposed legislative package of Regulations on Medical Devices and in vitro diagnostic (IVD) Medical Devices. Similarly to Clinical Trials and Medicines, this is to ensure product/patient safety, and allow device makers to market their products in all Member States under similar conditions.

## B. Public Health

The EU's jurisdiction in public health is based on the principle of 'complementary competence'. In practice this means that the EU can only provide guidelines and best practice in this area, while legislation is left to national governments. The very few pieces of legislation in this space are primarily led by internal market considerations with public health protection as a secondary aim.

EU wide Tobacco control measures through the tobacco products directive, is one example of this as the directive addresses packaging, labelling, health warnings, composition of products and fraud, but cannot impose an EU wide ban on smoking in all public places; such power remains with national governments.

Even on matters of cross-border health threats such as pandemics and outbreaks of diseases like measles and e-coli, the EU's role is limited to strengthening cooperation through data collection, evidence sharing and coordination of activities through committees of Member State experts from national authorities.

Another area where the EU can address public health is in matters of food and food safety, including health and nutritional claims on food and food supplements. Food safety is relatively straight forward and mostly consists of technical regulations relating to, for example, hygiene measures in food processing facilities.

The 2006 Regulation on health and nutritional claims on food aimed to harmonise the varying national regimes across the EU, some of which were rather scant. The regulation sets nutrient

profiles (primarily maximum levels of fat, salt and sugar) for different types of food products, so that for example, a high fat, high sugar product such as chocolate cannot make a health claim e.g. "high in calcium" as this could make the product appear healthy, when in fact it contains unhealthy levels of fat and sugar.

Health and nutritional claims are authorised by the European Food Safety Authority (EFSA). There has been criticism levelled at EFSA, as the agency has with a couple of notable exceptions (lycopene in tomatoes and cholesterol lowering plant stanols/sterols) only approved claims that relate to vitamins or minerals. EFSA has not for example authorised any health claim for any probiotic containing food products, although there are peer reviewed randomised controlled trials available for some probiotic strains.

The other food regulation, which has caused a great deal of controversy in the UK (and Ireland) is the food supplements directive ([http://ec.europa.eu/food/food/labellingnutrition/supplements/index\\_en.htm](http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm)), which sets out common rules on labelling and product safety. The reason for the controversy is that the UK and Irish markets for food supplements were larger and longer standing than in many other countries and contained some products which had been available for some years but failed to comply with the new rules, in particular in relation to maximum permitted levels of vitamins. The UK food supplements industry and some consumer groups have been very active on this directive, even going as far as a complaint to the ECJ (<http://www.nutraingredients.com/Regulation/Industry-backs-ECJ-food-supplements-ruling>).

### C. Services and workforce

The legislation which impacts upon UK healthcare professionals (doctors, dentists, nurses, pharmacists, vets and midwives) also exists for internal market purposes. Legislation on working time, and minimum training standards for certain careers ensure the free movement of workers across the EU. This means that subject to a background checks to verify a clean bill of professional health from the regulatory body in the Member State in which a health professional has most recently been working i.e. proof that they are not subject to any disciplinary sanction, they are able to work in another Member State. The NHS obviously benefits from this by being able to easily recruit from other EU countries when necessary.

The qualifications of healthcare professionals have been subject to minimum training requirements set at EU level since the 1970s. These minimum training requirements have gradually extended from doctors only to apply to pharmacists, nurses, midwives, vets and dentists.

The directive on the mutual recognition of professional qualifications is revised every few years. Since the last revision in 2004, concerns were raised in relation to language skills (and not just in the UK). The directive did not allow Member State authorities to automatically or systematically check the local language skills of EU health professionals seeking to work in their territory. This is contrary in the UK to what can be done in relation to a non-EU health professional, who can be asked to demonstrate a high level of English through one of the recognised English proficiency exams such as the TOEFL.

Measures could (and have been) taken in relation to EU health professionals when problems arose, as a sufficient command of local language to communicate with and understand colleagues and patients is a requirement of the ethical or deontological code of most health

professions. At the time of the last revision, it was thought that market forces would take care of this, but that did not prove always the case in some countries including the UK. The current (ongoing) revision of the mutual recognition directive is addressing this issue more carefully.

There have been some concerns raised in the UK as to whether the standard of education and training in some medical schools in other EU countries is sufficient. By doing so they are hoping to challenge the EU to ensure that minimum training standards are adequate within each Member State. In spite of this, the key battle for the UK in the current revision of the Directive is to ensure that our elite Medical courses, such as those at Oxford and Cambridge (which involve 5 rather than 6 years of training) are able to continue under the new Mutual Recognition regime. Like most areas of EU competence, the UK has nuances to its priorities, and it is rarely as simple as 'UK high standards versus EU lower standards'

Similar concerns are at play when it comes to access to healthcare services in other EU countries. For example, access to emergency care when a person is temporarily in another Member State has long been allowed through the European Health Insurance Card (EHIC, formerly the E111 form) for example. We hope to ensure that basic health care can be accessed in any Member State, either for emergency reasons, or for those that choose to live abroad.

Cross-border health care is facilitated by the EU rules on the coordination of social security systems through Regulation 883/04. EU national health systems cannot refuse to reimburse a patient for their treatment purely on the basis that it happened outside the patient's country of residence (established in the Kohl and Decker ECJ judgements from 1998) but safeguards are in place to avoid "healthcare shopping". Emergency care is available without restrictions, but requires the patient to show their EHIC so the healthcare system providing the care knows which organisation (national healthcare system or social health insurance fund) will reimburse them.

There is another procedure for patients wishing to have planned care in another EU country, known as the E112 procedure. To benefit from this procedure, a patient has to get prior approval from their healthcare system (in the UK, their local NHS) to obtain care in another EU country. The patient has to fund the care themselves and then ask for reimbursement afterwards and they can only be reimbursed for care that would be covered by the NHS, so for example travel costs would not be covered.

However, there have been ECJ court cases where payers refusal of prior authorisation has been challenged, which established the principle of "undue delay" where a payer cannot refuse either prior authorisation or eventual reimbursement if the patient would suffer undue delay waiting for the treatment in their country of residence.

An EU directive on patients rights in cross-border care was approved in 2011 (see: <http://www.nhsconfed.org/NationalAndInternational/NHSEuropeanOffice/influencingEUpolicy/cross-border-healthcare/Pages/CrossBorderHealthcare.aspx>). The aim of the proposal was not to create any new rights but to codify those that exist already through the jurisprudence of the ECJ and to clarify rights for patients with rare diseases, specialist treatment for which may not be available in all countries, or where the patient lives in a cross border region and the nearest specialist treatment centre may be in another Member State.

Member State governments are understandably nervous of anything that may increase the cost of healthcare, hence the implementation will be done very carefully. It is worth noting that to date there have been around 10 cases where the NHS has been taken to the ECJ by patients

because it has refused to reimburse treatment obtained abroad on the grounds of 'undue delay' for NHS treatment.

The EU's working time directive, limiting the number of uninterrupted hours an employee may work, has been criticised by the UK's Royal (Medical) Colleges on the grounds that it limits the number of hours of training a doctor or nurse will be able to undertake before qualification. In particular, controversy rests on the fact that the EU considers 'on-call' time as working time. The UK has negotiated an opt-out of the working time directive which can be signed by doctors and nurses (and workers from other sectors too). This opt-out is one of the many which make up the patchwork of compromises to ensure the EU does not fundamentally jeopardise standard UK practices. Negotiation within the EU can provide these is done effectively.

'E-Health', including telehealth, are only subject to "soft" law, that is action plans, guidelines, recommendations etc. However, 'NHS IT' including electronic patient records would be impacted by data protection regulations set out by the EU to protect the confidentiality of personal data. Some UK health bodies have expressed concern about additional red tape which could impede research. Health concerned MEPs are working to find solutions that ensure adequate data protection standards whilst ensuring the possibility of continued health research and health innovation through new technologies.

EU Competition law currently applies to all private companies operating within the EU in order to protect the internal market. In the UK health sector, it is interpreted and applied by Monitor and the OFT/Competition commission alongside national legislation. Though such concerns are likely to be addressed in more detail by other submissions.

## Royal College of General Practitioners of Scotland

The Royal College of General Practitioners (RCGP) is the academic organisation in the UK for general practitioners. Its aim is to encourage and maintain the highest standards of general medical practice and act as the 'voice' of general practitioners on education, training and issues around standards of care for patients.

The College in Scotland came into existence in 1953 (one year after the UK College), when a Scottish Council was created to take forward the College's interests within the Scottish Health Service. We currently represent over 4000 GP members and Associates in Training throughout Scotland. In addition to a base in Edinburgh, the College in Scotland is represented through five regional faculty offices in Edinburgh, Aberdeen, Inverness, Dundee and Glasgow.

### Comments

Regarding free movement of health professionals across the UK, it is important that if a foreign EU qualification is to be recognised in the UK, and the professional is allowed to work in the UK without further checks of competence being carried out, we must be certain that the qualification is truly of equivalent level and value to the current UK standard.

This is especially important in primary care where the training provided may differ between countries.

The advent of appraisal means that overseas EU GPs must have had a satisfactory appraisal to the standard UK GPs are required to achieve. If not, they should be appraised after arriving in the UK before they are allowed to treat patients.

Employers should be satisfied that any non UK staff they employ satisfy an appropriate standard of fluency in the English language.

We support the concept of recognising equivalent qualifications and the free movement of equivalently qualified healthcare professionals, but it is essential that UK authorities satisfy themselves that the qualifications are indeed exactly equivalent and that proper appraisal has taken place before the professional sees patients. However, individual countries need to be satisfied that medical professionals they employ are able to practice at the level expected by that country.

## Royal College of Midwives

The Royal College of Midwives (RCM) is the professional and trade union membership organisation that represents the vast majority of midwives working in the United Kingdom.

The evidence set out in this submission principally addresses the balance of competences as they affect maternity services and midwives.

### **Coordination of healthcare provision and cross-border healthcare**

The RCM strongly supports the continued principles of mutuality and making provision of healthcare available across internal EU borders. We also strongly support the declaration in the Charter of Fundamental Rights of the European Union which states: *“A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.”*

In the context of maternity care, pregnant women and mothers with newborn children need ready access to planned and continuous care, including community-based midwifery and hospital-based services. This is no less the case for short-term visitors from other EU countries; it is not uncommon for unexpected complications to occur during or soon after pregnancy and quick and reliable access to health care needs to be available.

Few indicators are available for the impact of the free movement of labour on maternity services. The number of births in England and Wales to non-UK women born in EU states has increased from 43,881 in 2008 to 55,058 in 2011. It is impossible to say from these statistics how many births were to temporary visitors as opposed to permanent migrants. We do not have ready access to statistics showing how many UK-born women gave birth in other EU states, and it is therefore not possible to determine whether the impact on UK maternity services is commensurate with that experienced in other EU countries.

### **Public Health**

The RCM welcomes the priority given to public health and patient safety at EU level and recognises that some issues are best addressed at the supranational level due to the free movement of patients, doctors, and medical products across borders, and the prevalence of public health threats which do not respect European internal borders.

### **Employment policy**

The RCM notes that employment policy will be subject to a separate review to be led by the Department for Business Innovation and Skills (BIS) and the Department for Work and Pensions (DWP) later in 2013. There will also be a separate review of both the free movement of persons and the free movement of healthcare professionals to be led by the Home Office and the DWP also later in 2013.

The RCM will submit evidence to all of these reviews. For the purpose of this review we will therefore confine our comments to placing on record our support for the social and employment legislation that derives from the social chapter of the Maastricht Treaty.

The EU has, over many years, exerted a positive influence on the development of employment rights in the UK. The provisions that have emanated from the EU are, on the whole, reasonable and sensible provisions that have aimed to:

- improve the standard of working and living conditions;
- protect workers' health and safety;
- eliminate all forms of employment discrimination;
- implement the principle of equal pay;
- protect the rights of workers threatened with or subject to dismissal;
- and give workers greater rights to be informed and consulted about matters that affect them in the workplace.

These provisions have been implemented without placing an undue burden on UK businesses. Indeed successive UK Governments have frequently referred to the UK as having one of the most lightly regulated labour markets in the developed world.

Rules relating to working time have been particularly important protections derived from the Working Time Directive. The limitations on the length of the working day and the working week and the provisions for regular rest breaks, as set out in the Working Time Regulations, have established important protections for midwives and maternity support workers (MSWs). In 2012, an Income Data Services survey of NHS trade union members found that:

- 87% of midwives and 58% of MSWs reported that they 'frequently' or 'always' work more than their contracted hours.
- 27% of midwives and 23% of MSWs were working at least four additional hours every week.
- 46% of midwives and 44% of MSWs reported that all the extra hours they worked were unpaid; a further 20% of midwives and 14% of MSWs were not paid for some of the additional hours.
- 63% of midwives and 49% of MSWs believed their increased workload was having a negative effect on patient care.

Given the additional hours that midwives and MSWs are already working on a regular basis, and the risk this poses to the standard and quality of patients care, the RCM would be opposed to any relaxation of the working time regulations. This will become increasingly important in the context of the requirement for workers to work longer and delay their retirement. Employers will need to develop and implement strategies to support the extension of working lives in a way that does not compromise the health, safety and well-being of their employees. The Government is aware of the challenges this poses for both employers and employees:

- The 2009 Boorman Review of NHS Health and Well-Being identified and recommended good practice for employers. Boorman encouraged NHS organisations to develop and implement strategies for actively improving the health and well-being of their workforce and particularly for tackling the major health and lifestyle issues that affect staff.

- Last month the DWP's response to an independent review of sickness absence stated: *"as the workforce ages, an increasing number of employees will be managing long term health conditions. This means that the way we support employee health will become increasingly important, both at work and in terms of better management of chronic health conditions."*

Any attempt to repatriate social and employment protections from the EU will only undermine the efforts of employers and workers to resolve the challenges posed by working longer. The RCM is therefore of the view that the current shared competence on social and employment legislation should be maintained.

### **eHealth, health research and statistics**

Complex differences within the EU limit the ability to develop interoperability across healthcare systems, for purposes of integrated healthcare provision, research and statistics. However, there are likely significant benefits in designing protocols for sharing information and conducting health research jointly. For this reason, the RCM supports continued investment across these areas.

## **ABOUT THE ROYAL COLLEGE OF NURSING**

With a membership of over 415,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. RCN members work in a variety of hospital and community settings in the NHS and the independent sector. The RCN promotes patient and nursing interests on a wide range of issues by working closely with the Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations.

## **INTRODUCTION**

The RCN welcomes the opportunity to feed into a review which we hope will allow for an informed and objective discussion about the impact of EU policy, programmes and legislation on the UK, and in particular on the health service and wider population health. In an online survey of RCN members, over 65% of respondents thought that the UK's engagement with Europe was significant for them as a nurse.

The Department of Health's review focuses on the EU's powers or "competences". However it is important to note that the way in which these competences are exercised in proposing specific legislation or other action, and the way they are negotiated at EU level and then transposed into UK legislation all influence their impact in the UK. The UK government and many other UK stakeholders are closely involved in these negotiations.

The consultation outlines a number of areas where the Department of Health (DH) is particularly interested in receiving comments. The RCN's submission addresses those which are most relevant to nursing. And although our response does not seek to review comprehensively all aspects of the EU's powers which have some impact on health, we have highlighted a few additional areas of EU competence, not raised in the consultation, which are of particular concern to nursing.

For each area covered the RCN has outlined the nature of the competence, the impact on the RCN and nursing with specific examples and views on any advantages or disadvantages of EU action in this field.

The RCN also wishes to comment on ways of working at European level, including the role of nursing organisations, such as the RCN in this process and the wider benefits of these relations. The submission concludes with some reflections for the future, including where the UK could benefit from more or less action at EU level.

## **SUMMARY OF KEY POINTS**

The RCN and nursing in the UK have been affected most significantly by the following areas of EU competence:

The EU's public health remit, including ensuring a high level of health protection in all policies

The EU's social dimension including employment protection and working conditions, health and safety at work, equal opportunities, and the introduction of direct negotiations between trade unions and employers in the hospital and health care sector at European level

Free movement of health professionals in Europe, automatic recognition of qualifications and minimum standards for nurse education

Cross border health care

These competences have brought overwhelmingly positive benefits for nursing in addressing issues such as equal pay, reduction of risks to nurses in the workplace, enhancing patient safety and improving public health through tobacco control measures. UK membership of the EU has also engendered far greater collaboration between nursing organisations and trade unions in Europe, to share and learn from best practice and find collective solutions to improving health.

The current competences provide a solid base for constructive EU action, and whilst the RCN may not always agree with every detail of every piece of legislation adopted at EU level, RCN would not want a weakening of the EU's explicit health remit, but rather a strengthening of health protection in defining and implementing other areas of EU policy. The RCN would also want a stronger focus on patient safety, care quality and safe and healthy work environments to avoid market considerations dominating EU policy and legislation that impacts on the health service.

## **SPECIFIC COMMENTS**

### **1) Public Health**

Article 168 of the EU Treaty defines the EU's role in public health which is largely to support and complement national governments' actions. It is only in very specific areas, such as quality standards for medical products and devices and for organs, blood and blood derivatives, that the EU and the UK share competence.

The EU's powers allow it to adopt measures to protect and improve health, particularly in relation to cross-border health threats, such as infectious diseases, but also specifically in relation to tobacco and alcohol abuse. However, harmonisation of legislation at EU level on public health grounds in these fields is ruled out.

In fact the EU has far weaker powers in relation to public health than its powers to improve the way the single European market (or internal market) operates, although the EU Treaty 3

requires that "a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities" including internal market legislation.

*How does the EU's competence in health affect the RCN/nursing?*

*What evidence is there that EU action in health advantages or disadvantages nursing in the UK?*

The RCN has highlighted below two areas of particular importance in relation to nursing, which are either largely based on the high level of health protection requirement and the EU's public health remit. Examples are given of legislative but also "softer" measures which have been beneficial to population health and nursing in the UK.

### **Tobacco Control**

Nurses in the UK play a key role in caring for those with smoking related illness, in health promotion and in developing and delivering smoking cessation initiatives. They witness on a daily basis the impact of smoking on people's lives.

The tobacco industry continues to have a strong foothold in Europe and particularly given the cross border nature of electronic, digital and print media the RCN supported the introduction at EU level of legislation banning tobacco advertising and promotion, which was adopted in 2003. Since tobacco products can be purchased and imported from other member states, the RCN also supports EU intervention relating to the composition of cigarettes and tobacco products. The 2001 tobacco products directive was an important

milestone in tobacco regulation, particularly given that smoking is the primary cause of preventable illness and death in the UK.

Not all EU tobacco control measures have been legislative. The RCN also supported an EU recommendation, agreed in 2009, to encourage member states to protect people from exposure to smoke in public places, the workplace and transport<sup>1</sup>. This protects children and non-smoking adults from the harm of passive smoking, protects nursing staff and others in the workplace and contributes to the reduction in smoking levels. All EU member states now have some form of legislation to limit exposure to second hand smoke, although the level of protection varies significantly.

Although smoking rates in the UK have declined over the last 10 years, the current proposals to update the existing tobacco products directive is timely as it will ensure that EU legislation addresses recent developments as well as securing a continued common approach to tobacco legislation.

However, given previous legal challenges to the EU's role in this field the RCN welcomes the explicit clarification that the latest tobacco proposals are directly aligned to existing EU law ensuring a high level of health protection whilst improving the functioning of the internal market.<sup>4</sup>

### **Communicable Disease and Infection Control**

In an RCN online survey the power for the EU to act collectively in cases of major cross - border health was rated as most important by members. The European Centre for Disease Control (ECDC), in collaboration with the World Health Organisation, has an important role to play in managing disease surveillance and response and for detecting emerging health threats, such as pandemic influenza.

The RCN supported the adoption of an EU recommendation on patient safety, including healthcare associated infection (HCAI), as well as ECDC's role in supporting member states and evaluating the recommendation's impact . Although non-legislative, the recommendation is viewed as a positive step in raising and maintaining the profile of HCAI's and the impact of their burden from both a healthcare and public health perspective for current member states and accession countries alike<sup>2</sup>. It has also focused interest on exchange of good practice, including the development of link nurses in infection control.

In the case of routine infection control measures within member states, the RCN does not see the EU's role in harmonising the organisation and delivery of these services. But there are advantages in it facilitating exchange of good practice and adopting recommendations and guidelines, to support member state action. This is particularly important given the EU single market has meant greater movement of people for work and leisure purposes between member states.

We recognise the benefits of ECDC both directly managing and commissioning work to improve health. The RCN is currently involved in a multi-disciplinary expert project , supported by ECDC, which will develop much needed competences and a training strategy for infection control in the EU. Greater support for transparency of training standards are essential in order to protect patients and support employers. Further work may be required in future on the impact of patient rights to planned health treatment in other countries on the development of HCAs.

## **2) The Health Workforce and Employment Issues**

The Lisbon Treaty clearly affirms Member States' responsibilities for defining health

policies and for organising, managing, delivering and allocating resources to health services and medical care. However many other EU competences impact on health service delivery in the UK, in particular those relating to the functioning of the single European market and its social dimension, designed to ensure minimum social and employment standards. This is an area of significant importance for the RCN and its membership

Initiatives relating to the protection of employees have formed part of the European Community's role since its inception, although largely justified by the need to ensure fair competition within the Community. The Single European Act (1989) which launched the single market, strengthened Europe's role in adopting health and safety at work measures, and extended the areas of social and employment policy that no longer required unanimous agreement between member states.<sup>5</sup>

In 1999 the UK finally signed up to the so called "Social Chapter", as part of wider EU treaty changes, having previously negotiated an opt out. This reinforced the EU's social dimension. One of the important innovations of the Social Chapter was to introduce a system called "social dialogue" for involving the social partners – trade unions and employers representatives –in EU decision making.

The current EU Treaty also contains a social clause, similar to the health protection provision, to ensure a high level of employment and social protection are taken into account in defining and implementing other EU policies.

*How does the EU's competence in health affect the RCN/nursing?*

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### **Employment Protection and Working Conditions**

This area of competence has been significant for nursing staff and the health sector and, in particular, rules surrounding information and consultation on collective redundancies and safeguarding employment rights in the event of transfers of undertakings. An increasing proportion of UK employment law originates from the EU and provides important protections for nurses and healthcare assistants.

The NHS has seen significant changes in recent years, which has led to a growth in independent providers of publicly funded health services as well as the transfer of staff working in public health in England from the NHS to local government. It is important that nurses and other staff who continue to ensure continuity of care and service provision during these reforms are not disadvantaged in terms of working conditions and employment benefits if their employer changes. The EU's TUPE legislation has been a cornerstone in providing legal protection to staff when such reconfigurations take place.

Through cross industry "social dialogue" negotiations agreements have also been reached, and adopted as EU directives, to ensure part-time workers, of which there are many in the health service, and those on fixed term contracts are treated no less favourably than full time permanent employees, in terms of leave, and access to training, for example.

**Health and Safety at Work** The EU's key health and safety related directives (known as the six pack) provide a legal framework for employers to reduce the risks of

musculoskeletal disorders (MSDs), biological hazards, stress and violence to health care staff. MSDs and stress are particularly prevalent in the nursing workforce and the main cause of sickness absence in the sector and, arguably, without the directives the situation would be worse. The implementation of hoists and other lifting equipment, as required by the manual handling directive, has significantly reduced the risks for nurses and patients. The UK has led the way with the development of management standards to ensure that organisations are identifying and managing work related stressors, as required under the framework directive. Policies and practices put in place as a result of the implementation of the standards has led to improved working conditions for nurses and in some NHS organisations, reductions in sickness absence.

Research commissioned by the Health and Safety Executive (HSE) on the implementation of the *Manual Handling Operations Regulations* and the *Provision and Use of Work Equipment Regulations* which evolved from EU directives found evidence of

effectiveness.<sup>3 4</sup>

Within the health sector the manual handling operations regulations have had a positive impact on the health of our members working as nurses and health care assistants. In NHS acute hospitals effective implementation of risk assessments has put an end to the dangerous practice of manually lifting patients in all but extreme circumstances. Lifting equipment, training and policies are now common place within the health sector. The driver for this was regulation with many of our members reporting that “*things changed overnight*” following the introduction of the regulations.

European directives are generally fairly broad in scope and leave discretion to member states about the way in which they are implemented. This sometimes means that opportunities to reinforce domestic provisions are missed. For example, a number of European countries have been more explicit in their requirements for occupational health service provision within the framework directive. They have recognised the important role that occupational health services can make towards the prevention, management and surveillance of occupationally acquired disease, a message now mirrored in Dame Carol Black’s report *Working for a Healthier Tomorrow*.<sup>5</sup> A further issue is UK level enforcement arrangements. An under resourced inspectorate and subsequent lack of inspection and enforcement activity to ensure that legal standards are being met will hinder any improvements. In 2011/2012, a major review of the health and safety systems in Britain (Lofstedt) recommended an end to routine health and safety inspections in health care environments.

The European working time directive also emanates from the EU’s competence to address health and safety at work. It provides a framework to reduce fatigue within the nursing workforce and put safeguards in place such as compensatory rest and controls on working time to address the health and safety effects of shift work and long working hours. The RCN strongly supported its adoption in the 1990s and the need subsequently for updating<sup>6</sup>. Fatigue, long working hours, lack of rest breaks and poorly managed shift rotas are not only a risk factor that can impact on the health of nursing staff, but can also impact on patient safety. Working time provisions are particularly important to ensure the health and safety of employees where the business is 24 hours. There is evidence to demonstrate the link between the employment environment for NHS staff including nurses and healthcare assistants and the quality of patient care. Good employment practice correlates with a better quality patient experience.

With an ageing workforce, having to work longer it is important that legislative safeguards

around working hours, night shifts, prevention of work related musculoskeletal disorders and prevention of work related psychosocial hazards are in place. Nurses exposed to workplace hazards early in their career may develop long term injuries or cumulative damage which can limit their ability to work. These are issues which, if addressed at European level, ensure a baseline for protection at work for nursing staff and other health workers regardless of where in the EU they seek employment, and also enables these<sup>7</sup> standards to be based on relevant evidence and best practice pooled across member states.

**Equal Opportunities** The right to equal pay for equal work between men and women was enshrined in the original Treaty of Rome (1957) as part of the social and employment provisions of the new Economic Community. In 1999 this was extended to “equal pay for work of equal value” and a new competence was introduced for EU action, with the agreement of all member states, to combat discrimination not just on the grounds of sex, but race or ethnic origin, religion, disability, age or sexual orientation.

Equal pay and equal treatment legislation agreed at European level and implemented in the UK have influenced pay, terms and conditions in the National Health Service so that roles predominantly carried out by women are not discriminated against. Equal pay requirements were a driving factor behind the development of the Agenda for Change pay terms and conditions agreement for NHS staff, which ensures equal pay for work of equal value for nurses and healthcare assistants working for the NHS.

Equal pay legislation has also been very important in outlawing the discrimination in occupational pension schemes in the UK and the impact of this on the NHS pension scheme, ensuring equal access to the scheme for part-time nursing staff.

### **The Social Dialogue and Negotiation of Agreements**

The introduction of the EU social dialogue has given employer and trade union representatives the opportunity to negotiate directly European agreements with each other, which can subsequently be turned into EU legislation. It also means the social partners are consulted on any social and employment proposals the Commission is considering. The RCN pushed for the UK to sign up to the Social Chapter<sup>7</sup> and has actively contributed to social dialogue negotiations through its European alliance, the European Federation of Public Service Unions (EPSU).

In addition to the general cross-industry negotiations which led to agreements and legislation on part-time work, agency workers and fixed term contracts, and third party violence at work, there have also been sectoral negotiations between employers and trade unions in the hospital and health care sector since 2006.

These have led to a European code of conduct on cross border ethical recruitment of health workers<sup>8</sup>, a framework for action on recruitment and retention<sup>9</sup>, and most recently the RCN played a major role in negotiating a framework agreement between EPSU and European healthcare employers (HOSPEEM) on the prevention of sharps injuries to healthcare workers<sup>10</sup>. The social partners agreed this should be implemented through European legislation. It is a good example of employers and trade unions working in partnership to create a workable legislative solution to a recognised workplace hazard<sup>8</sup> which, if not managed correctly, has a financial impact on the employer and the State as well as causing significant distress and life threatening disease to staff.

### **3)The health workforce and free movement of health professionals**

Facilitating the free movement of workers was one of the cornerstones of the original Treaty of Rome establishing the European Economic Community. For health professionals the key to making free movement a reality, has been the original “sectoral” health professions directives, adopted in the 1970s, which allowed for automatic recognition of qualifications where certain minimum education requirements were met. These have since been integrated into an overarching piece of EU legislation which covers over 800 professions. The directive was founded on the EU’s internal market competences rather than its public health remit, which created some tensions in relation to the balance between free movement objectives and public protection.

*How does the EU's competence in health affect the RCN/nursing?*

*What evidence is there that EU action in health advantages or disadvantages nursing in the UK?*

The requirements in the directive covering nurses in general care have had a number of important implications for UK nursing. Nursing is a global profession and nurses have been one of the professional groups to benefiting most from the free movement arrangements across Europe. Whilst the number of EU nurses coming to the UK has been relatively small traditionally, this number has been rising over the last ten years. Some individual trusts in England are recruiting nurses from Spain and Portugal and the number of nurses registering in the UK from these countries rose to over 500 each between April 2011 and 2012.<sup>11</sup>

For mutual recognition of qualifications across Europe to work, there also has to be an underpinning set of standards for the preparation of nurses to ensure patient safety and care quality and that is why requirements for the content and length of education need to be agreed at EU level. The directive has therefore also been an important lever for raising standards of nurse education in countries wishing to join the EU, and in women’s access to further education<sup>12</sup> and it has provided some assurances on patient safety.

Given its early adoption it provided a focus for national nursing organisations to begin to contribute collectively to shaping European legislation and has led to collaboration on other EU nursing and health issues.

Under the current revision of the directive, the RCN has sought the strengthening of public protection measures such as clear ability of health regulators to make language checks for all EU nurses , a duty to alert other regulators if a health professional has been banned from practising in any member state and exclusion of health professionals from possible “partial access” to that profession in another member state. Given developments in nursing over the last 35 years the RCN and the European Federation of Nurses<sup>9</sup>

Associations (EFN) has also pushed for the minimum requirements in the directive relating to nursing to be aligned with today's expectations of nurses as autonomous practitioners who assess and respond to patients needs, develop and manage services, and apply the current evidence base to their practice.<sup>13</sup> These minimum standards continue to set a benchmark for countries wishing to join the EU and access free movement arrangements. But there is a danger that the EU's powers to ensure free movement, override more paramount concerns in the UK and amongst nursing staff for patient safety and public health.

**4) Other Cooperation on health workforce issues** As part of the EU’s public health remit national governments are also encouraged to work together voluntarily on health issues and the European Commission can also initiate work to share good practice and

establish guidelines. These non-legislative initiatives provide a means for member states to discuss issues related health services and agree work funded through the Commission's modestly funded public health programme.

Significant non legislative developments include a variety of initiatives directly connected to the European health workforce, outlined in an action plan issued in 2012, following a previous green paper in 2009 to explore potential areas where the EU could add value<sup>14</sup>. *How does the EU's competence in health affect the RCN/nursing?*

*What evidence is there that EU action in health advantages or disadvantages nursing in the UK?*

The RCN highlighted the need for greater mapping of trends that influence workforce planning and expert advice and better comparative data across the EU in its submission to the green paper and one of the current initiatives is a joint action between member states on workforce planning.

All member states face a similar profile of an ageing population with an increasing number of individuals requiring treatment and care for long term chronic conditions carried out in non hospital settings. Equally the impact of growing numbers of nurses and midwives required in other non EU states, such as the US, impacts on health workforce planning in individual member states. There are therefore advantages to sharing experience, evidence, data and practical tools between EU countries given that all share common challenges in training, developing and planning their nursing workforce.

The EU health workforce action plan, and in particular the joint action on health workforce planning due to commence in spring 2013 for two years, offers an opportunity for all member states to share data, experience and best practice in relation to addressing the complex issues surrounding their own health care workforce as well as the EU workforce as a whole. Such initiatives should also encourage member states to think about the health professional workforce from a global as well as European perspective and to look at innovative ways to retain their workforce for example through ensuring a healthy health

workforce by developing effective occupational health measures and guidelines. These initiatives need to be informed by both front line professionals and health system managers alike. The RCN is involved in this work through its European alliances, EFN and EPSU, and through its UK links with national health workforce advisory arrangements.

##### **5) NHS and Patient Services – cross border healthcare**

Despite the restrictions on the EU's role in determining the financing, organisation and delivery of health services, it has applied its competence in relation to free movement of people to develop rules which more directly impact on patients' access to health services in Europe.

One of the early provisions under the EU's competence in relation free movement of workers and social security was to provide access to certain benefits when an EU citizen, who would have been covered by social security legislation in their home member state, was working in another EU country. The categories have been extended over time from workers to cover those visiting or residing in another member states

Regulations adopted under this provision mean that there are reciprocal arrangements

between member states for access to emergency care when visiting another EU country, for pensioners living in another member state (eg UK pensioners in Spain) , for home health services to send a patient for planned treatment in another country (eg when highly specialised care is required). UK nationals benefit from these arrangements if they are visiting or living in another EU country.

Under the EU's competence to facilitate free movement and access to services, some patients have also taken their cases to the European courts to seek reimbursement for planned treatment they have chosen to have outside the member state they are living in. Given the confusion about these rights the European Commission and member states have sought to introduce a clearer legal framework.

To achieve this the patients rights to cross border care directive was adopted in 2011 and is due to be implemented in the UK this year.

*How does the EU's competence in health affect the RCN/nursing?*

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The EU's intervention was based on free movement principles and whilst the RCN supported the need for patients, professionals and health services to have greater clarity, we highlighted some of the practical challenges. These included concerns about continuity of care once a patient returned to their home member state and equity, given that the system was to be based on "reimbursement" requiring patients to have some means of funding the care up front.

Whilst in an online survey of RCN members 90% of respondents rated as important the EU's powers to introduce reciprocal arrangements for access to emergency care, this dropped to just over 50% in relation to planned care in another member state. Given that the overwhelming majority of UK citizens choose to access healthcare in this country, the

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RCN is clear that arrangements to implement the cross border care directive should not undermine domestic planning, provision and financing of health services.<sup>15</sup>

The history of these initiatives also shows some of the challenges in balancing dual EU objectives of free movement and health protection. The original attempt to incorporate free movement of health services into a wider directive liberalising trade in services, and treat health services like other commercial services, drew strong opposition from many parts of the health community, including the RCN. It did not recognise the important public policy and public protection aspects of health service delivery. It would have allowed healthcare providers from one member state to establish in another member state, based on "country of origin" principle ie a French health care provider operating in the UK based on standards set in France. After much debate health services were removed from the services directive, which was adopted in 2006. This experience reinforced the need to ensure that single market trade rules do not override other complementary competences such as health protection.

The European Commission had sought, as part of the later directive on patients rights to cross border care, to place some requirements for convergence between countries in a number of areas of health service delivery, such as quality and safety, health technology assessment and e-health. These were modified so as to promote cooperation rather than common standards. Because of the very different systems that exist in Europe, the RCN believes that harmonisation is neither realistic nor desirable. In relation to e-health the RCN is supporting the development of standards for the nursing content of electronic re-

cords in the UK and is working with the Royal College of Physicians on the development of clinical content standards for medical records. Clearly these are areas for potential cooperation in Europe, as is consensus building on practice guidance for those directly involved in implementing e-health solutions.

## **6) Medical Devices and Medicines**

The RCN acknowledges the need for safety standards for these products to be regulated at EU level given the range of medical device producers across Europe and the importance for patients, the public and healthcare professional alike of having access to safe, high quality medical devices. The RCN has welcomed moves to strengthen the EU's ability to ensure greater clarity and more uniform application of the rules through a legal regulation as opposed to a directive. For nursing the extension of medical devices to cover certain "non-medical devices" such as breast implants and self testing kits is welcome. This will give greater confidence to nursing staff when ordering devices, in supporting patients using self testing kits who wish to seek advice or where nurses have concerns about the safety of any products.<sup>12</sup>

## **7) The EU role in global health**

We are aware that a separate consultation is underway, led by the Department for International Development, on the EU's competence in development cooperation and humanitarian assistance. The RCN will not be responding directly to the DfID consultation but wishes to acknowledge the significant role the EU plays in overseas development aid. About 60% of global aid assistance comes from the EU or its member countries. Given pressure on resources and the expansion of global health initiatives with different funding and delivery channels it is important that the EU continues to play a coordination role.

More significantly for the EU's health competence, the European Commission also needs to ensure greater coherence between its external and internal policies, in particular in relation to the health workforce and potential "brain drain"<sup>16</sup>. The UK is not currently recruiting extensively from the developing world. But given predicted future nursing shortages in England<sup>17</sup>, (estimated at 200,000 by 2016) and in other EU member states such as Germany, the EU will need to ensure that its policies on investment and support for planning of the health workforce in Europe, are aligned with EU initiatives to strengthen human resources for health in developing countries. From the RCN's networks with sister associations in Africa, it is clear that nursing shortages, challenging working environments and lack of training and planning continue to affect health services in these countries.

EU policy also needs to adhere to the principles of ethical international recruitment of health workers in the World Health Organisation's code and EPSU/HOSPEEM's charter, whether recruitment is from within or from outside the EU.

## **8) Working together in Europe**

EU action needs to be considered for its impact across 27 different member states, but also provides immense opportunities for learning and for this reason the RCN works closely within a number of key European alliances to help shape EU policy and legislation. The European Federation of Nurses Associations (EFN) brings together national nursing organisations in 34 countries and communicates a collective nursing view to the European institutions. This is particularly important since EU legislation often covers a broad range of sectors, and the implications for nursing and health are not always apparent or considered when initiatives are first drafted. The RCN is also a

member of the European Federation of Public Service Unions (EPSU) through which it is part of the sectoral social dialogue negotiations on health. The RCN also collaborates within the European Public Health Alliance's (EPHA) with the public health community.

The RCN has found that negotiating successfully within these alliances and with the EU institutions requires an ability to listen to and understand the different approaches in other countries, to articulate clearly the practical implications of a proposed initiative on those within the UK most likely to be affected, and to be prepared to compromise to find a workable solution for 27 countries.<sup>13</sup>

By building strong relationships, membership of these alliances has also provided a forum for wider discussions and exchange on nursing issues, which are not necessarily areas of current EU action, such as nursing leadership, better integrated care, skill mix, and continuing professional development.

EU-funded projects and partnerships provide great opportunities for a broad range of UK partners, including universities, NGOs and NHS organisations, to share knowledge and ideas with colleagues in other member states. They bring funding to the UK and promote British expertise, for example the adaptation of the community nursing model from Northern Ireland, which won the RCN's innovation award, for collaborative projects with France, Lithuania and Greece on developing cost effective integrated institutional to community care<sup>18</sup>.

## **ISSUES FOR THE FUTURE**

*How might the UK benefit from the EU taking more or less action in health?*

*What are the future challenges/opportunities we face in EU health competence?*

*How could action in this area be taken differently?*

As the previous sections of this response have outlined, nursing in the UK has benefited enormously from the UK's membership of the EU, from free movement of professionals and from agreed minimum employment and working conditions in Europe. It has also heralded much closer cooperation between counterpart organisations and greater understanding and sharing of best practice to deliver better health services and improve health. The RCN does not currently see the need for an expansion of EU competences, nor would it want to see repatriation of the EU's existing powers in relation to health or social affairs. However, the balance between differing EU competences, whose objectives at times may conflict with each other, do need to be addressed.

## **Planning Health Services and Markets**

Since the European Union was established with the single market as a core element, health and social concerns have sometimes been overridden by this strongly market orientated approach (eg the original proposed services directive). The prime consideration for health services in the UK should be to serve the needs of the population and not the liberalisation of services in the EU. EU competition, state aids and public procurement policy should not undermine this principle.

In the case of the application of patients rights to cross border care, EU action in future in this area needs to be proportionate to achieving the aim of giving patients clear information and a transparent process for accessing health treatment in another country. Free movement and choice should not be seen as a way of introducing cross border competition in health care, which could undermine planning and delivery of more integrated services in the UK. Planning and delivering effective services requires

cooperation between providers, professionals and across the acute to community interface within the local health economy.

Gaining a better balance between health system and EU market interests has also been made more challenging by the lack of competence in the EU for determining how health services are financed, organised and delivered, despite other EU competences" significant impact on the NHS. Whilst the RCN would not propose an extension of EU powers into this area, we would like to see far greater collaboration between the European Commission, member states and health actors to ensure that health systems issues are not overlooked in other policies, or that health policy is developed in an ad hoc way by the European Court of Justice. From a UK perspective these discussions need to involve consultations with governments across the UK to ensure compatibility with health services perspectives in the devolved administrations. The high level reflection group on health services and medical care may go some way to addressing this, but its work and deliberations need to be more accessible and widely discussed.

### **Mobility and Patient Safety**

Similarly in considering recognition of health professionals and their ability to practice in 15

another EU country, precedence has often been given to "removing barriers to free movement" rather than considering the paramount importance of patient safety and public protection. This has been witnessed most starkly in the discussions over the ability of health regulators to undertake language controls of EU doctors and nurses, but also in attempts to block updating education standards for nurses, to fit with the demands of modern day nursing. The RCN would want to see EU level development of robust measureable education competences for nursing, using the relevant professional expertise, with greater emphasis placed on the EU's competence to ensure a high level of health protection in other policy areas rather than free movement principles being the overriding concern.

### **Public Health, Markets and Austerity**

The RCN strongly endorses the EU's role in addressing public health issues that cross borders, or where there is added value from joint action at EU level, which the current competence is designed to achieve. This includes intervention in relation to major health threats from non-communicable disease such as tackling obesity, tobacco and alcohol harm and other risks, particularly if voluntary action has failed to tackle the problem. It is important to ensure that at a time of economic downturn in Europe with a focus on austerity measures and EU policies to boost growth and trade, the EU does not neglect public health concerns designed to improve the health of the population, just because these may place restrictions on goods produced and traded in the single market. For example, the RCN has supported minimum pricing for alcohol in the UK and would be disappointed if such public health measures could not be applied because of EU trade rules.

Given that health is influenced by so many other areas of EU intervention such as environmental policy, agriculture, consumer protection and transport, the EU's health in all policies approach should be more actively pursued in relation to public health issues.

### **Health Services and Economic Growth**

Currently across Europe immense pressure is being placed on public finances by

austerity measures, and the push for the EU to coordinate more effectively its collective response to the economic crisis. There is a danger in this climate that Governments seek short term quick fix spending cuts in the health sector, which will have long term detrimental impacts on the quality of services but also on health services' ability to contribute to cost-effective care delivery and a healthy productive working population. Both the RCN and EFN have highlighted some of the impacts on nursing and patient services from such actions.<sup>19,20</sup>

The RCN would want to see a number of EU wide principles applied and areas of EU action and sharing of best practice strengthened in relation to the health sector, its role in supporting the vulnerable in times of austerity and its contribution to maintaining an active population, to economic prosperity and innovation. This includes:

- ensuring that the shared set of values and principles agreed by EU member states in 2006 for Europe's health systems, based on universality, access to good quality care, equity, and solidarity<sup>21</sup>, are not undermined by EU austerity measures

### **Nursing Workforce, Working Conditions and Quality Care**

The RCN has strongly supported the provision of decent standards of employment and working conditions across the EU as a contributor to economic prosperity and health and wellbeing. The European Commission estimates that the health and social care sector represents on average about 10% of employment in each member state, so this contribution is not insignificant<sup>23</sup>. The RCN would not want to see a weakening of the EU's functions in continuing to uphold these standards or a repealing of existing social provisions, including social dialogue, in the hospital and health care sector.

The working conditions of nursing staff and others in the health service are also closely linked to the patient experience and patient safety. There is evidence to demonstrate the link between the employment environment for NHS staff including nurses and healthcare assistants and the quality of patient care. Some of this evidence has come from research undertaken collaboratively across Europe and funded through the EU's research and development framework programme<sup>24</sup>. At a time when the nursing workforce is ageing, and demands on the health sector are increasing, the RCN sees a strong role for the EU in initiatives that invest in the health and wellbeing of the workforce as part of plans to improve recruitment and retention of nursing and other healthcare staff, for example through social dialogue negotiations. The RCN also supports greater collaboration and sharing of best practice on workforce planning given the new health care challenges facing all EU member states. This is all possible under the current competences.

1 [http://ec.europa.eu/health/archive/ph\\_determinants/life\\_style/tobacco/documents/r-112\\_en.pdf](http://ec.europa.eu/health/archive/ph_determinants/life_style/tobacco/documents/r-112_en.pdf)

2 Evaluation report 2012

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<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2006:146:0001:0003:EN:PDF>
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[http://ec.europa.eu/health/strategy/docs/swd\\_investing\\_in\\_health.pdf](http://ec.europa.eu/health/strategy/docs/swd_investing_in_health.pdf)
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- capitalising on the rich experience within Europe's health systems to exchange experience and best practice between EU countries, including improving primary care, spreading innovation and investing in the health workforce

## Royal College of Ophthalmologists

The Competencies document is calling for comments on three aspects of Health:

1. Medicines & Devices
2. Public Health – e.g. Smoking, alcohol etc.
3. Clinical and Research

The following are a few thoughts on the response to the EU Competencies document:

1. Medicines and Devices: There is a potential benefit in having a pan-European body licensing Medicines and endorsing Equipment. However measures should be in place to ensure that the EMA (European Medicines Agency) and the MDEG (Medical Devices Expert Group) seek advice from Specialists before making decisions who need to respond promptly. Otherwise there is a risk of being caught in complex and remote bureaucracy. There are no medical doctors (experts) on the staff of the MDEG (experts) or representatives from the producing industry. The members of the MDEG are from ministries and health agencies and they are not familiar with the products. A recent example of its decision-making is the decision of the EMS to alter the status of Fluorescein in Europe from being a device to a drug. Manufacturers of Fluorescein are not prepared to go through the process of registering Fluorescein as a drug (with the exception of the UK where it is registered as a drug). This has resulted in a major shortage of Fluorescein (in all its forms) in Europe and it is taking a very long time to resolve this crisis.

2. Public Health: There are several examples of good European legislation having been accepted and implemented in the UK, perhaps faster than might have been the case otherwise. Working conditions and environmental issues are bound to be amongst the aspects that are seen in favour of European legislation.

3. Clinical and Research:

Training:

Facts:

1. Training in Ophthalmology in Europe varies from three years (only in two countries) to a minimum of seven years in the UK and the Netherlands. The majority have a four year training programme. The current EU recommendation is for four years. This inevitably results in a discrepancy in the abilities of Specialists.

2. The content of the training is variable. In some countries, for instance Switzerland, training in General Ophthalmology is four years long. Ophthalmologists wishing to be licensed to operate have to go through another two years of training. Ophthalmologists trained in France for four years are able to cross the border and practise in Switzerland and perform surgery while locals who trained for four years cannot perform the surgery.

3. UK trainees have to complete a long training AND pass the RCOphth exams to enter the Specialist Register while other European trainees complete a shorter training and are expected to pass a local exam or the EBOD which is known to be an easier test.

Action needed:

A committee should look at equivalence of training before allowing European specialists to take on the same level of responsibilities as UK-trained Ophthalmologists. Managers and patients may not be aware of the differences in length and quality of training. Particular restrictions should apply when specialists are either allowed to practise in the private sector where they may work in relative isolation or in short term employment.

Revalidation:

Facts:

1. A minority of Countries have compulsory appraisals and few have revalidation in place.

Examples

(a) An Ophthalmologist who was stopped practising in The Netherlands is now practising in Portugal.

(b) A French trainee practising in the UK, whose appointment had been based on references, turned out to be well known in his unit in France for being an incompetent surgeon but this fact only came to light after a series of disasters in various hospitals in the UK. Considerable harm to patients can be inflicted by non-UK doctors taking up short term posts.

Action: In the short term there is a need, perhaps at the level of the GMC, with input from Colleges, to ensure equality of training and revalidation – perhaps a medical passport. The European Board of Ophthalmology (EBO) aims at harmonising training across Europe and has set an examination that has become recognised by many European Countries. In the long term, making the exam compulsory and raising its level of difficulty will go some way towards securing an acceptable level of knowledge. This must be followed by a standardised process of appraisal and revalidation to ensure that knowledge and good practice are maintained.

Compliance with Directives vs Laws:

The problem: In some countries, national law supersedes European Directives. e.g. consequently hospitals in Belgium are not obliged to comply with EWTD. The UK has

completely revamped its Training program in order to comply, while most European countries did not.

Action: A level playing field is required

Research:

There are great opportunities for research collaborations in ophthalmology in Europe. The European Commission understands the importance of building a strong research program in medicine and science in Europe and has a significant research budget. The aims of the funded research are to improve health and to boost competitiveness of health related industries in Europe. The Commission funds collaborative projects that cross national boundaries. The main funding is through its framework funding. Several research projects in ophthalmology and vision science have been funded by the EU and these have led to longstanding collaborations across the various countries in Europe. Such collaborative projects have led to the foundation of the European Vision Institute (<http://www.europeanvisioninstitute.org>) which serves as an alliance of ophthalmologist and scientists involved in research which aims to promote research in Europe. Alongside these initiatives there are a number of organisations within Europe such as Euretina, EVER and the SOE that organise successful pan European scientific meetings. There are also many European subspecialty groups that meet regularly and encourage research collaborations. Overall there are strong research links within members of the EU. However the opportunities for research training for young ophthalmologist varies in the different countries and it is possible that the European Commission could do more to develop programs to widen opportunities for young clinicians, particularly from those countries poor research infrastructure to participate in strong research programs available elsewhere in Europe. This would help build up a cadre of young researchers who can build the research expertise in their own country

English Language special status:

The popularity of the English language is a double-edged sword. It has helped the UK to lead in many aspects of Medicine. NICE guidelines are recognised by many countries and UK Colleges are held in high regard. The UK exam system, clinical guidelines etc. have been copied by many.

The majority of doctors across Europe can manage some English as they refer to English language journals and textbooks. There is a need in most medical specialities for doctors to be able to communicate adequately with patients. They should be able to understand them and explain to them diagnoses and management. Elementary knowledge of the language is not sufficient.

Considering the relatively lower number of Ophthalmologists and the higher GDP in the UK, there is likely to be a higher flow of doctors from most European countries towards the UK than in the opposite direction. This special status must be recognised. There is a great need to maintain standards and ensure that patients are treated by safe and competent doctors.

Finally, it is also important to bear in mind the problems faced by other European countries like Bulgaria who see their best and most ambitious doctors move to Western Europe after having received many years of training in their home country. This has a detrimental effect on the service to patients as well as future training in those countries.

## How does the EU's competence in health affect you/your organisation?

### What evidence is there that EU action in health advantages or disadvantages patients and citizens?

1.1 The RCPCH supports the continuation of the EWTD and strongly advocates that other Royal Colleges take note of its solutions to implement the Directive. By having the WTD in place, this leads to safer and more sustainable services by concentrating acute inpatient services on fewer sites, and there is, in turn, a beneficial impact in training of junior doctors.

These solutions to implement the EWTD and improve standards of care, are highlighted in the publication Facing the Future (FTF) which lists 10 minimum service standards for acute paediatric services. FTF gives the following interlocking recommendations (RCPCH, Facing the Future: A review of Paediatric Services, RCPCH, April 2011, <http://www.rcpch.ac.uk/system/files/protected/page/FTF%20Full.pdf>)

- Reconfiguration of acute services onto fewer specialised sites
- Expansion of consultant numbers and in consultant resident shift working
- Expansion of GP training
- Expansion of the extended and advanced role of nurses
- Reduction in the number of paediatric trainees.

The RCPCH draws to the attention of the Government the fact that by the end of April 2013, there will be evidence available from an audit of all acute units as to whether the 10 standards are being met

1.2. In the lead up time to the implementation of the EWTR in 2009, there were gaps in the middle grade rotas but over time and by finding solutions, the vacancy rate has reduced.

In response to this, the RCPCH expanded the models of consultant delivered care, particularly aimed at consultant resident shift working for the provision of acute paediatric services. This is a step toward meeting, in particular, Standard 8 of the RCPCH's FtF 10 acute service standards. Evidence from the 2009 and 2011 RCPCH Workforce Censuses has shown that the numbers of doctors participating in resident shift working in acute paediatric and neonatal care <http://www.rcpch.ac.uk/what-we-do/workforce-planning/workforce-census/workforce-census>

1.3 The RCPCH supports the evidence from 2 other reports

- Workforce models described as the 11 and 9 cell models for Tier 2 rotas (middle grade) have been designed to meet the EWTD and to include resident shift working patterns- Delivering Safe Services: Consultant Delivered Care for Maternity, Paediatric and Neonatal Services (teamwork Management Services 2008)
- In the NW of England a survey was undertaken to evaluate the introduction of consultant posts which would deliver resident emergency shifts at Tier 2 (middle grade) as a trained doctor solution to the EWTD and other standards (Edwards H, Ewing C, Bluck M, et al (2011) Evaluation of the introduction of 'Resident Shift Working Consultants across the North West Strategic Health Authority, copies available from [halcyon@hrmenterprises.co.uk](mailto:halcyon@hrmenterprises.co.uk). Posts within a managed clinical network were developed in Greater Manchester as part of a large scale reconfiguration Making it Better

(NHS, Making it Better For Children, Young People And Families, Greater Manchester CYPF Network <http://www.makingitbetter.nhs.uk>) which redesigned 12 to 8 paediatric and maternity units and 2 to 3 neonatal intensive care units to meet the EWTD standard, to concentrate service on fewer sites and to enhance senior clinical presence. 12 consultant paediatricians, 9 consultant neonatologists and 16 consultant obstetricians /gynaecologists were interviewed in 2009/10. The posts in the main were reported as having a net positive effect on the quality of service provided, patient safety and on the training of junior staff.

1.4 The RCPCH also published a project in 2012 entitled the Benefits of Consultant delivered care which showed that this pattern of delivering acute care resulted in better day-time training, improved quality of care for patients, good quality handovers and better communication with parents

<http://www.rcpch.ac.uk/system/files/protected/page/CDC%20full%20report%2024%2004%2012%20V2.pdf>

1.5 The RCPCH gave evidence to Medical Education England in 2009, (MME EWTD Review – Written Evidence, Medical Education England, 2009) in which we stated that the RCPCH support the introduction of the EWTD in the interests of both patient safety and a more family friendly lifestyle for doctors. Further we supports the assertion in the Temple report which was published in 2010 that a more senior opinion in principle leads to higher quality care and allows mechanisms for better day time training.

(Temple, J. (2010) Time for Training: A Review of the impact of the European Working Time Directive) on the Quality of Training, Medical Education England. [Online] Available at: [www.mee.nhs.uk/PDF/14274%20Bookmark%20Web%20Version.pdf](http://www.mee.nhs.uk/PDF/14274%20Bookmark%20Web%20Version.pdf)

1.6 The RCPCH is concerned that any potential derogation beyond 48 hours will not be to the benefit of training as the extra time will be used mainly to cover out of hours work rather than optimise training opportunities. Further arguments can be found at

<http://careers.bmj.com/careers/advice/view-article.html?id=20004482>

It also needs to be remembered that juniors working practices are also governed by the “New Deal” as well; a voluntary agreement between Royal Colleges, BMA and DoH and this is a constraint which would still exist given any change to EWTR.

There is a recognition that members of other Colleges e.g. surgeons work differently and medicine is not heterogenous. The RCPCH is concerned about the safety issues related to high volume acute specialties and believes acute specialties are safer on 48 hour rotas.

The RCPCH reiterate our support for the EWTR as it was agreed by the European Council.

## Royal College of Pathologists

I am responding in my capacity as Director of Research for the Royal College of Pathologists. My attention was drawn to the proposed changes to Data Protection Regulations by the President and reading through this I became very concerned that this proposal poses a potential loss of research ability that would have major consequences on the research community going forward. This would be a clear loss for EU citizens.

The issue is really about consent. My understanding from this new proposal is that “specific” informed consent is proposed that must be obtained for every occasion in the medical research field for the use of human biomedical material and related data.

It is unfortunate that we have only recently thoroughly overhauled this process of biobanking and consent not only in the UK with the Human Tissue Act of 2004 but also internationally with the OECD guidance and an update of the Declaration of Helsinki. These guidelines and legislation all have one thing in common, the agreement that patient data needs to be attached to the human tissue stored for research and that broad consent but informed needs to be obtained in all cases. Quoting from article 4.6 of the OECD recommendations on human Biobanks: “to permit human biological specimens and/or data to be used to address unforeseen research questions. Subjects must be informed of the breadth of such consent and additional safeguards put in place to protect participants.”

In the same Article 4 it also clearly states that there is a right to withdraw consent at anytime without explanation. All of these safeguards are in UK legislation within the 2004 Human Tissue Act and protected by the Human Tissue Authority. This proposed legislation from the EU goes against this and international standards for medical research. This is because the research community have understood the need for flexibility as new discoveries are made in medicine and new avenues of research can benefit from properly controlled biobanks. The recent UK Dept of Health Human Genome Steering Group (HGSG) set up to oversee the implementation of the 2010 House of Lords committee on Genomic Medicine clearly stated the need for Biobanks to clearly link Genotype to Phenotype for them to be any use for medical research and the benefit of patients. This would be very limited by the EU proposal as at every stage a new consent would be required. The proposal to sequence 100,000 genomes in the UK which may be a hugely beneficial project for human disease would require a new consent every time a new gene function was explored in the 100,000 participants and there are at least 30,000 genes in the human genome before other modifications are taken into consideration. The reality is that research would not be possible on these 100,000 genomes although the sequence data were completed and available. It would be a bit like buying a grand master painting but not being permitted to look at it. Consent although flexible consent is paramount to all of the international recommendations and the real practice of medical research.

The problem I can see lies in the issue that very important modernisation of the protection of data for the provision of our everyday European Citizen living requirements in the form of internet usage, finances, insurance, shopping profiling advertising and the commercial world are being considered together with the medical research world. Their requirements and protections are fundamentally very different. In addition, the medical research, biobanking and related consent and data protection issues have already been unified both within individual countries and internationally with OECD and The Declaration of Helsinki within the last few years and in particularly within the UK with the Human Tissue Authority. The safeguards are already in place but this new proposal ignores these non commercial issues and in so doing will destroy the ability to move medical research forward rapidly. Finally it is worth noting that Medical research including the use of biobanked material and patient data all has to receive appropriate ethics

and follow ethical principles before it can be legally performed. This process is rigorously legislated for and the provision of consent understood in a manner that ensures this is not unduly burdensome to the participant. I am sure it is not the intention to harm medical research but this will be the consequence if amendments are not made to this Draft.

I would urge very strongly that the above points are considered and catered for within revisions of the current Draft and keep the provisions in the original legislation as they stand for medical research specifically. This should include a more generic but fully informed consent (see Article 83 in original legislation) and ethical requirements. This would make the legislation conform with recent international revisions and ensure that patients in the EU will be the winners rather than the legislators.

## Royal College of Physicians

The Royal College of Physicians (RCP) plays a leading role in the delivery of high quality patient care by setting standards of medical practice and promoting clinical excellence. We provide physicians in the United Kingdom and overseas with education, training and support throughout their careers. As an independent body representing over 28,000 fellows and members worldwide, we advise and work with government, the public, patients and other professions to improve health and healthcare.

The RCP welcomes the opportunity to respond to the [Department of Health's call for evidence](#) for the health section of the [EU Balance of Competencies Review](#).

This paper covers

1. Public health
2. NHS and patient services
3. Medicines and medical devices

### 1. PUBLIC HEALTH

#### Responsibility to ensure human health protection in all EU policies

The EU has responsibility to address public health problems such as tobacco, alcohol misuse and nutrition by complementing national actions, as stated in Article 168 of the Treaty. EU competence in health is not confined to actions by the Directorate-General for Health and Consumers; rather, the Treaty specifies that 'a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.'<sup>64</sup>

Currently protection of health is not given adequate weight across EU policy areas. In particular, protecting trade within the internal market should not be at the expense of protecting public health.

This section will cover the following topics:

- Alcohol
- Tobacco
- Obesity, nutrition and food labelling

#### Alcohol

Alcohol is the world's number one risk factor for ill health and premature death among the 25-59 year old age group and Europe is the heaviest drinking region in the world.<sup>65</sup> Due to the scale and pervasive nature of alcohol misuse across the UK and Europe, it is essential that there is a comprehensive, coordinated response at the local, national and European level.

There is clear evidence that effective alcohol strategies must address the price, marketing and availability of alcohol products, which requires concerted action from a range of policy areas, such as trade, agriculture, enterprise and industry.

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<sup>64</sup> Official Journal of the European Union 2008. Consolidated Version of The Treaty on the functioning of the European Union

<sup>65</sup> World Health Organisation Europe (2012) Alcohol in the European Union, Consumption, harm and policy approaches

For example, the European Commission (EC) is currently reviewing the Scottish legislation that introduces a minimum unit price for alcohol. Failing to give adequate weight to the public health implications of this initiative could delay, or even prevent, Scotland from implementing a proportionate measure that evidence shows will target young and heavy drinkers.<sup>66</sup> That said, a ruling in favour of minimum unit pricing would demonstrate how EU law must prioritise effective public health measures over commercial interests. This would be a valuable precedent that could encourage member states to introduce other public health legislation, such as standardized nutritional labelling, that addresses national dietary concerns.

### **Establishing a new EU Alcohol Strategy**

AHA UK supports the development of a new EU Alcohol Strategy for 2013-2020 that builds upon the current progress by individual member states and the EU collectively to effect greater change. There are a number of ways that coordinated action through an effective EU strategy can contribute to reducing alcohol misuse. These include:

- Establishing clear standards on the marketing and promotion of alcohol. The exposure of young people to alcohol advertising and marketing, particularly digital marketing, is a growing cross-border issue that cannot be solely addressed by individual member states and requires effective EU action.
- Providing a platform for organisations that are active at European level to share approaches and develop joint actions to tackle alcohol related harm
- Ensuring that existing EU nutritional labelling regulations are expanded to include calorific labelling on alcohol.

### **Tobacco**

#### **The EU can support member state actions in public health effectively and efficiently**

The EU has previously passed directives on tobacco packaging, labelling and advertising and promotion, all of which supported the UK's own legislative and non-legislative approaches in these areas. Including flexibility into the implementation of directives has allowed the UK to provide a higher level of protection in some of these areas, such as introducing picture warnings on packs. The provision in the proposed revised Tobacco Products Directive allowing member states to pursue standardised packaging is also most welcome.

#### **Standardised packaging of tobacco products**

The proposed revision of the Tobacco Products Directive mandates picture warnings on packs of cigarettes and requires larger health warnings than at present. This would benefit the UK by helping to dissuade people to smoke, because tobacco is still the largest cause of premature death in the UK and the EU.

#### **Nicotine containing products**

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<sup>66</sup> Foresight. *Tackling obesities: future choices* – Project report, 2007. [www.bis.gov.uk/foresight](http://www.bis.gov.uk/foresight) [accessed 13 December 2012].

The RCP believes that nicotine-containing products, such as electronic cigarettes, have potential to improve public health by offering a competitive alternative to conventional cigarettes. Although smokers who want to quit smoking with medical help have access to other nicotine products, smokers who do not want to quit can be encouraged through free market principles to substitute cigarettes with alternative nicotine containing products. The UK is moving towards making this a realistic possibility. It is important that the revised Tobacco Products Directive does not impose regulation that makes this impossible.

The RCP supports the full ASH consultation response, which focuses on tobacco.

### **Obesity, nutrition and food labelling**

Almost two thirds of adults and a third of children are either overweight or obese,<sup>67</sup> and whilst the rate of increase may be slowing, projections from the Foresight report remain valid – namely that by 2050 the majority of Britain's population will be obese.<sup>68</sup> There is good evidence that effective nutrition and food labelling strategies enable people to correctly identify healthy choices. The obesity epidemic has a serious effect on the social and economic development in Europe; food labelling is one step towards tackling the problem and enhancing better information for consumers. Due to the scale of the obesity epidemic in the UK and Europe, it is essential that there is a comprehensive, coordinated response at the local, national and European level.

The EU has responsibility to address public health problems such as obesity by supporting national actions, as stated in Article 168 of the EC Treaty. Food production now involves complex international food supply chains beyond the remit of one jurisdiction, and so EU action on important issues such as labelling is necessary. As such, the RCP welcomes the development of EU strategies around Front of Pack labelling, based on EU regulation 1169/2011, to ensure that the current progress by individual member states and the EU collectively can be built upon to induce greater change.

There are a number of ways that coordinated action at the EU level can continue to improve the nutritional quality of food and reduce obesity levels. These include:

- Providing a platform for organisations active at European level to share approaches and develop joint actions on diet, physical activity and health (thereby encouraging national, regional and local initiatives across Europe). Such actions need to include health improving targets, with regular evaluation to see whether such targets have been achieved.
- Developing voluntary initiatives to improve the nutritional quality of food and consumers' diets through the EU frameworks; given the importance to public health, such initiatives

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<sup>67</sup> Craig R, Mindell J (eds). *Health Survey for England 2006*. London: Information Centre, 2008

<sup>68</sup> Foresight. *Tackling obesities: future choices* – Project report, 2007. [www.bis.gov.uk/foresight](http://www.bis.gov.uk/foresight) [accessed 13 December 2012]

need to be agreed with an understanding that legislation may follow if they are not progressed.

## **2. NHS AND PATIENT SERVICES**

This section will cover

- EWTD
- EU directive on professional qualifications
- Data

### **European Working Time Directive**

The Royal College of Physicians supports the broad aims and objectives of the Directive, which are to ensure that patients are not treated by exhausted doctor. Whether these aims are achieved through legislation in Brussels or Westminster is not our primary cause for concern – good legislation, wherever it derives, is our priority.

There is evidence from the UK that many medical trainees have found an improvement in work-life balance since the EWTD came into full force. Some do not want to work more than 48 hours and so would not support a wholesale increase in the limit. However, the same group report a fall in quality of patient care and training, and so there is no doubt the issue needs to be reassessed.

Although laudable in its original aims, the application of EWTD to Member States' healthcare systems, and the often generic, cross sectoral approach taken, did not foresee the unintended impacts that have occurred, largely due to the different pressures and organisation of healthcare in each country. However, these unanticipated difficulties have been partly due to the lack of engagement between the medical sector and the UK Department of Health going back to the early 1990s when the legislation was first developed.

This experience demonstrates the need for better assessment of the impact on health system of EU policies, and more effective EU engagement from the medical profession and UK policy-makers when formulating EU legislation. The health sector needs to be treated on its own merits in developing EU laws - not the UK. It would seem perverse that any EU regulation would endanger patient safety in one EU member state and not another.

More recently, discussions in Brussels to revise the EWTD have demonstrated a higher degree of engagement from the UK medical community and consequently a greater responsiveness to our concerns from the European Commission. Flexibility in applying the Directive is key, and we are pleased that our concerns regarding compensatory rest and on-call have at least been acknowledged in the various consultation processes and responses from the European Commission, although the process of finalising a new Directive is a long way off given the recent failure of negotiations by the social partners.

We acknowledge that revising the Directive will not provide a single solution to all our problems in the UK. Indeed, EWTD illustrates the complex interplay between EU legislation and UK healthcare policies. Hospitals are restricted by co-existing UK legislation (the New Deal) and

this needs to be reassessed before the EWTD can be effectively applied. There is no ‘single pill’ to be found in Brussels or Westminster and can hinder the search for solutions, portraying Europe as the sole cause of many of our problems. Focusing too much on EWTD may sometimes be a distraction from achieving more complex workforce and training solutions at home.

***RCP Response to revision of EWTD:***

<http://www.rcplondon.ac.uk/update/rcp-responds-eu-consultation-european-working-time-directive>

**EU Directive on Professional Qualifications**

The RCP welcomes the greater opportunities provided under this Directive for EU doctors to train and practise in other Member States, both as a fundamental right to free movement in the Single Market and to acquire new skills and experience. The NHS relies on mobility and UK doctors enhance their skills by working in different health systems. Therefore, the Directive is not just about “foreign” doctors as is often suggested in the media when problems arise. In terms of balance of competence in this field, an EU framework for setting basic standards is needed to ensure that mobility can happen across borders, and must be agreed by all countries: Westminster cannot do this alone.

Given the Directive’s importance, the RCP has played an active role in helping to reform the existing EU Directive on Professional Qualifications. While we welcome recent efforts to relieve doctors of unnecessary administrative burdens related to the EU mutual recognition of their qualifications, we have been concerned that underlying economic objectives to promote Single Market mobility should not occur at the expense of patient safety.

The process of reforming the Directive has demonstrated the great benefits of engaging with the EU process and, to date, we were generally pleased with the European Commission’s original proposal and particularly welcomed the recent vote in the European Parliament that made changes to the text. In particular, our concerns about language competence and patient safety have been taken on board to improve linguistic assessment in future.

Perhaps the process has also highlighted some naive assumptions at EU level that national medical training/assessment systems are comparable, which they are not. CPD systems vary or do not exist in some Member States, and so efforts must be made to build and reinforce national systems and not just ‘coordinate’ them.

As with EWTD, a cross-sectoral approach to EU rules on professional qualifications has sometimes meant that the specific impact on health systems has not always been appreciated, such as the particular importance of language to healthcare. Therefore, we would like to see “more health”, not less health, when developing EU policies in areas such as the Single Market and Employment that impact directly and indirectly on healthcare.

*RCP Position on Professional Qualifications Directive:*

<http://www.rcplondon.ac.uk/sites/default/files/rcp-response-to-consultation-on-eu-professional-qualifications-directive-15-march-2011.pdf>

## **Data**

The complexity and, in places, ambiguity of the existing EU Data Protection Directive have contributed to a risk-averse culture among those using data for research. Better regulation is needed to ensure that the different types of data used in health research are protected proportionately.

## **Harmonisation of rules**

Can a single regulation produce equalised protection for data sharing and processing when applied to national frameworks with distinct cultural and legislative frameworks, which will remain as before?

The regulation allows little flexibility in some areas and in others relies on delegated and implementing acts that have yet to be drafted.

- We would like to see a more even handed approach, with less prescriptive detail in the provisions for data protection officers and more detail on proposed delegated or implementing acts in other areas.

## **Prescription and over-regulation**

The new regulation requires demonstrated and evidenced compliance at a much greater level. The potential financial burden on private and public organisations to achieve such a high level of documented compliance will be immense.

The proposed criteria for the requirement to have a qualified and experienced data protection officer will offer a good level of general protection for data subjects, although many organisations with small staff numbers and large amounts of personal data, such as GP surgeries, may find the financial and operational impact of compliance with the precise requirements for appointing a data protection officer to be large.

- We would like the supervising authorities to be empowered to offer support for such organisations for what will be a major change to their operations

International transfer of pseudonomised data between collaborators for health research is already constrained and restricted. It is important that health research should not be inhibited unnecessarily.

- We feel that the requirements in article 34 relating to international transfers would only add to the compliance burden relating to research projects and not provide further protections.

## **Consent and the burden of proof**

The definition of personal data is widened considerably in the regulation and the rules for consent are more prescriptive. Consent is often a difficult issue in healthcare provision and in medical research.

Under the regulation, explicit and informed consent would have to be clearly and distinctly demonstrated in virtually all processing, and the burden of proof would fall on the data processor/controller. This would add yet another administrative burden in the health care sector, which is already bureaucracy heavy.

- We would like to retain the legitimate processing protections that support current health care provision, while ensuring that demonstrating consent does not become a barrier.

## **Research**

Patient records are an invaluable resource for health research, forming the basis of studies into the causes and risk factors of disease, and helping researchers to identify suitable participants for studies such as clinical trials. Health research benefits society and promotes economic growth. We support the messages of the joint statement published by several UK organisations involved in health research

<http://www.acmedsci.ac.uk/download.php?file=/images/project/133128476992.pdf>

We are concerned that removing research from the exemption for processing sensitive personal data in recital 42 and the limits on exemptions introduced in article 81, will erode the support for legitimate scientific research in the health sector.

We welcome the derogations in article 83, which aim to balance research with the protection of participants' interests. However, the ability for member states to provide for research exemptions may create a similar patchwork of protection for research that exists under current data protection legislation.

- We would like confirmation that articles 81 and 83 are intended to support and enhance the current level of support for research, rather than impose additional restrictions.
- We would like protection for research across member state boundaries to ensure that individual member state exemptions do not create new barriers.

## **Personal data and research**

Health research studies use different types of data, including anonymised data (cannot be linked back to an individual's original records) and pseudonymised or key-coded data (do not directly identify an individual, but an identifier enables the data to be re-connected). Such data underpin a substantial amount of research, including large-scale population-based studies, that provide insights into the factors underpinning health and disease. While anonymous data fall outside of the scope of the Regulation, the act of anonymisation itself, ie removing identifiers, will fall within the definition of processing and be subject to the Regulation.

- We would like the Regulation to permit anonymisation, but to prohibit the re-identification of data.

## **The right to be forgotten**

There may be potential conflicts between the right to be forgotten and scientific research, specifically regarding the application of the right to be forgotten to research studies and the

consequences to the validity of the study of applying that right in the middle of an on-going study.

- We would like protection for ongoing research studies from missing data due to data transfer (right to portability) or data deletion (right to be forgotten)

### **Fitness to practise**

Under article 82 it is proposed that processing of personal employment data is derogated to national employment legislation. However, the fitness to practise data sharing initiatives struggle with the patchwork nature of state to state transfer of qualification and employment data. The proposal to restrict the harmonisation of employment data means that fitness to practice initiatives may continue to struggle.

- We would like the derogation for employment data to be removed or modified so as to allow the free sharing of fitness to practise data.

## **3. MEDICINES AND MEDICAL DEVICES**

This section will cover academic research and medical devices.

### **Academic research and medical devices**

The EU Clinical Trials Directive was introduced to deliver greater harmonisation across the EU in the regulations and legislation around clinical trials. It is important that the EU remains an attractive location to carry our medical research, including clinical trials, given the potential benefits of research to patient care and economic growth. Regretfully, the Directive did not fully achieve these harmonisation aims. However, the RCP still endorses the objective and stresses the benefits of continuing to work towards this goal. In a recent joint statement, of which the RCP was a signatory, we welcomed the European Commission's proposal for a Clinical Trials Regulation. The Regulation appears to improve the legislation associated with running clinical trials. This will give clinicians and researchers a better framework for developing and testing treatments to benefit patients across Europe, while maintaining the high standards of patient safety that currently exist in European clinical research. The harmonisation of clinical trials legislation and the streamlining of the application process for starting trials should particularly benefit the set up and running of multi-national trials in Europe.

We urge the government to continue working towards this important goal. The joint statement outlines the areas of agreement within the health and research communities on where the Regulation will improve the research environment. Aspects of the Regulation that could be improved to further support clinical research are also highlighted; for example, where more effective and proportionate approaches to certain aspects of the legislation could be sought.

The statement can be downloaded in full from

[http://www.rcplondon.ac.uk/sites/default/files/documents/2012\\_joint\\_statement.pdf](http://www.rcplondon.ac.uk/sites/default/files/documents/2012_joint_statement.pdf)

**Impact on the national interest**

**1) *How does the EU's competence in health affect you/your organisation?***

The EU's competence in health impacts significantly on the core business of our organization, which is medical training. Along with other Colleges, we have previously expressed concerns that medical training, especially in procedural disciplines, is very dependent on experiential learning, gained through exposure to hours of clinical work. Previous published work has noted the reduction in total hours of such experience gained, by those attaining consultant status today, as compared with their predecessors 10 years ago<sup>1</sup> and concerns, not just within the UK, that effective quality training cannot be delivered within the available hours<sup>2,3</sup>.

We concur with the view expressed in the Temple report<sup>4</sup>, that 'what matters most in training doctors is not just the hours of work but what they do in those hours' and we believe that considerable efforts to structure training and its assessment and to focus hours of work on the delivery of training have been very beneficial. However, we remain convinced that the actual hours of clinical exposure are also important. Training, however structured, supported and assessed, is negatively affected by rigid restrictions on hours that can be worked by trainees.

Just as the reduction in contact hours with relevant clinical scenarios is a concern, so too is the reduction in continuity of contact with a single trainer or mentor. The more personal relationship that such continuity of trainer-trainee contact permits is an important, and now often absent, contributor to a trainer awareness of issues with trainee development and to the fostering of excellent skills and clinical leadership. Similarly, continuity of trainee contact with the patient is important to the trainee understanding of the totality of their patient's journey and the impact that their clinical decisions may have had. Both types of contact are restricted by the working patterns that are a direct result of the European Working Time Directive.

In addition, the number of medical staff required to sustain a viable acute care rota, is made much greater, under EWTD restrictions, than would previously have been necessary. There appears to be a conflict, between the numbers required to fulfill patient care within the EWTD, and the numbers projected as necessary to train to create a consultant workforce. We believe that this is having particular impact on care within 'district general' hospitals. The quality of care such hospitals can provide for the communities they serve, is jeopardised by the frequent staff transitions and vacant rota gaps that result from the above conflict. Moreover, despite the EWTD, trainees continue to work long shifts with resultant stress and the potential for risk to patient care<sup>5</sup>.

**2) *What evidence is there that EU action in health advantages or disadvantages:***

**a) *The UK national interest***

The national interest is served by measures that ensure that clinical supplies, sourced from across the EU, comply with safety standards acceptable to the UK and measures across the EU support control of infection and identification of disease.

However, the UK has enjoyed a reputation for excellence of its medical training and its healthcare delivery. Both are compromised by the inability to take decisions on hours of work within the UK and, as below, by EU influences on recruitment of medical staff.

The quality of health care that can be delivered to British citizens, within the projected limits on healthcare spending, may also be potentially adversely affected by the definition of UK resident in respect of access to healthcare, in the context of EU competence on co-ordination of healthcare provision and free movement of persons.

**b) *Business and industry***

Other than noting support for trade of clinical supplies, we cannot comment.

**c) *Patients and citizens***

The assurance of clinical care for citizens wherever they are across the EU is important, as are the benefits in terms of safe clinical supplies, measures to control infectious diseases and other cross-border threats to health and clear food labeling.

However, as described elsewhere, we are concerned that there is EU impact on medical training and recruitment that poses a risk to patient care.

**3) *Please consider what evidence there is to demonstrate;***

**a) *the extent to which the EU's role in public health supports member state actions effectively and efficiently***

We support the member state co-ordination of policy and procedure in respect of the response to communicable diseases, and the safety and quality control measures required for blood, tissues and organs, new technologies and pharmaceuticals. Similarly we believe that monitoring of disease states across the continent is beneficial. We support collaboration on measures to limit public exposure to tobacco and alcohol and would hope that these are regarded as a minimum to be applied within states, rather than limiting action within states. For example, the EU's role in alcohol underlines and supports the national commitment to promoting good public health. Other EU policies such as agricultural and fisheries policies should support the EU role in prioritising public health and ensuring improving health and tackling health inequalities are key objectives.

However, we believe that issues relating to the management of the health of the individual and of their society as a whole, are better managed by the individual state to which that individual or society belongs. We are doubtful that collaboration on workforce planning across the EU will have significant benefit.

**b) *the opportunities and costs for the delivery of health and social care in the UK that flow from wider EU competences and policies such as the free movement of workers or the single market generally***

Recruitment of specialized individuals required to perform a role that impacts immediately on public safety should have as its first priority the selection of those most equipped for that role. This should not be made secondary to their country of origin or free movement of workers. Clinical training in certain EU countries has been found on several occasions not to be equivalent to that of a similar grade in the UK. We believe that recruitment of such individuals has placed local service delivery under strain and created additional pressure on

training delivery and the training of other UK trainees. Either greater assurance is needed, over the equivalence of degree courses and postgraduate training, or greater freedom, to source staff from those countries known to train to UK standards.

**c) *the extent to which EU competence and policies intended to allow EU citizens to access healthcare across the EU are effective and proportionate***

We cannot comment for the service on the impact such competence and policies have on the equitable and manageable delivery of health care.

**d) *the extent to which health objectives are effectively and proportionately taken into account in wider EU policies***

No additional comment.

## Future options and challenges

### **4) How might the UK benefit from the EU taking more action in health?**

Collaboration over key disease research, e.g. cancer, heart disease, diabetes

Collaboration over classification and management of drug misuse

Ensuring other EU policies take account of the possible health effects on the population.

### **5) How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?**

We have addressed this largely elsewhere but would also note that EU decisions on IT in healthcare could cause unnecessary levels of complication or cost when systems come to relate to others in the country.

### **6) How could action in this area be undertaken differently e.g.**

**a) Are there ways of improving EU legislation in health, e.g. revision of existing legislation, better ways of developing future proposals, or greater adherence to the principle of subsidiarity and proportionality?**

Legislative measures support effective delivery but are limited by the time required to respond to any later change. They are preferred for matters relating to serious threat to public health, e.g. control of infection, but especially those that are unlikely to change in respect of the detail described in the legislation. We believe that for the majority of health matters sufficient subsidiarity and proportionality should be re-instated. State-based flexibility to respond to local need should be established. In some 'middle ground' areas of particular cross-border concern but not such as to require legislation on detail, legislation could perhaps be used to endorse principles of action against which member states could submit implementation plans. Such plans could be open to resubmission and indeed reviewed after a set duration, perhaps by an EU medical advisory committee.

**b) Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest?**

Please see 6a

**c) Could action be taken at any other international level i.e. by the WHO?**

We think this should support management of cross-border concerns and help identify them but not oversee them.

**d) What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?**

Please see 6a

### **7) How else could the UK implement its current obligations?**

No additional comment.

**8) *What future challenge/opportunities might we face in EU health competence and what impact might these have on the national interest?***

We are not sure

**9) *What impact would any future enlargement of the EU have on health competence?***

We have concerns about the level of clinical competence assured by qualifications elsewhere.

**General**

**10) *Is there evidence of any other impacts resulting from EU action in health that should be noted?***

Addressed elsewhere

**11) *Are there any general points you wish to make which are not captured above?***

No

**12) *Are there any published sources of information to which you would like to draw our attention for the purposes of this review?***

1) [http://www.asit.org/assets/documents/ASiT\\_EWTD\\_Position\\_Statement.pdf](http://www.asit.org/assets/documents/ASiT_EWTD_Position_Statement.pdf)

2) <http://archsurg.jamanetwork.com/mobile/article.aspx?articleid=406024>

3) [http://www.gmc-uk.org/static/documents/content/Training\\_survey-FINAL2010.pdf](http://www.gmc-uk.org/static/documents/content/Training_survey-FINAL2010.pdf)

4) <http://www.mee.nhs.uk/PDF/14274%20Bookmark%20Web%20Version.pdf>

5) <http://www.gmc-uk.org/about/research/14413.asp>

## Royal College of Physicians of Edinburgh

The Royal College of Physicians of Edinburgh (“the College”) is pleased to respond to the Call for evidence on the Government’s review of the balance of competences between the United Kingdom and the European Union regarding health.

The College has the following comments on specific questions:

### **IMPACT ON THE NATIONAL INTEREST**

#### **▪ *How does the EU’s competence in health affect you/your organisation?***

The EU’s competence in health affects the College in a variety of ways. Examples of areas under EU jurisdiction which affect the College include:

#### *Regulatory matters:*

- An effective and timely warning system across EU member states to indicate restrictions on practice and removal of professional registration;
- Testing of language skills and mobility of health professionals across EU member states: there are a number of implications for patient safety in this area.
- Competent English language skills for doctors working in the UK need to be supplemented with good communication skills and cultural awareness.
- Medicines and technology regulations, including packaging and supporting information including dosage – standardisation would reduce confusion caused by multiple formulations and packaging.

#### *Training and Quality:*

- Curricula leading to medical qualifications such as the Certificate of Completion of Training (CCT) across the EU states are not always comparable or transferable in the medical specialties and sub specialties;
- Restrictions on UK ability to change the length of medical training by specialty;
- The European Working Time Directive (EWTD): The EWTD has had unintended adverse consequences on both training and service. While the improvement in trainees’ work /life balance has been positive, it has had detrimental effects on continuity and quality of patient care and the training of junior doctors;
- Consistency of quality standards across EU member states: there is significant variation in health systems across the EU member states.

#### *Public health matters:*

Restraining measures on access to and consumption of tobacco and alcohol, and legislation on food regulation.

- ***What evidence is there that EU action in health advantages or disadvantages:***

- *The UK national interest*

The effect of EU action on health generally has a positive impact on the UK. Examples of this include social measures, health protection and security across borders.

Through the EU's various instruments and institutions, it assures basic standards in a number of respects, although the application of these standards needs to be equivalent across the European Union. There are examples of arbitrary or partial implementation, not least the most recent example of the introduction of horse meat into the beef food chain in countries across the European Union.

Negative effects include the inflexibility of the EWTD, where relaxation could improve continuity of patient care in the UK and the quality of medical training.

- *Business and industry*

No comment.

- *Patients and citizens*

The UK benefits from EU action on public health, particularly relating to alcohol and food.

- ***Please consider what evidence there is to demonstrate:***

- *the extent to which the EU's role in public health supports member state actions effectively and efficiently*

The EU's role, overall, is beneficial to public health. Through the creation of wealth, assured processes and supporting institutions, the EU can regulate a very large market in consumer products, so limiting related harm. However, it is clear that the failure on occasions to apply a proportionately common sense approach demonstrates the need for proportionality in assessing the risk and restricting market opportunities. The entry of horse meat into the beef food chain and the sourcing of fish from European waters, marketed through non-European intermediaries in the 1990s where the public health hazards were low, are good examples.

Generally, the role of the EU in health seems appropriate to support individual member states ie the focus is on areas where cross-border/supra-national action is appropriate for example, medicines, public health, nutrition, health screening, radiation etc.

- *the opportunities and costs for the delivery of health and social care in the UK that flow from wider EU competences and policies such as the free movement of workers or the single market generally*

No comment.

- *the extent to which EU competence and policies intended to allow EU citizens to access healthcare across the EU are effective and proportionate*

No comment.

- *the extent to which health objectives are effectively and proportionately taken into account in wider EU policies*

No comment.

## FUTURE OPTIONS AND CHALLENGES

- ***How might the UK benefit from the EU taking more action in health?***

**Addressing health inequalities:** These are more likely to be reduced by regulation, legislation and assurances that are applied equally to the whole population across the EU. This removes an element of voluntary activity but upholds the rights and interests of people who have the most to gain, whose choices are narrowest, and whose health is the poorest. There are numerous examples of health inequalities, and plenty of evidence and literature to underpin this principle.

**Public health interventions:** particularly in noting the importance of social determinants in creating health and balancing economic drivers and commercial interests. It could be perceived that the EU has a tendency to weigh in favour of business and commerce and, despite its commitment to consumer affairs and health (within the same Directorate), they often come second best to the interests of governments and private companies. A current example is the pressing need to reduce alcohol-related harm in high consumption countries such as Scotland, and the unfettered activities of food producers and retailers in promoting and sustaining over-consumption and unbalanced nutrition, with adverse effects on many consumers. Whilst competitiveness and free markets serve to drive up wealth and opportunity, it is well known that price and competitive pressures on potentially harmful substances that are legally marketed in the EU, such as alcohol and tobacco, require a firm and progressive framework of protections. The EU has embarked on a series of specific nutritional measures, e.g. on salt and fat, but more is required to reduce health related harm from over-nutrition as well as poor nutrition.

- ***How might the UK benefit from the EU taking less action in health, or from more action being taken at the national rather than EU level?***

One particularly important example might be the application of the EWTD to junior hospital doctors. There could be benefit if the application of the EWTD could be relaxed where there is clear evidence that it interferes with the quality of training and provision of safe patient care.

One of the few examples of public health benefit if the EU had less influence would be the removal of protection on alcohol minimum unit pricing allowing the UK to take unilateral action immediately to protect its citizens from excessive consumption of cheap alcoholic beverages.

- ***How could action in this area be undertaken differently e.g.***

- *Are there ways of improving EU legislation in health, e.g. revision of existing legislation, better ways of developing future proposals, or greater adherence to the principle of subsidiarity and proportionality?*

See above for the example of alcohol, and national restrictions or its actions to reduce alcohol related harm through restrictions on price and availability, currently in court and with the European Commission.

- *Are there ways the EU could use its existing competence in health differently which would deliver more in the national interest?*

No comment.

- *Could action be taken at any other international level i.e. by the WHO?*

The WHO may set frameworks and encourage action but, without the legal frameworks of member governments and the European Parliament, their influence would be insufficient on matters such as tobacco control, alcohol and food. Nonetheless the influence of WHO drives European policy and stimulates national action.

- *What evidence is there on the relative merits of legislative and non-legislative measures in relation to health, and on how they are implemented?*

There are plenty of national and international organisations that are able to advocate in a non-legislative manner in relation to health. It is essential that legislative bodies are able to act on recommendations that are binding on legislative and member states. However, measures are inadequate if enforcement, monitoring and effective sanctions fail.

- *How else could the UK implement its current obligations?*

No comment.

- *What future challenge/opportunities might we face in EU health competence and what impact might these have on the national interest?*

The EU has a potential to narrow the gradient in health inequalities within member states and across the EU area. Its current redistributive policies serve to enhance this matter, and the EU may be able to influence the social determinants of health in a manner that would increase overall levels of health across populations.

The unforeseen consequences of EU Directives on specific applications require greater scrutiny and an ability to seek exemptions quickly as the EWTD and language issues for health clearly demonstrate.

- *What impact would any future enlargement of the EU have on health competence?*

The major risk of enlargement at present is that member states' institutions and resources may not have the ability to assure and comply with EU treaties and regulations, particularly in such areas as professional and medicines/devices regulation, the mobility of health care professionals and the recognition of training programmes.

## **General**

- *Is there evidence of any other impacts resulting from EU action in health that should be noted?*

Analysis of the legal annex (pages 29-44).

2. Medicines – the authorisation, free sale and purchase of medicines across the EU does promote appropriate safe treatment. However the diverse packaging and formulation of a particular drug means that appearances of medication can be different from one prescription to the next, and this can cause confusion to patients, as while the active ingredients are regulated, the presentation is not.

3.2 Medical Devices – clearly, strengthening controls, safety, transparency and surveillance of devices across the EU is highly desirable. It is not clear whether there is any common ground or discussion on equipment such as laboratory, radiology or endoscopy. Certainly, for endoscopic equipment, there seem to be significant variance in pricing structures in different EU countries.

4.4 Clarity is required that the surveillance of practices across the EU is sufficiently robust to ensure that the standards set are adhered to.

6.3 It is to be hoped that there will not be a significant delay beyond early 2013 in the adoption of the revised Directive concerning tobacco.

6.7 Since the Commission has been active in trying to reduce the number of smokers in the different EU countries, it would be helpful if comparative data could be detailed, country by country, of annual percentage reduction in smokers over the last 5 years.

7.1 The UK is currently exploring a minimum pricing strategy per unit in relation to alcohol, and it would be of great assistance in this important public health measure if EU legislation facilitated rather than obstructed such legislation.

The College supports the response from Scottish Health Action on Alcohol Problems (SHAAP) in relation to this, and along with other leading health groups, we are supportive of minimum unit price on the basis that price will impact on consumption, which will have a positive impact on public health. The EU has argued that minimum unit price would impinge on the free trade and unfairly disadvantage some producers. We are quite clear that the principle of protecting public health (Article 36) overrides concerns about free trade.

12.2 It is important that, particularly in the area of medical and surgical training, the EWTD is not required to be implemented rigidly in member states, such as the UK, where there is clear evidence that such a Directive interferes with the quality of training and subsequent safety of service provision.

13.2 Although the recognition of professional qualifications has been harmonised, the practice of medicine requires effective communication. Doctors wishing to work in the UK from outside of the EU are required to achieve a score of 7 or more in each of the domains of the IELTS exam, and this standard should be equally applicable to non-English speaking EU countries.

16.2 An eHealth network is commendable, and efforts should be made to co-ordinate any new initiatives. The College commends advancing UK national integration of IT systems before extending this into Europe.

- *Are there any general points you wish to make which are not captured above?*

The document rightly states that representation in the EU and in international organisations such as WHO is at UK level. As the healthcare systems in the UK increasingly diverge, the practicalities of a single 'voice' from the UK are an area which would benefit from discussion. Stronger arrangements for devolved administrations to contribute to the single UK voice could be beneficial in more accurately representing the needs of the four nations of the UK.

- *Are there any published sources of information to which you would like to draw our attention for the purposes of this review?*

No comment.

## Royal College of Radiologists

There is considerable variation in the health systems of different member states and as a general principle it is where there are cross-border health issues that EU competence is most likely to be relevant. The focus should be on the health and welfare of the patient and the citizen recognising that national interests have a role.

As identified in the consultation document there are a number of areas of EU competence that are not specifically related to healthcare which nevertheless have a significant effect on the quality of care of UK patients.

The RCR wishes to comment on the following specific areas:

### **Section 9 – Radiation**

The EU has produced the very valuable Euratom Directive on the use of ionising radiation in patients which has increased the safety of patients throughout Europe including the UK.

The UK has a commendable history through the work of the Royal College of Radiologists, the Society for Radiological Protection, the Radiation Protection Agency and the Department of Health in reducing and managing the patient radiation burden over many years, and played a very significant part in the development of the Euratom (97) Directive. However, due to the fact that radiation comes under the Environment Directorate-General (DG) and the European atomic energy community, there is very little input from doctors into their deliberations.

Recently there has been a major issue on Magnetic Resonance Imaging (MRI) resulting from a directive on the electromagnetic exposure of workers which emanated from a DG with no health input. This led to a situation where radiographers who were helping patients through the MRI were banned from exposure under the directive. The upshot has been the temporary withdrawal of the directive and expensive and tortuous renegotiation. There clearly must be a workable solution for MRI in the directive whether by derogation or otherwise. This is an example where EU wide action has been implemented with too little thought or consultation; it has taken years of work aiming to correct the situation and avoid detriment to patients. To avoid this situation being repeated, the healthcare sector must be better represented in such areas of policy.

### **Section 12 - Implications of employment policy**

#### *12.2 European Working Time Directive (EWTB)*

The strictures caused by the EWTB have impacted negatively on the training of doctors and have reduced the continuity of care of patients in hospitals. There is a delicate balance to be struck for medical trainees. Trainee doctors must receive comprehensive learning opportunities and exposure to patients and medical systems which often means shift work to ensure that they gain relevant experience. Patient safety must, of course, remain paramount, and therefore whilst not wishing significantly to extend the hours of work of doctors in training, the healthcare sector should be reviewed separately to find an appropriate formula which ensures the breadth and quality of training and appropriate working hours for doctors.

### **Section 13 - Implications of free movement of persons: healthcare professionals**

The co-ordination of specialty training requirements for doctors throughout Europe has improved significantly over the last decade and many specialties now have European qualifications to supplement those achieved at national level. There is however still considerable

diversity of training quality and standards through the 27 countries of the EU and assessing equivalence of training and understanding of different healthcare systems may prove difficult for potential employers.

There is also increased diversity in the continuous medical education and professional development requirements between member states and especially in the UK with the requirement for revalidation.

While this is not so important for patients receiving treatment in their own member states, it is of considerable importance for cross-border healthcare. In particular it is a considerable risk for patients who are being assessed via telemedicine. In clinical radiology patients can unknowingly have their radiological examinations reported through a cross-border teleradiology service. This is further discussed in the next section.

It appears there is still no EU wide legal requirement for member state regulatory bodies to share information on the registration status of all doctors although progress on this was made in the EU Cross-border Healthcare Directive. Again this is particularly relevant for patients having cross-border teleradiology.

The RCR supports the change in legislation which will introduce testing of the language skills of doctors from EU countries who wish to work in the UK which will in turn help to ensure that patient safety remains paramount.

## **Section 16 - eHealth**

The EU promotion of eHealth is to be welcomed. However this term covers a wide variation in services including electronic monitoring of patients, e-prescribing and electron paramagnetic resonance (EPR). Unfortunately telemedicine and particularly teleradiology have been included in this overarching term as they are very different, involving as they do the direct input of a specialist doctor.

The EU has been discussing the issues over a considerable period of time and has received a great deal of input from the European Society of Radiology. This has resulted in a working paper from the Commission on the legal issues involved. Unfortunately this paper has substantially restated the present position without moving the debate forwards. The majority of legislation related to teleradiology falls into the Information Technology and Cross-border Contract Directives rather than the Cross-border Healthcare Directive despite considerable efforts to include it in the latter.

The present position is absurd in that in some member states the reporting of a teleradiology examination is not considered a medical act whereas in the UK the radiologist reporting the examination has to be a specialist subject to revalidation.

It is therefore of considerable concern that the consultation document states in clause 10.3 that the UK seeks assurance that “areas such as e-health and health technology assessment would remain matters of voluntary co-operation”.

It is essential that patients are fully informed as to where their radiological examinations are being reported, by whom, together with the status of the reporting doctor prior to the examination and that they are provided the opportunity to give or withhold informed consent for a cross-border service. They should also be able to seek redress for negligence in any cross-border service in their own country of domicile. Patients should be informed of this right to

redress before an examination is performed, both in terms of the examination itself and the reporting of it.

The RCR has for several years called for a change in the legislation which would enable the General Medical Council as the UK competent authority for the regulation of doctors to require the compulsory registration and revalidation of all doctors who practise on or offer services to UK patients wherever those doctors are located. This is becoming increasingly urgent with the growth of teleradiology and telemedicine and the likely growth in the number of providers of radiology services in England, some of whom may not be based in the UK.

### **Section 17 – Health research**

The European Clinical Trials Directive was clearly intended to protect the interests of patients. However it has had almost the opposite effect by making the bureaucratic burden very difficult to negotiate, and at best slowing down, at worst preventing research for patient benefit from taking place. In terms of the review which is underway, it is vital that new regulations take a more common sense, risk-adapted approach.

### **Section 19 - Further legislation and case law**

The extensive influence of legislation in many areas outside of health causing problems for delivering high quality and efficient patient care is recognised by the Commission. It is therefore fundamental that the implications of any legislation in preparation should consider the impact and be widely discussed with derogation where necessary.

There is a strong case for specific legislation to cover health issues; a directive on teleradiology and telemedicine separate from other e-Health related issues is particularly necessary.

The general message is that EU competence in many areas of health legislation and associated areas as discussed above can be positive but there are many examples where the application of one size clearly does not fit all. More thoughtful, appropriately wide consultation and greater consideration of short and long term consequences is clearly needed to avoid time and money being devoted to work that has either little value or is wrongly directed - and worse still in putting things right when poor decisions have been made.

The Royal College of Surgeons welcomes the opportunity to submit evidence to the EU balance of competences review health report.

The College is a professional body committed to enabling surgeons to achieve and maintain the highest standards of surgical practice and patient care. There are a number of EU rules and regulations which have implications for frontline medical professionals, and our views on these are set out in the following submission.

Our key concerns relate to the European Working Time Directive. The College has consistently called for the application of this regulation to be limited in the NHS. This submission also examines the EU's recently proposed revisions to the regulations on medical devices, and the Directive on the Recognition of Professional Qualifications.

As a non-political organisation we do not address whether the issue in question is best decided at an international, European, national, or regional level. Instead we address the impact of existing or proposed directives and set out possible solutions. The College would be pleased to contribute to any further discussions on these directives.

### **1. The European Working Time Directive**

The College expressed reservations about the application of the European Working Time Directive (EWTD) in medicine even prior to its phased introduction in the UK. We continue to be concerned about its impact on patient care in the NHS and the training of the workforce.

#### **Evidence of impact**

In August 2010, a study of RCS members showed that 80% of consultant surgeons and 66% of surgical trainees felt that patient care had deteriorated as a result of the EWTD.<sup>1</sup> According to our estimates, every month 400,000 surgical hours are lost due to the EWTD.<sup>2</sup> This has a detrimental impact on patient care due to the reasons we set out below.

#### **a) Staff handovers and rotas**

There is a particular impact on patients due to the number of handovers between doctors and difficulties in constructing staff rotas.

The implementation of EWTD led to drastic changes in how NHS trusts staff hospitals. In the past doctors would work a standard daytime week, and participate in an on-call rota to provide cover at nights and weekends.

This system meant that there was always a range of people available with the right level of skills to deal with problems or emergency admissions out of hours. However, because time spent on-call would count towards doctors' and surgeons' limit of 48 hours a week, these arrangements have had to be scrapped in favour of full-shift rotas.

The shift system means that a surgeon frequently never sees a patient through their surgical treatment. In our 2010 survey, more than a quarter of senior surgeons reported that they were no longer able to be involved in all of the key stages of a patients' care.<sup>3</sup>

Handovers have always happened, but the shift system means that they happen more frequently. In October 2009, a survey of RCS members found that 33% of participants said that handover arrangements have been inadequate.<sup>4</sup> Less than a year later – in August 2010 – 41% of consultants and 37% of surgical trainees said that handover arrangements had deteriorated.<sup>5</sup>

Frequent and inadequate handover arrangements mean there is an increased risk of something important getting missed. 49% of survey participants who considered the handover arrangements inadequate said there had been specific instances where patient care or safety had been compromised.<sup>6</sup>

The problems created for handovers were underlined by a recent GMC-commissioned report on the impact of working time regulations on medical trainees<sup>7</sup>.

## **b) Availability of staff**

In many hospitals there are not enough available surgeons and other hospital doctors in the NHS to staff full-shift rotas. Staff are stretched too thinly, particularly over nights and weekends. This often leads to a reliance on locum doctors to cover gaps in rotas. As a result, hospitals are struggling to cope and patient safety is put at risk.

Under the on-call system, a network of surgeons at all levels of experience and expertise could be called out if required. Under a rota system, whole levels of cover have been removed, often leaving only a junior surgeon and consultant to cover patients on the ward and any new admissions. Evidence shows that such arrangements have put patient safety in jeopardy, particularly during busy times.

It also means spending on locums has increased to ensure staff are available to fill gaps in rotas.

## **c) Staff tiredness**

Full-shift rotas have proved exhausting for surgical staff. Surveys by the Association of Surgeons in Training (ASiT)<sup>8</sup> and the British Orthopaedic Trainees Association (BOTA)<sup>9</sup> have shown that working in a full-shift pattern is more tiring than working under an on-call system. It creates an environment detrimental to patient safety.

## **Reduction in time available for quality training**

The amount of time available for training has been dramatically reduced. One year on from EWTD, our survey found that 65% of surgical trainees said their time for training had decreased.<sup>10</sup> It is also impaired by the fact that fewer consultants are available to offer their support to surgical trainees.

As previously outlined, the nature of full-shift working leaves surgical trainees exhausted. This style of working is not conducive to surgical training. It also makes it impossible for surgical teams to stay together at all times, which is detrimental to the trainee-consultant relationship. A survey by the Postgraduate Medical Education and Training Board (PMETB) found that only 38.1% of trainers for surgical specialties said they would be able to maintain training standards under EWTD.<sup>11</sup> Similarly, a 2009 survey by the Association of Surgeons in Training – which surveyed 1,600 surgical trainees – found that 66% of trainees felt that the standard of their surgical training had deteriorated since the EWTD.<sup>12</sup>

## **Solutions**

The College does not wish to see the return to the days when doctors worked excessively long hours; this was equally unprofessional and put patient safety at risk. However, the working time regulations go too far the other way.

While we appreciate the Government's commitment towards seeking a necessary EU-level agreement to amend the Directive, we are concerned about the slow pace of change and we wish to see greater flexibility on all regulations affecting working hours at a national level. We therefore welcome the Government's recent announcement to review the junior doctors'

contract as this has the potential to improve working patterns and to release time to train and provide care.

While we await an EU level agreement, we also wish to see a lifting of the Jaegar and SiMAP judgements around the definition of rest periods to provide greater flexibility to the rules around surgeons' working hours.

## **2. The medical devices directive**

Medical implants and devices have brought significant benefits to patients; continual innovation in the field should thus be encouraged and facilitated. However, it is imperative that this does not happen at the expense of patient safety.

The College has a particular interest in the regulation of medical implants, as surgeons are the core users of these devices in the delivery of treatment. It is vital that they have confidence in the safety and performance of the devices they are using on patients.

The European Commission has recently proposed a new regulation on medical devices, intended to replace two previous directives (medical devices and in vitro diagnostic medical devices).

The evidence below illustrates our general concerns around the regulation but also explicitly sets out our views on these latest proposals.

### **Transparency**

The College has supported the recent calls for increased transparency and accountability across the regulatory framework for medical devices in both the UK and the EU. We feel manufacturers and regulators should publish rigorous clinical data to enable the health service and patients to make informed decisions about which implants to use.

### *Clinical investigations*

We are concerned that new proposals would remove a member state's right to request further information about manufacturers' applications to conduct clinical investigations. By only leaving them with the option to approve or deny, clinical research standards may be undermined and this could delay the introduction of innovative devices.

### *Centrally held information*

The College would like to see a central information service established which can provide details of the notified bodies in each EU member state.

We support proposals to introduce a new central European database, bringing together registration details of devices, which we feel will simplify the system. We agree that Unique Device Identification (UDI) codes should be used in this database, and believe it should also include key information on the manufacturer, approving notified body, evidence base and post-market surveillance.

We feel that the requirement to produce a summary of safety and performance information will also help to increase transparency for patients and clinicians.

These recommendations require initial investment, but in the long-term we believe that they will prove cost-effective. They will help to speed up approval decisions, provide earlier indications of safety issues and drive up regulatory standards through the increased potential for public scrutiny.

### *Patient card*

The College supports the European Commission's recent proposals to require manufacturers of implantable devices to provide an implant card for patients. This will provide crucial information – such as the UDI code, any relevant warning, the expected lifetime of a device – which will be of significant benefit to patients.

### **Role of surgeons and clinicians**

Ensuring the safety and performance of medical implants should involve a joint approach, from regulators, industry, clinicians and patients. The roles and responsibilities of each of these groups need clarification.

The clinician has an important role to play (for example, in monitoring implant performance once on the market) and this should be acknowledged. It is important to define and mandate at European level how surgeons and other health professionals report performance and safety concerns.

There is greater potential for surgeons to fill a mandatory implant monitoring duty, through audit and procedures registries. Evidence suggests that where audits and registries are well established, it is possible to identify problems with specific implants and devices, as well as to assess clinical outcomes and surgical performance more broadly.

### **Maintaining consistently high regulatory standards across Europe**

The College is concerned that the potential variability in the standards and expertise of national competent authorities and notified bodies (to which they delegate responsibility for approving medical devices) poses risks to patient safety and high quality care.

### *Expertise and standards of notified bodies*

We have concerns that a device failing to meet the approval criteria of one notified body may gain approval from another, less stringent, notified body elsewhere. We see this as a public protection risk, and one which is a barrier to increasing public confidence in the system. We welcome the European Commission's recent proposals to ensure that manufacturers cannot apply to multiple notified bodies simultaneously, that they will inform each other if an application is withdrawn prior to a decision being made, and that there will be more careful and process-driven movement between notified bodies. We also support calls by the Medicines and Healthcare products Regulatory Agency (MHRA) to take this further, and require manufacturers to disclose their previous interactions with other notified bodies.

We feel that only notified bodies with the highest expertise and standards should be able to approve devices. We have called for greater member state collaboration and coordination in order to develop more stringent harmonised standards, in consultation with all member states and stakeholders.

### **The Professional Card**

We support the current proposals for a 'Professional Card' which would contain validated information about an individual's qualifications and professional status with the appropriate regulator.

We are concerned about the quality assurance of the information on the Card and believe that competent authorities in the host member state (for example, the General Medical Council) should at all times retain the right to verify an individual's identity and qualifications pre-registration, whether they are using the Card or not. This is imperative if we wish to maintain the

standards and integrity of the register. This principle should extend across all categories for automatically recognised professions.

Further, on the grounds of public protection, the College does not believe doctors or dentists should be placed on such a register without the explicit satisfaction of the competent authority (regulator) in the host member state. 'Tacit authorisation', whereby professionals could start practising if the regulator does not respond by a set deadline, is insufficient.

### **Partial access to a profession**

The College was disappointed that the recent revisions to this Directive did not propose an explicit derogation for health professionals regarding 'partial access'. An individual unable to meet the required standards in the maximum allowable adaptation period (as currently defined), should not be granted access to the health professions, especially with the possibility of accessing patients and other vulnerable groups.

### **Notification of disciplinary sanctions**

We support the proposal for compulsory notification through the Internal Market Information (IMI) system which allows competent authorities to securely access information on a health professional if they are no longer able to practice due to disciplinary sanction.

We would also recommend that notifications are issued for other sanctions which lead to a restriction of practice, e.g. temporary suspension or supervision order.

### **Competency requirements**

It must be made clear that the move towards acknowledging and incorporating competencies as a useful qualification indicator should not equal standardisation. Member states must retain the right to develop and evolve their own competency requirements, as determined by the health systems and needs of their country. It should be emphasised that employers are responsible for ensuring the doctors and dentists are only employed in roles that are within their competence.

The Faculty of General Dental Practice (FGDP), a faculty of the College, notes that dentists – unlike surgeons – often work in relative isolation (rather than as part of a team) while in practice. This means that problems with their competency may not be immediately apparent.

FGDP are concerned that some EU dentists, who have qualified outside of the UK but wish to practise here, have a lack of understanding about the system for the provision of oral healthcare in the UK. They also feel that some dentists who come to practise in the UK lack the clinical competence to do so.

The FGDP believe that this problem could be minimised if all EU dentists were required to undertake an induction course when they first arrived in the UK.

### **Continuing Professional Development**

We believe the inclusion of Continuing Professional Development (CPD) – a term used to refer to ongoing training and development of professionals – is an opportunity to raise standards, by requiring that CPD is mandatory in all member states.

In the context of both competencies and CPD, we remain concerned that the Directive omits the issue of recent practice. This means that a doctor with a qualification gained decades ago can be included on the medical register, even if s/he has not practised medicine for several years.

Regarding dentistry, the Faculty of General Dental Practice is concerned that, while most EU member states require their dentists to undertake CPD throughout their practising careers, this is still not a requirement across the EU.

- 1 [http://www.rcseng.ac.uk/news/docs/rcs\\_ewtd\\_survey\\_results\\_jul\\_2010.pdf](http://www.rcseng.ac.uk/news/docs/rcs_ewtd_survey_results_jul_2010.pdf)
- 2 <http://www.rcseng.ac.uk/policy/documents/RCS%20EWTD%20briefing.pdf>
- 3 [http://www.rcseng.ac.uk/news/docs/rcs\\_ewtd\\_survey\\_results\\_jul\\_2010.pdf](http://www.rcseng.ac.uk/news/docs/rcs_ewtd_survey_results_jul_2010.pdf)
- 4 <http://www.rcseng.ac.uk/news/docs/Summary%20of%20results%20from%20RCS%20EWTR%20survey%20Oct09.pdf>
- 5 [http://www.rcseng.ac.uk/news/docs/rcs\\_ewtd\\_survey\\_results\\_jul\\_2010.pdf](http://www.rcseng.ac.uk/news/docs/rcs_ewtd_survey_results_jul_2010.pdf)
- 6 <http://www.rcseng.ac.uk/news/docs/Summary%20of%20results%20from%20RCS%20EWTR%20survey%20Oct09.pdf>
- 7 GMC (2013): The Impact of the Working Time Regulations on Medical Education and Training
- 8 [http://www.asit.org/assets/documents/ASiT\\_EWTD\\_Position\\_Statement.pdf](http://www.asit.org/assets/documents/ASiT_EWTD_Position_Statement.pdf)
- 9 British Orthopaedic Trainees Association (BOTA) survey, *BOTA position statement on EQTD and training in trauma and orthopaedic surgery*, January 2009.
- 10 [http://www.rcseng.ac.uk/news/docs/rcs\\_ewtd\\_survey\\_results\\_jul\\_2010.pdf](http://www.rcseng.ac.uk/news/docs/rcs_ewtd_survey_results_jul_2010.pdf)
- 11 <http://www.rcseng.ac.uk/policy/documents/RCS%20EWTD%20briefing.pdf>
- 12 Association of Surgeons in Training (ASiT) survey, *Optimising working hours to provide quality in training and patient safety (January 2009)* and British Orthopaedic Trainees Association (BOTA) survey, *BOTA position statement on EQTD and training in trauma & orthopaedic surgery (January 2009)*

## Royal College of Surgeons of Edinburgh

The Royal College of Surgeons of Edinburgh is pleased to have been afforded the opportunity to contribute evidence to the review of the Balance of Competencies Related to Health. The College is a membership organisation representing the surgical workforce, with over 19,000 Fellows and Members in around 100 countries; only half of whom reside in the British Isles. The Prime purpose of the College is the pursuit of the highest standards of surgical practice and surgical training.

The College has an interest in the balance of competencies relating to health in two important respects, firstly, as health services in the UK and those of other European countries in which we have Members and Fellows are directly influenced by legislation and policy agreed at the EU level and secondly, in terms of the impacts on surgical outcomes and patient safety that can result from such policies and legislation.

### **Medicines and Devices**

The recent experience in regard to the PIP Breast Implants has evidenced the need for a robust system for ensuring that devices and drugs adhere to strict safety standards. Whatever the balance of competence that is determined, it is important to ensure that where such items are imported for use they meet the same safety standards as those produced within the UK.

### **Public Health**

We do not have any objections to the current position in respect of organs, tissues and cells. In terms of alcohol and tobacco, there are currently policy differentials between the UK Government and those of the devolved nations. Whilst the college does not have a view on the balance of powers in this area, any arrangements must not stifle attempts to reduce harm caused to individuals that is connected to these substances.

### **NHS and Patient Services**

It is difficult to provide evidence of the benefits or dis-benefits of allowing free movement of health care professionals, however, in respect of surgical qualifications, the EU has a role in determining the equivalence across European countries and this in turn impacts on who may or may not practice surgery in the UK. It is important that poorly qualified individuals, who would not meet the usual UK standards, are not able to practice in the UK. Therefore, in considering the balance of competences, there must be clarity over what is considered equivalent and how such equivalence is determined. Robust and integrated UK and EU systems are required involving the GMC and the various specialty and collegiate organisations. In particular the examination methodology employed must be deemed equivalent to determine and confirm individuals who are fit for purpose and fit to practice in the UK.

## Royal College of Veterinary Surgeons

1. The following response is made on behalf of the Royal College of Veterinary Surgeons (RCVS). The RCVS is the regulatory body for veterinary surgeons in the UK. The role of the RCVS is to safeguard the health and welfare of animals committed to veterinary care through the regulation of the educational, ethical and clinical standards of veterinary surgeons and nurses, thereby protecting the interests of those dependent on animals, and assuring public health. It also acts as an impartial source of informed opinion on relevant veterinary matters.
2. The RCVS strongly supports the notion of 'One Health' and that human wellbeing and animal health are very closely linked. This is evidenced by the fact that over 70% of human pathogens originate from animals.
3. This consultation exercise focuses upon competences relating to human health and the regulation of the human healthcare profession. As the regulatory body of the veterinary profession, however, the RCVS considers that human health should not be considered in isolation from animal health or the regulation of the veterinary profession, and that by taking an integrated approach to veterinary and human medicine the prevention and control of diseases would be improved.
4. The RCVS has therefore taken the opportunity to respond to this consultation by highlighting those areas where European legislation impacts upon the way the RCVS regulates veterinary surgeons in the UK. The RCVS has also submitted a version of this response to the Defra Call for Evidence: Animal Health, Welfare and Food Safety Review.

## Mutual Recognition of Professional Qualifications and Language Testing

5. Every year, around half of all new registrants with the RCVS come from overseas and the majority of these are from EU or EEA countries. Due, however, to the way the Mutual Recognition of Professional Qualifications (MRPQ) Directive has been implemented in the UK, the College has no power to test the English language competency of graduates from the EU.
6. On 19 December 2011, the European Commission released its proposals for the revision of the Directive. These proposals appeared to provide healthcare professions with a greater ability to test applicants' language skills in the native language of the receiving Member State, but veterinary regulators appeared not to have a right to check the language skills of all registrants.
7. The RCVS and the Federation of Veterinarians of Europe (FVE) maintain that veterinary surgeons should be considered in the same group as the other healthcare professions and should be afforded the same powers to test language ability. Following discussions between the Department for Business, Innovation and Skills (BIS), Defra and the RCVS, however, BIS has indicated that the provisions which are outlined in the proposed Directive clarify that the Commission would allow case-by-case language testing after recognition of qualification. As the Directive is still subject to a number of amendments, which have not yet been agreed, it is unclear what position will finally be adopted on language testing.
8. Commission officials have also confirmed that, under the current regime, testing could take place on a selective basis where there are concerns about an applicant's language ability. Consequently, BIS has agreed that the guidance originally provided by Defra and other departments may have been too restrictive. BIS has therefore given Defra clearance to work with the College to revise this guidance, so as to provide the RCVS with the ability selectively to test the English language skills of EU registrants where there are serious and concrete doubts about their language ability.

9. During 2012 RCVS representatives met with Defra officials to begin to consider how the guidance could be amended, what sort of protocol the RCVS could apply to identify when an applicant's English skills were not adequate, and the sort of tests that might be implemented.
10. Over the coming months the RCVS will be liaising with Defra and developing proposals for the introduction of a fair and transparent system for the selective testing of the English language competence of EU registrants.

### **Mutual Recognition of Professional Qualifications and Accreditation of Training**

11. Veterinary surgeons, together with other healthcare professionals, are part of the automatic recognition system of professional qualifications throughout the EEA, this means that minimum training requirements have, in theory, been harmonised and veterinary surgeons that trained in one member state are eligible to register as veterinary surgeons in another.
12. The RCVS applies a rigorous methodology to ensure that uniform standards are applied at the seven UK veterinary schools. Elsewhere in Europe, a scheme adopting similar parameters operates under the auspices of the European Association of Establishments for Veterinary Education (EAEVE), but this is essentially a voluntary scheme with no legal basis, and not all EU veterinary schools have been approved by EAEVE. However, the RCVS and other EU regulators are required to register EU graduates even if the school they attended has failed its inspection. Failing such an inspection means that the veterinary degree course concerned does not comply with the Directive's minimum training standards.
13. The proposed new Directive may go some way to improving the situation if it is to require Member States to report at five-yearly intervals on arrangements for initial training. However, it is not clear whether this provision will be included in the new Directive, and, even if it is, there is no explicit provision in the proposals to permit Member States to refuse registration to someone holding a degree which has been found not to comply with the Directive's minimum training standards. The College considers that Member States should be required to report on the ongoing accreditation status of their veterinary qualifications and that the Commission should take action against those found no longer to be complying with the training requirements in the Directive. Recent proposals appear to support the involvement of accreditation bodies in the recognition of new qualifications, but it is not clear what the consequences would be if there was evidence of an existing qualification ceasing to comply.
14. RCVS has commented on proposals for the new Directive, including supporting proposals to strengthen the coverage of public health and food safety in the specification for minimum training requirements. However, there needs to be an equal strengthening of requirements for clinical skills and competence to assure the quality of animal health and welfare training within veterinary schools across the EU. We await the outcome of ongoing deliberations on the Directive on this point.
15. RCVS also welcomes suggestions in the proposed new Directive that ongoing continuing professional development should become mandatory for professionals, although it is not clear yet whether the current proposals include the veterinary profession. RCVS has commented to this effect.

## **Working Time Directive and 24-hour emergency veterinary cover**

16. The RCVS Code of Professional Conduct requires veterinary surgeons in practice to take steps to provide 24-hour emergency first aid and pain relief to animals according to their skills and the specific situation.
17. Providing such 24-hour emergency veterinary care and complying with the Working Time Regulations presents unique difficulties for the profession. If the current understanding of on-call time changes, and a veterinary surgeon on call from home is considered to be working, even when not answering calls, there could be a serious impact on the provision of emergency veterinary care in the UK, with a consequential effect on animal health and welfare. A further issue for the profession is that veterinary surgeons must count time spent sleeping on veterinary premises during on-call periods as 'working time', even on occasions when they may not have been interrupted during these periods or required to undertake any work.
18. The RCVS has concerns that any reduction of the maximum working week could seriously affect the delivery of veterinary services. RCVS survey data suggests that veterinary surgeons only just work within the 48-hour maximum. Furthermore, any changes to the current on-call rules, or reduction in the working week, would seriously affect the cost and practicality of the delivery of veterinary services, particularly as veterinary services are largely provided by a number of small businesses with limited staff resources.

## **Rare diseases**

19. The consultation notes that the 2009 EC Recommendation on Rare Diseases encourages Member States to develop plans to tackle Rare Diseases. The RCVS commends the UK for seeking to develop such a Plan, but notes that it is important to involve the veterinary profession in such planning. This will ensure that potentially zoonotic rare or emerging animal diseases are identified at an early stage and tackled appropriately.
20. If clarification on the above comments is required, please do not hesitate to contact the College. Representatives from the RCVS would be happy to meet with officials to discuss and expand upon this evidence.

## Royal Pharmaceutical Society

The Royal Pharmaceutical Society (RPS) is the new professional body for every pharmacist in Great Britain. We are the only body that represents all sectors of pharmacy in Great Britain.

The RPS leads and supports the development of the pharmacy profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

Its functions and services include:

**Leadership, representation and advocacy:** promoting the status of the pharmacy profession and ensuring that pharmacy's voice is heard by governments, the media and the public.

**Professional development, education and support:** helping pharmacists to advance their careers through professional advancement, career advice and guidance on good practice.

**Professional networking and publications:** creating a series of communication channels to enable pharmacists to discuss areas of common interest.

### General Comments

European legislation encourages a pan European approach to best practice and attempts to provide improved patient and public health outcomes for all citizens of the EU. This approach has addressed issues which would otherwise perhaps not been as high on the UK agenda. Although there are long term benefits to the UK citizens, this can sometimes prove initially disrupting or potentially have financial consequences. Pharmacy systems differ considerably across the member states and there are examples where the EU directive is not a good fit for UK models or practices, raising the potential for disruption to health services and increased risks to patient safety. Examples are provided below.

The RPS has a commitment to make Great Britain one of the safest places to take medicines and will champion advances in patient safety and improved patient outcomes. However apparent lack of stakeholder consultation by the UK regulator and subsequent negotiations at an early stage in proposed EU legislation has sometimes hampered progress. In our response to the recent consultation on the MHRA corporate plan we have requested earlier stakeholder engagement and more transparency to address these issues.

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#### **1. MHRA Consolidation and Review of UK medicines legislation. The EC directive 2011/62/EU**

This is an example of Shared Competencies where it would have been helpful for the UK to adapt the directive to be a better fit with pharmacy practice in the UK.

Section 10 of the Medicines Act traditionally allowed pharmacists to move small amounts of stock (up to 5% of turnover) without the possession of a Wholesale Dealers Licence (WDL) This facilitated supplies to GP surgeries, ships medical rooms, sports clubs, mountain rescue teams, universities, other pharmacies, between hospital sites and other such examples, in the normal course of community pharmacy business.

The amendment of an EC directive removed this exemption, requiring a solution to be found, or for widespread disruption to be caused to healthcare supplies across the UK.

Unfortunately by the time this was addressed by UK regulatory authorities, the opportunity to work with the EU legislators to find a suitable solution that addressed the issue had passed. It is understood that the UK had a period of 18 months to adopt the legislation. Advice was sought from the Royal Pharmaceutical Society and other stakeholder organisations after 14 months had elapsed.

The amount of work required to be undertaken in a very short period of time, following the passing of European legislation, was beyond what should be expected and the only possible outcome partially ameliorated the key issue for the UK. In order to provide continuity of patient care registered pharmacies are now required to purchase WDLs at considerable cost, making many small business transactions financially prohibitive. This has resulted in restriction of movement of medicines, with some pharmacies no longer able to supply their customers and difficulties in obtaining supplies for some organisations.

In this example there was no discernible benefit to pharmacy practice or patient care in the UK to be gained from implementing this aspect of the directive as it stood, and engagement with the EU Institutions before the Directive was published, or engagement with key stakeholders 14 months earlier would have resulted in a Directive that recognises UK practice or a more pragmatic outcome.

## **1. Falsified medicines**

This is another example of where difficulties will be experienced by pharmacists and other stakeholders, due to the perceived reticence of the UK Government to engage fully with all stakeholders.

The wording of the EC directive 2011/62/EC has resulted in differences in interpretation by member states rather than a unified approach to this issue. The adoption of the Directive in the form set out by the MHRA does not recognise current pharmacy practice in the UK. It offers no benefits to those responsible for using the system and it appears there is little potential to police the National IT system the Directive introduces. There appears to be little reason why this Directive will be implemented in this form.

Directive 2011/62/EU has the potential to improve patient safety and reduce the incidence of falsified medicines in the legitimate medicine supply chain – if the spirit of the Directive is followed and it is implemented as fully as other member states.

However, if implemented in the form currently proposed by MHRA stakeholders have given views to the UK Government that there is no incentive or rationale for pharmacists to use the new system.

To date, the UK regulator appears to be unwilling to engage. The result is a reduced period of time to introduce the required systems, which will incur additional cost and resources. It is anticipated that software providers will be required to use additional resource to meet shortened deadlines rather than merge the creation of new software with existing work streams.

The directive will conflict with several current practices in pharmacy, which are interwoven into other pieces of UK legislation and will present pharmacists with conflicting legal frameworks. Currently prescriptions in the UK are not always for original pack quantities and pharmacists frequently split packs to accommodate this. In other member states original pack dispensing is the norm and the EC Directive reflects this.

RPS is fully supportive of the need to recall medicines where there is a risk to patient safety however there are areas where the proposed requirement to recall individual supplies could cause significant disruption to patient care including:

- Hospital pharmacies where medicines are still frequently distributed to individual patients from pharmacy stock, rather than using patient's own supplies.
- People whose medicines are supplied in multi-compartment compliance aids to support medicines adherence. This will include many of the growing care home and frail elderly population.

There is the potential to create a national IT system that is a benefit to those who will use it, in addition to the patients who this legislation seeks to protect.

Engagement with the EU Institutions before the Directive was published, or engagement with key stakeholders earlier would have resulted in a Directive that recognises UK practice or a more pragmatic outcome.

## **2. Free Movement of Persons. The Directive 2005/36/EC of the European Parliament and Council; The Professional Qualifications directive.**

The directive has enabled the free movement of pharmacists between EU member states despite professional activities being quite different across the EU. For instance, in the UK, pharmacists deliver additional activities above the limited list of authorised activities described in the Directive. Thus, the current role of the pharmacist in the UK is much wider than that described in the directive and therefore compared to other healthcare professions such as medicine and dentistry, the impact of free movement has been limited for pharmacy.

An analysis of the General Pharmaceutical Council's (GPhC) register of pharmacists indicated that of the 46,310 pharmacists (in England, Scotland and Wales), 5,460 qualified overseas (11.8%) and of these, about half (49.5%) entered via the European route.

The impact of the free movement of pharmacists between EU member states can also be assessed from the GPhC register of pharmacists in 2011. In 2011, there were 3,526 new entrants to the register, 791 of these (22.4%) qualified overseas and 517 of the new registrants (65.4%) came from Europe.

RPS responded to the consultation on this directive to highlight the omission of the need for language testing in some instances when employing health professionals from the EU. This can have serious patient safety measures. There appears to be an anomaly between qualified professionals with English as a first language from outside the EU who must negotiate many steps before practicing in the UK and EU nationals whose English can present safety issues but who in theory have no barrier to practicing.

## **3. Pharmacovigilance Transposition of Pharmacovigilance Directive 2010/84/EU**

The Pharmacovigilance Directive is an example of where EU directives have been very effective in streamlining practice across the EU, minimising the bureaucratic burden and improving patient safety overall.

The new black symbol proposals build on the established UK black triangle reporting principles but extend these European wide to streamline and widen the breadth of the response,

giving speedier access to patient safety information. It also extends the scope by introducing risk management plans for individual medicines, for reporting to include adverse reactions caused by errors and to highlight important safety warnings on high risk drugs.

#### **4. EU Proposal for a clinical trial regulation**

These proposals aim at reducing administrative burden and streamlining the application process for clinical trial regulatory and ethical approval by introducing a single process European wide. This would enable faster recruitment of patients EU wide and could speed up clinical trial results with resulting improved patient outcomes and earlier detection of adverse events. Presently a similar process must be carried out in each member state where the trials are taking place resulting in an unnecessary bureaucratic load with no additional patient benefits. These proposals should be supported to encourage more UK participation in European wide clinical trials.

## Royal Society for Public Health

We are sure that our work at the RSPH is influenced by EU competencies, and can provide examples of areas of our work where this influence is likely to be present, for example, our role in developing the European Professional Standards for Health Promotion Capacity (CompPH project) and our presence on the board of the International Union for Health Promotion and Education (IUHPE) based in Paris. It is likely that in developing our qualifications in food safety and health and safety, we are complying with legislation that originally derived from beyond the UK.

However, to what extent our work is limited or supported by EU competencies is not clear to us – we are unable to provide a clear cut example of an EU competency affecting our work. It may be that public health in the UK is a sector largely influenced by UK rather than EU policy, or that EU competencies are hidden within UK legislation and policy (for example, it is not clear how EU legislation influences NICE guidelines – although we assume this does occur).

This is a gap in our knowledge and understanding of the EU policy context that we would like to address.

## Royal Surrey County Hospital Foundation Trust

1. It is very difficult to enforce EU rules. It is not essential for Trusts to obtain a patient's EHIC as the Trust (at present) is paid by the PCT anyway, with or without EHICs.
2. As DWP reporting portal is only "voluntary" many trusts don't report, therefore losing money into NHS pot.
3. Prescriptions for EU citizens, I would recommend as being private. Most EU citizens in my opinion receive medication free of charge.
4. The fact and EU citizen can live and work in the UK thus entitling his family/dependants to a UK EHIC is a huge cost to the NHS
5. I would say 90% of citizens from the EU seeking healthcare know the rules and bed them accordingly.
6. We do need some sort of identification system for those entitled to free NHS care. I think the majority of British citizens would accept this form of identification (to protect the NHS) – first step to full ID cards possibly?
7. Cross border health care and the obtaining of S2s for patient does not work well. The Republic of Ireland have a really good system but in my experience when British citizens request treatment in the UK, they are usually refused by the authority in the country they are living in.

## Royal Wolverhampton Hospitals NHS Trust

The UK has enormous *potential* advantages when negotiating within the EU

Population and GDP relative to many Member States

English language

Role in World War 2

Talent for Administration

Leading role in NATO and the UN

Global networks through the Commonwealth

Unfortunately in recent years successive Governments have weakened the UK negotiating position within the EU.

Gordon Brown, when Prime Minister, deliberately arrived several hours after all the other Prime Ministers had signed the *Lisbon Treaty*. He chose instead to delay travelling so he could attend an *elective* meeting in Westminster with Chairmen of Commons Select Committees ....a decision that did not impress other Member States, and was remembered.

Inexplicably, for a country whose patients frequently have their imaging reported by teleradiologists abroad, both Labour and Coalition Governments consistently opposed inclusion of telemedicine regulation during the 3 year parliamentary passage of the *EU Directive on the application of patients' rights in cross-border healthcare* into law 2011.

The European Parliament has 754 Members representing 500 million citizens in the world's largest economy. Maximum impact is achieved by working closely with other similar minded parties. In the case of the Conservative Party, the natural allies would be the Christian Democrats. The grouping of these type of parties within the European Parliament is the European Peoples Party [EPP]. This block contains the government parties in many Member States including Germany, Spain, Sweden and up until recently France and Italy. The EPP Group has 270 members.

Unfortunately, and to the bafflement of leaders like Angela Merkel and Nicholas Sarkozy, the Conservative Party left the EPP Group in 2009.... to join a tiny grouping of 27 other MEPs representing fringe parties in small Member States. This greatly weakened the influence of the Conservative Party in the European Parliament and as a result the subsequent UK negotiating position of the Coalition Government.

Last year, the UK legal competence in running the NHS was weakened, not in Brussels- but in London, by the passage into law of the *Health and Social Care Act*. This removed the legal protection the NHS had as a State Service and as the authors below concluded "*further opens up the NHS to EU Competition Law*".

*Reference:*

*R Dumbar Reece, R M C Gough. Challenges of EU Competition Law for General Practice Commissioning. British Medical Journal 2011: 342: 852-854.*

The 2012 Nobel Peace Prize was awarded to the European Union, because, *"for over six decades it has contributed to the advancement of peace and reconciliation, democracy and human rights in Europe"*.

In a calculated snub, David Cameron was the only EU Prime Minister to be absent from the 2012 Nobel Peace Prize Award Ceremony. This act was a gross offence to hundreds of millions of our neighbours and major trading partners, and will not be forgotten.

The commitment by the Prime Minister to hold an in / out referendum in 2018 on UK membership of the EU is yet another self-inflicted weakening of the UK negotiating position within the EU.....potentially for five years, as well as a widely condemned disincentive to inward investment.

Micheal Heseltine wrote of that referendum commitment *"To commit to a referendum about a negotiation that hasn't begun, on a timescale you cannot predict, on an outcome that's unknown, where Britain's appeal as an inward investment market would be the centre of the debate, seems to me like an unnecessary gamble"*

*"Why put your factory in Britain when you don't know, -and they can't tell you, the terms upon which you will trade with us in the future?"*

It typically takes at least 3 years for legislation to be drafted and proposed by the European Commission and then pass through various stages in the European Parliament and be approved by Governments of Member States. This is followed by a further 2 or 3 years before implementation in Member States.

The recent commitment to an in/out UK referendum in 2018 , if the Conservatives are elected to Government, means that EU legislation introduced henceforth may not apply in the UK if we ceases our membership of the EU in 5 years. That backdrop is another weakening of Britain's influence in the EU

This Review of Competences is yet another example of self-inflicted UK weakening its influence in the EU by engaging in exceptionism rather than being constructive.

All the other 26 Member States could engage in such a review of the balance of competences. They don't because they look forward , not back.

This Review of Competences , added to all the other own goals described above, risks setting Britain on a path towards exit of the EU which would have immediate and catastrophic effects on the UK economy and our future lives.

The family and friends test is rightly held up as a good way of assessing whether a particular health service is satisfactory.

I personally would not wish myself, family or friends to be treated by healthcare professionals who had not had 11 hours rest in the previous 24 hours and/or who did not have a day off in the previous week.

Seeking to achieve a UK opt out from the European Working Time Directive would be deleterious for patients as well as the occupational health of employees.

I consider the Balance of Competences between the EU and its Member States to be satisfactory.

## Safety of Bloods, Tissues and Organs

The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) advises UK Ministers and Health Departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs used in transfusion, transplantation and other forms of treatment. SaBTO members include clinical experts in all these areas, as well as others with more general and complementary expertise.

There are EU Directives governing all the areas in SaBTO's remit: the Directives on Blood and Blood Components, the Tissues and Cells Directives and the more recent Organ Donation and Transplantation Directive. All have been transposed into UK law. There are also other EU Directives which have an impact on these areas, such as the Medicines Directive.

Members have raised a number of points in response to the Department of Health's Call for Evidence for the EU Balance of Competence Review, based on their experience in the NHS, which are summarised here.

The Directives set minimum standards of safety and quality, and in general, Members welcome the effects they have had in raising standards. For example, the traceability of blood and blood components is greater; many laboratory facilities were improved, and some variable practice in the field of tissues was ended. Members note, however, the significant effort and cost required both to meet standards initially and to demonstrate continued compliance with the regulations. Overall, they consider the benefit has been limited in the UK, because there was already excellent practice in most areas, particularly in organ donation and transplantation, and good regulatory systems in many.

The assurance of minimum standards as a result of the Directives has meant patients can have greater confidence in their treatment, and has also facilitated the importation of safe treatments; for example, in several clinical situations UK patients receive commercially produced solvent detergent treated plasma in preference to fresh frozen plasma; voluntary unrelated donor haemopoietic stem cells are imported, and cell based treatments not available in the UK can be imported for named patients. Hospitals have the opportunity to benefit from an EU wide supply chain.

The free movement of substances across Europe has not, however, been achieved to the degree intended. Variations in the way different Member States interpret the Directives' requirements, or have transposed the Directives into national law, have created barriers and complexities. For example, tissues including gametes and embryos can only be imported into the UK if they have been collected in accordance with the requirements of UK legislation. Some countries have developed mutually acceptable service level agreements with common standards, and this works well for 'standard' tissues, but problems remain for bespoke tissues and cells.

In a number of areas, Members consider the UK has 'gold-plated' EU requirements, which has increased the regulatory burden on UK health services, potentially offering a commercial advantage to some European producers. For example, premises providing tissues for research need to be licensed in England, but not in Scotland; and the licensing of organ retrieval and transplant units is not required by the Directive.

Members have noted other areas which do not fall wholly within the scope of the Directives, where national differences in regulation produce similar difficulties. For example, co-operation between different EU based laboratories on some cellular therapies, including advanced therapy medicinal products (ATMPs), is very difficult. This is problematic as ATMPs are often produced to treat small, specific patient groups, and multi-centre trials are particularly important.

In the case of reproductive medicine, variation in the treatments available in different Member States arises from differences in belief, reflected in national legislation, rather than from varying regulatory requirements. This has given rise to 'reproductive tourism', in which financially mobile couples travel to the country that can provide the treatment they need, such as egg donation.

National variation is also considered appropriate for donor selection criteria. The work carried out recently by SaBTO which led to amendment of the criteria relating to men who have sex with men illustrated that such criteria need to be evidence-based, and much of the evidence is country-specific.

Members would welcome greater consistency in testing. Infectious risk from known and emerging infectious agents varies between EU Member States, and testing is not uniform across the EU. Even within the UK, most tissues are tested for HTLV, but not all. The use of imported blood and tissue therefore requires vigilance, education and research in the UK and across the EU if risks to patients are to be properly managed.

Amendment of the Directives, by consensus, is a lengthy and complicated process. This creates problems when the Directives include detailed specifications, such as the Technical Appendices of the Blood Directives, which need to be updated in response to new evidence or other changes. Members consider an alternative, more streamlined decision-making process is needed, or the detailed specifications should be set at national level. By comparison, the process for market authorisation of ATMPs, facilitated by EU regulation, is streamlined.

Some of the benefits of the EU Directives reported by Members arise indirectly. For example, the Directives have encouraged and facilitated closer working and co-operation between UK and European colleagues, which tends to improve clinical practice. Up to date information is also shared between European countries on the incidence of new and emerging infections, supporting the surveillance role of UK organisations such as the Health Protection Agency and strengthening the evidence base for measures to combat potential infection risks such as donor deferral or the testing of donations. For example, SaBTO has recently been updated on the testing by NHS Blood and Transplant of blood donated by people returning from areas affected by West Nile Virus. This was introduced as an alternative to deferring them from donating, to avoid any impact on the blood supply. Decisions by the blood services in Wales, Scotland and

Northern Ireland on whether to test donations or defer donors, ahead of the 2013 West Nile Virus season, will be informed by epidemiological information from across Europe.

SaBTO Members also feel the focus on safety issues has been beneficial, reinforcing the importance of maintaining consistently high standards, and has attracted funding to ensure compliance which has helped improve services.

Despite the problems and reservations noted, overall SaBTO Members have welcomed the EU Directives, and the improvements in safety and quality driven by them.

## Scotch Whisky Association

The Scotch Whisky Association (SWA) welcomes the opportunity to provide input to the UK government's Balance of Competences review.

The SWA is the industry's officially recognised representative body, responsible for protecting and promoting Scotch Whisky both at home and abroad. The Association's members export to over 200 markets worldwide; in 2011 industry exports were worth £4.23 billion, representing nearly 25% of all UK food and drink exports. (With member companies also owning the import and sales teams in many overseas markets, the real value to the industry and UK plc is far higher.)

Sales of Scotch Whisky within the 27 EU Member States totalled more than half a billion bottles, or about 42% of the industry's volumes. The EU is vital to the industry's long term sustainability, both as an internal market and as a strong voice in international trade negotiations.

The trade environment within the EU internal market, in which one set of common rules applies, is immeasurably simpler than the alternative in which 27 different regulatory regimes would operate. The EU rules, agreed with considerable and very helpful input from UK officials and MEPs, impact on almost every facet of trade in Scotch Whisky. These include: spirits definitions; protection of 'geographical indications' (such as Scotch Whisky); labelling; taxation; a standardised range of bottle sizes; holding and movement of excisable products; and environmental issues.

While the internal market is not perfect, the existing arrangements permit the UK Government to help shape the rules which govern it; they also greatly facilitate the resolution of problems arising from the inappropriate application of EU rules. Securing and maintaining an optimal trading environment requires a strong UK presence when legislation is being prepared or amended.

The influence of the EU extends well beyond the single market. The Commission, again with considerable input from UK officials, has been a strong and effective supporter of the industry's wider interests in international trade negotiations whether at the multilateral, regional or bilateral level. It has also successfully secured the removal of tax and other discrimination against Scotch Whisky in third countries using the World Trade Organisation's dispute settlement mechanism. As the world's foremost internationally traded spirit drink, Scotch Whisky derives enormous benefit from the EU's expertise and negotiating muscle in the areas of trade policy and market access globally.

Consequently, the SWA is a strong supporter of maintaining the UK's active involvement within the EU. In the fields of internal market regulatory harmonisation and international trade policy, we see no issues which require subsidiarity or to be repatriated to national level.

The section below provides SWA views on the consultation questions of most relevance to our sector.

### **Impact on the National Interest**

#### **What evidence is there that EU action in health advantages or disadvantages the UK national interest.**

Our comments relate specifically to the issue of tackling alcohol misuse.

- We very much welcomed and support the EU strategy to support Member States in reducing alcohol related harm. It is focussed on delivering support to tackle harmful and hazardous consumption. One of the supporting pillars of the strategy is the EU Alcohol and Health Forum. The SWA has been a member of the Forum since its inception. Forum members commit to taking concrete action to address alcohol related harm. Shared learning across the EU through reports to the Forum can be an aid to encouraging partnership working.
- In designing measures to tackle alcohol misuse it is very important to ensure that cultural and national circumstances are taken into consideration. There is no 'one size

fits all' approach. Alcohol misuse needs to be tackled at national level, while ensuring measures developed maintain proper regard for international treaty obligations and do not stray into unevidenced measures such as minimum unit pricing which has consistently been ruled illegal in the EU.

- The industry both at national and EU level has called for the Alcohol Strategy to be renewed on the same basis as the current strategy and with the same objectives. The Commission has stated the current strategy will continue as is. We are still awaiting the report into the EU strategy and its implementation. Indications given at the November 2012 meeting of the Alcohol and Health Forum were that the Forum had contributed to mobilising action to reduce alcohol related harm. It has shown what can be achieved through voluntary approaches and partnership working.
- Successfully tackling alcohol misuse cannot be achieved through legislation alone. Voluntary and co-regulatory/self-regulatory approaches are important, as recognised in the UK through initiatives, such as, the Responsibility Deal and advertising controls.

### **Future options**

- We believe that when it comes to tackling alcohol misuse the issue of subsidiarity and proportionality is vitally important. It is not an issue to be addressed at EU level; it is very much an issue for Member States to tackle.
- The current role of the EU in supporting Member States is the correct approach.
- If the EU was to be given more powers in this area we believe that could be contrary to the UK interest as it may lead to the imposition of measures which may not be relevant to the UK context. National policy development permits a holistic approach that considers wider government objectives such as growth and investment and can thus avoid overly restrictive policies that have failed elsewhere being adopted to the detriment of the alcohol industry and the jobs across the supply chain that depend upon it
- Action to reduce the harmful use of alcohol is addressed at international level through the WHO's Global Alcohol Strategy. We support this strategy as it sets out a menu of policy options for consideration as appropriate at national level, taking into account national circumstances, such as religious and cultural contexts and national priorities.

### **Conclusion**

The SWA firmly believes the UK's EU membership and the Single market in particular have provided significant benefits for Scotch Whisky. We support the current status quo in this area in terms of the current balance of competences.

**How has the scope of the EU competence for this policy area changed over time?**

Over the last ten years the EU agenda for eHealth has been similar to that of Scotland. The EU's first eHealth Action Plan was adopted in 2004, and it set out a plan to encourage the widespread adoption of information and communication technologies (ICT) in the healthcare sector by 2010. A new action plan was agreed and published in 2012. This second eHealth Action Plan is for the period 2012-2020 and the emphasis is now on the aging populations and the ability to provide services for them when the work-age population is decreasing. eHealth is now seen as key to managing provision of services to patients, focussed on telehealth and telemedicine and use of m-health (mobile health) technologies. The action plan is particularly concerned with cross-border activities. It is more focussed on the barriers to eHealth and its actions include work to devise guidelines on a dataset for patient summary records to be exchanged across borders; recommendations on legal aspects of interoperability; and areas of further research.

**How have the legislative procedures for adopting measures under the Treaties changed (e.g. a move from consultation to co-decision, or a move from unanimity to Qualified Majority Voting) for this policy area?**

N/A

Does the UK enjoys any special status under the Treaties in respect of this policy area?

No

**Why is EU-level action most appropriate (rather than e.g. UN/G20 or national/ regional level) for this policy area?**

The health services across the EU have more similarities than those of countries outside the EU and therefore support for collaboration across European borders can lead to significant benefits.

**How does EU action in this policy area advantage the UK?**

Organisations in Scotland benefit from, and are actively engaged in, European eHealth activities. For example

- The Commission launched its European Innovation Partnership for Active and Healthy Ageing (EIPAH) in 2011. This is a flagship development and has clear synergies with Scotland's priorities for 2020 with regard to telehealth/care. The Scottish Government has been working directly with the European Commission in the development and design of the partnership.
- Three regions within Scotland (Ayrshire, Renfrewshire and Lanarkshire) are involved in the European United4Health Project to support the management of Long Term Health Conditions, which is part of the European Smart Care Project to support the redesign of integrated care pathways.

- eHealth Division is supporting the work of the European SUSTAINS project which provides citizen access to their own health information.
- Scotland will host the first European Telemedicine Congress conference in Edinburgh in October.
- NHS Scotland (via NHS 24) has committed itself to 5 out of 6 of the current EIP on AHA (European Innovation Partnerships on Active and Healthy Ageing) action groups, including acting as coordinator of the largest action group (B3 Integrated Care).
- NHS 24 represents Scotland in five ongoing project and programmes: United4Health (telehealth deployment at large scale in long term conditions); SmartCare (pathways for improved integrated care); Momentum and CASA (thematic networks); and Advanced Care Coordination and Telehealth (identifying the best in organisational, patient and staff practices to enhance sustainability).

Funded initiatives such as the Sustains project on supporting users to access health information, do help countries to improve services but many European countries have significant problems with infrastructure and need to build/renew/develop this before achieving the longer term eHealth aims of the EU.

The added value for Scotland lies in the:

- sharing of experiences and best practices across European regions and institutions
- pooling of efforts and resources to address pan-European challenges and possibilities - while taking in to account and allowing for local differences in provision of health and social care
- establishment of new partnerships to advance development, innovation and research.

### **How does EU action in this policy area disadvantage the UK?**

EU action in this area does not disadvantage Scotland and the UK.

### **What future challenges might we face in this policy area and what impact might challenges have on the balance of competences?**

From 2013 the Commission will engage in discussions on legal issues on cross—border interoperability affecting eHealth. It is not yet known how this might impact on the balance of competencies.

What are the main EU Treaty articles (what they mean in terms of the split of competences between the UK and EU); the key European Court of Justice case law and the major pieces of legislation applicable to this policy area?

There is a considerable amount of legislation that effects this area, but none specifically targeted at eHealth. The main pieces of legislation include:

- Data Protection Directive
- E-commerce Directive
- Medical Devices Directive

- Directive on distance contracting
- Directive on electronic signatures
- Competition law

The EU policy direction falls under the e-Europe initiative and the eHealth Action Plans, the latest of which was published in 2012.

**Have your team been involved in any stakeholder engagement or stakeholder events related to the Balance of Competences?**

No

**Are you aware of any of your stakeholders being involved in consultations, events or other activities organised by the UK Government?**

Yes – NHS24 are aware of the call for evidence, but did not, as far as we are aware, submit a response. Information from NHS24 has been included in this response.

**HEALTH AND MEDICINES AND MEDICAL DEVICES**

**How has the scope of the EU competence for this policy area changed over time?**

The health of the people of Scotland and the medicines available to them is of special importance. Scope has developed over time to ensure more coordinated and consistent arrangements are in place across EU member states for dealing with licencing of medicines, safety issues and supply issues.

**How have the legislative procedures for adopting measures under the Treaties changed (e.g. a move from consultation to co-decision, or a move from unanimity to Qualified Majority Voting) for this policy area?**

Medicines is a reserved area with the Medicines and Healthcare products Regulatory Agency (MHRA), a NDPB of Department of Health representing all 4 countries,

Having the lead role. MHRA have representatives who attend EU committees and then apply in the UK. Our understanding is that the process works well but is often a majority decision which can at times have a negative impact on UK/Scottish policy.

**Does the UK enjoy any special status under the Treaties in respect of this policy area?**

No.

**Why is EU-level action most appropriate (rather than e.g. UN/G20 or national/ regional level) for this policy area?**

It helps to ensure consistency and continuity in licencing and supply of medicines across all member states.

### **How does EU action in this policy area advantage the UK?**

It opens up access to medicines in the UK which may otherwise not be available if, for example, the medicine was produced and only licensed in a single member state.

### **How does EU action in this policy area disadvantage the UK?**

EU decisions can on occasion cut across UK policy. For example not all member State processes are as advanced and EU decisions can create difficulties in terms of safety with the “cross border” flow of medicines.

### **What future challenges might we face in this policy area and what impact might challenges have on the balance of competences?**

Future challenges include ensuring that EU Directives offer some flexibility but are also applied consistently across the EU and are not misinterpreted in some countries. Continuing to increase input/involvement in decision making process is also highly important.

### **What are the main EU Treaty articles (what they mean in terms of the split of competences between the UK and EU); the key European Court of Justice case law and the major pieces of legislation applicable to this policy area?**

The Medicines Act 1968 and the Human Medicines Regulations 2012 which are reserved.

### **Have your team been involved in any stakeholder engagement or stakeholder events related to the Balance of Competences?**

Yes. Attended the Balance of Competence Review workshop held in London on 5 February 2013.

### **Are you aware of any of your stakeholders being involved in consultations, events or other activities organised by the UK Government?**

Stakeholders were given the opportunity to attend the workshop. Not aware of any separate engagement.

## **HEALTH POLICY RESPONSIBILITIES**

### **How has the scope of the EU competence for this policy area changed over time?**

The FSA in Scotland is responsible for several areas of EU legislation under the health remit and the labelling of products caught by this regulation e.g. information on allergens and nutrition content, food supplements, vitamins & minerals, foods for particular nutritional uses (Parnuts), nutrition & health claims etc.

In recent years there has been a shift from Directives – requiring implementation in national law, to Regulations – which are directly applicable in all Member States.

**How have the legislative procedures for adopting measures under the Treaties changed (e.g. a move from consultation to co-decision, or a move from unanimity to Qualified Majority Voting) for this policy area?**

None that we are aware of, although in order to ensure the uniform implementation of the new Parnuts Regulation (due to be published shortly, the Commission may adopt implementing acts to decide:

- whether or not a given food falls within the scope of this Regulation;
- to which specific category a given food belongs.

**Does the UK enjoys any special status under the Treaties in respect of this policy area?**

None known.

**Why is EU-level action most appropriate (rather than e.g. UN/G20 or national/ regional level) for this policy area?**

Most food legislation, including that which sits under the health remit, is set at European level in the form of a Directive, or (more commonly these days) a Regulation which is directly applicable in all Member States. The reason why most food legislation is set at EU level is due to the fact that the sale and marketing of food is subject to the Treaty of Rome which introduced the concept of the single market in order to minimise trade barriers within the EU.

This is also important for the food industry in the UK, and thus the UK economy, as having controls set at a European level is advantageous in terms of minimising burdens on business and facilitating growth.

Nevertheless, it allows for local determination in respect of the execution and enforcement, so for example, penalties and offences can be set under the wider justice policy context of individual member states.

**How does EU action in this policy area advantage the UK?**

Consistent legislation across the EU, providing businesses with a level playing field, harmonisation of statutory requirements. The fact that food is traded internationally, both within Europe and wider impacts on where competence to make legislation is best placed. This impacts on considerations in relation to business needs and on consumer protection.

**How does EU action in this policy area disadvantage the UK?**

None identified.

**What future challenges might we face in this policy area and what impact might challenges have on the balance of competences?**

What are the main EU Treaty articles (what they mean in terms of the split of competences between the UK and EU); the key European Court of Justice case law and the major pieces of legislation applicable to this policy area?

Treaty of Rome (establishing the Single Market), Lisbon Treaty etc

**Have your team been involved in any stakeholder engagement or stakeholder events related to the Balance of Competences?**

No

**Are you aware of any of your stakeholders being involved in consultations, events or other activities organised by the UK Government?**

In terms of the 'Animal Health & Welfare and Food Safety' aspects of this review, the FSA held a stakeholder event in Scotland with industry and enforcement bodies with regards to the Defra/FSA competency review.

**How has the scope of the EU competence for this policy area changed over time?**

EU has been interested in combatting threat of antimicrobial resistance for some time. Successive presidencies have taken this on as a key area and if anything there is increased interest. However, a European parliament (2009-2014) committee report on the environment, public health and food safety in 2012 was very critical of member states' progress in implementing Council conclusions and indeed in Council progress in this area.

The European Centre for Disease Prevention and Control (ECDC) was established in 2005 and is first body with a remit of a coordinated approach to health protection (inclusive of HAI and AMR) across Europe.

**How have the legislative procedures for adopting measures under the Treaties changed (e.g. a move from consultation to co-decision, or a move from unanimity to Qualified Majority Voting) for this policy area?**

We don't know the answer to this. Much of our work is not specifically related to legislation.

**Does the UK enjoys any special status under the Treaties in respect of this policy area?**

We are not aware of any special status. The national focal point for ECDC is the Department of Health (DH) and the Health Protection Agency (HPA) (which will become part of Public Health England from April 2013).

**Why is EU-level action most appropriate (rather than e.g. UN/G20 or national/ regional level) for this policy area?**

Microbes and infections do not respect national or administrative boundaries (as evidenced by, for example, the rapid spread of pandemic swine flu in 2009 from Mexico to first European cases diagnosed in Scotland, or the spread of highly resistant NDM-1 carbapenemases from India to the UK).

Action to control and prevent these infections requires a multinational coordinated response.

EU-level action is also advised by/works closely with WHO Europe.

**How does EU action in this policy area advantage the UK?**

Because of the propensity of microbes and particular concern around those which carry selective antimicrobial resistance to cross international boundaries it is essential that EU countries work together.

A particular current area of AMR policy action intended to curtail the ready sales of antibiotics to the public, especially in southern European countries such as Spain, will have direct benefit in decreasing global consequent AMR and in spread to the UK.

The EU Transatlantic Task Force on Antimicrobial Resistance (TATFAR), set up to combat this threat and to encourage development of new antibiotics, could be particularly helpful in this regard.

**How does EU action in this policy area disadvantage the UK?**

We are not aware of anything although delivery of TATFAR objectives has been slow.

**What future challenges might we face in this policy area and what impact might challenges have on the balance of competences?**

The continuing spread of AMR, especially from Asia.

**What are the main EU Treaty articles (what they mean in terms of the split of competences between the UK and EU); the key European Court of Justice case law and the major pieces of legislation applicable to this policy area?**

We are not aware of any. However, EU legislation on sharps will be implemented 11 May 2013 through Health and Safety Executive legislation.

**Have your team been involved in any stakeholder engagement or stakeholder events related to the Balance of Competences?**

No.

**Are you aware of any of your stakeholders being involved in consultations, events or other activities organised by the UK Government?**

Health Protection Scotland (HPS) may respond to the consultation direct.

**INTERNAL MARKET**

**How has the scope of the EU competence for this policy area changed over time?**

The details of changes to the scope of EU competence are laid out in the consultation paper that accompanied this request and I wouldn't think it necessary to detail them here.

**How have the legislative procedures for adopting measures under the Treaties changed (e.g. a move from consultation to co-decision, or a move from unanimity to Qualified Majority Voting) for this policy area?**

Single European Act 1986 moved from unanimous to qualified majority voting.

**Does the UK enjoys any special status under the Treaties in respect of this policy area?**

The UK has an opt out of the Schengen agreement on free movement of persons. Colleagues in International Division will be able to provide lines on this.

**Why is EU-level action most appropriate (rather than e.g. UN/G20 or national/ regional level) for this policy area?**

Only the EU can legislate on an EU-wide internal market.

**How does EU action in this policy area advantage the UK?**

Para 11 of the UK paper sets out the advantages. There is no obvious Scottish dimension to this.

**How does EU action in this policy area disadvantage the UK?**

Other than the need to trade off some autonomy against the benefits of an internal market – nothing.

**What future challenges might we face in this policy area and what impact might challenges have on the balance of competences?**

Whether an independent Scotland would want to, or be able to, opt out of Schengen. See above.

**What are the main EU Treaty articles (what they mean in terms of the split of competences between the UK and EU); the key European Court of Justice case law and the major pieces of legislation applicable to this policy area?**

See the UK paper.

**Have your team been involved in any stakeholder engagement or stakeholder events related to the Balance of Competences?**

No.

**Are you aware of any of your stakeholders being involved in consultations, events or other activities organised by the UK Government?**

No.

## **INTERNATIONAL DEVELOPMENT**

### **How has the scope of the EU competence for this policy area changed over time?**

Growth in both scope and competence. Development cooperation is a shared competence between the EU and the Member States, with EU development policy undertaken as complementary to the policies pursued by the Member States.

The EU is the largest global Official Development Assistance (ODA) donor, accounting for the half of the total ODA to developing countries and funding work in 150 countries.

The Lisbon treaty was significant in establishing the European External Action Service (EEAS). In addition EU action in the field of development policy is also based on the European Consensus on Development, signed on 20 December 2005, by EU Member States, the Council, the European Parliament and the European Commission agreeing a common EU vision of development.

Within the European Commission, EuropeAid is the Directorate-General responsible for formulating and implementing EU development policy. EuropeAid works together with the European External Action Service to finance allocations and strategy papers by country and by region, as well as national and regional programmes.

### **How have the legislative procedures for adopting measures under the Treaties changed (e.g. a move from consultation to co-decision, or a move from unanimity to Qualified Majority Voting) for this policy area?**

Increased focus and attention on multilateral level agreements, including outcome of the Busan High Level Forum on Aid Effectiveness as well as MDG review and follow up to commitments made at Rio as well as UN target of 0.7% of GNI spent on ODA, which EU aim to achieve in 2015.

### **Does the UK enjoys any special status under the Treaties in respect of this policy area?**

No – Scottish, UK governments and EU Commission have a commitment to maintain development spending within reduced budgets.

### **Why is EU-level action most appropriate (rather than e.g. UN/G20 or national/ regional level) for this policy area?**

EU development policy seeks to be complementary to work undertaken by member states, however the scale of the resources EU is able to mobilise in comparison to individual members states is significantly enhanced, both in budgetary terms, for example in response to addressing the aid gap for newly established South Sudan, as well as drawing on specific expertise from within members states.

The scale of funding offered through the EU development programmes is also able to effectively fund work in many developing countries to support and enable development work to be undertaken across borders to achieve a regional level outcomes. Impact maternal health project based in Aberdeen University is one positive example of regional level engagement in

southern Africa made possible by the range of countries funded through EU and including Scottish Government development grant to fund work of the project in Malawi.

### **How does EU action in this policy area advantage the UK?**

EU development funding offers source of funding to support development work for UK NGOs in addition to funding provided through aid budgets in UK and access to EU funding for UK in effect provides for further funding options and combinations to UK based NGOs.

### **How does EU action in this policy area disadvantage the UK?**

No disadvantage.

### **What future challenges might we face in this policy area and what impact might challenges have on the balance of competences?**

2011 was the first year that total global aid spending decreased in real terms. While the EU has looked to maintain aid budgets the impact of the economic downturn could provide basis for challenge to this position.

What are the main EU Treaty articles (what they mean in terms of the split of competences between the UK and EU); the key European Court of Justice case law and the major pieces of legislation applicable to this policy area?

Development cooperation is based on Articles 177 to 181 of the Treaty of the European Community.

The basis for the External Action Service is set out in article 13a-III of the Treaty of Lisbon.

Cotonou Agreement providing basis for ACP cooperation (African, Caribbean and Pacific states) was signed in June 2000 (revised in 2005 and 2010).

The European Consensus on Development, signed on 20 December 2005, by EU Member States, the Council, the European Parliament and the European Commission outlines approach to international development.

### **Have your team been involved in any stakeholder engagement or stakeholder events related to the Balance of Competences?**

Attended an initial briefing on the Balance of Competences review given by Whitehall leads on visit to Scottish Government on 24 September, 2012.

### **Are you aware of any of your stakeholders being involved in consultations, events or other activities organised by the UK Government?**

No, not aware of any consultation being undertaken with the development sector in Scotland, either directly or through umbrella organisations.

## **MEDICAL DEVICES**

### **How has the scope of the EU competence for this policy area changed over time?**

The scope of EU legislation has not changed in recent years, however, EU legislation on devices is being revised to include all devices implanted within the human body for either medical or cosmetic purposes. This is vital in the light of learning from the breast and metal on metal hip implants events.

DH & the Medicines and Healthcare products Regulatory Agency (MHRA) are in the lead and provide both the legislative and non legislative initiatives. NHSScotland supports the work on the safety of medical devices through a range of mechanisms including the work of the Incident Reporting and Investigative Centre (IRIC)

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric>  
at Health Facilities Scotland

### **How have the legislative procedures for adopting measures under the Treaties changed (e.g. a move from consultation to co-decision, or a move from unanimity to Qualified Majority Voting) for this policy area?**

Not known.

### **Does the UK enjoys any special status under the Treaties in respect of this policy area?**

No, however, UK is regarded as having one of the stronger competent authorities in the EU (Medical and Healthcare products Regulatory Authority).

### **Why is EU-level action most appropriate (rather than e.g. UN/G20 or national/ regional level) for this policy area?**

Medical devices are extremely important in the NHS – one NHS Board probably has 15,000 in use at any one time and having agreed EU standards is necessary both for ensuring safe healthcare provision and improving the market opportunities for Scottish companies.

### **How does EU action in this policy area advantage the UK?**

There is no particular advantage for the UK, however, it allows the UK to participate in a wider market which works to a common approach on the regulation of medical devices.

EU regulation support the UK in ensuring medical devices sold within the UK are regulated appropriately and where there are issues identified, appropriate action can be taken by the appropriate competent authority.

### **How does EU action in this policy area disadvantage the UK?**

It does not.

### **What future challenges might we face in this policy area and what impact might challenges have on the balance of competences?**

Following recent medical device issues there is increased demand for additional scrutiny and safety but also more pressure on the regulatory framework as more products become available and more markets open up.

Ensuring the NHS Scotland gets the best value for money and choices and that patients are informed and served reliably including when items need to be recalled are all challenges.

Supporting local investigations and referrals of problems in non-adversarial terms are equally important as is the need to ensure the volume of potential problems is recorded and interrogated so longer term and sometimes subtle problems can be found and managed.

**What are the main EU Treaty articles (what they mean in terms of the split of competences between the UK and EU); the key European Court of Justice case law and the major pieces of legislation applicable to this policy area?**

Directive 90/385/EEC on active implantable medical devices (AIMDD)

Directive 93/42/EEC on medical devices (MDD)

Directive 98/79/EC on in vitro diagnostic medical devices (IVDD)

(the Commission recently adopted two proposals to replace the existing 3 directives with 2 regulations – one to include AIMDD&MDD , the second on IVDD)

These are implemented in the UK in the Medical Devices Regulations 2002 (S.I. 2002/618)

**Have your team been involved in any stakeholder engagement or stakeholder events related to the Balance of Competences?**

No

**Are you aware of any of your stakeholders being involved in consultations, events or other activities organised by the UK Government?**

No

## **REGULATION OF HEALTHCARE PROFESSIONALS**

**How has the scope of the EU competence for this policy area changed over time?**

### **European Health Directives**

The Mutual Recognition of Professional Qualifications Directive 2005/36 EC (MRPQ) facilitates professional mobility in the EEA. It was agreed in 2005 and transposed into UK Law in 2007, allowing those practising in regulated professions to have their qualifications obtained in one Member State recognised in another. Thus the professionals are able to be employed anywhere in the Single Market, regardless of where they have been trained. This Directive replaced several, separate earlier Directives which covered nurses, dentists, veterinary surgeons, midwives, architects, pharmacists and doctors. These professions are subject to automatic

recognition. It should also be noted that there is a general system of recognition for over 800 regulated professions across the EU.

An extensive review of the MRPQ is underway and has reached the stage of member states negotiating revised text at Working Groups amending rules in respect of the seven professions subject to automatic recognition. For health professionals, the most significant change seems likely to be a relaxation of member states' ability to make checks on the language skills of professionals in the interests of patient safety.

The Cross Border Health Directive was passed in 2011 and will be transposed into UK and Scottish Law by 25 October 2013. It contains a requirement which will require all statutory regulated healthcare professional to have an insurance or indemnity policy in place prior to registration with the appropriate healthcare regulatory body.

**How have the legislative procedures for adopting measures under the Treaties changed (e.g. a move from consultation to co-decision, or a move from unanimity to Qualified Majority Voting) for this policy area?**

We have no details as the Professional Standards Team within the Department of Health are in the lead with the amendments to the MRPQ and also the transposition of the relevant article in the Cross Border Health Directive.

**Does the UK enjoys any special status under the Treaties in respect of this policy area?**

We have no details due to the reserved nature of the work and the Department of Health being in the lead.

**Why is EU-level action most appropriate (rather than e.g. UN/G20 or national/ regional level) for this policy area?**

The MRPQ is necessary to allow for the free movement of the 7 relevant healthcare professions with recognised and equivalent qualifications throughout the Member States. This has obvious patient safety benefits.

**How does EU action in this policy area advantage the UK?**

The MRPQ allows for cross border working of the relevant healthcare professions. This means that fluctuations in UK demand for the professions can be accommodated by EEA workers with equivalent qualifications to those educated and trained in the UK. In addition it offers UK trained and qualified workers to be able to have the freedom to work in Member States and benefit from the automatic qualification system.

The new requirement in the Cross Border Health Directive to require relevant professionals to have an insurance or indemnity policy will mean that patients will have a form of redress resulting from cases of negligence. This was also a separate UK wide policy agreed by the four Health Departments, however, the Directive requirement has driven the current timing of the policy's implementation.

**How does EU action in this policy area disadvantage the UK?**

With the MRPQ It is important that certain issues such as language checking of overseas workers are considered carefully and are indeed subject to review under the current consideration of the MRPQ. This will help to protect patient safety issues. It is important to note that in this area the interpretation of the legislation is critical.

The MRPQ also states the length of secondary and tertiary education for healthcare professionals and it is important that any Scottish and UK developments comply with EU law.

**What future challenges might we face in this policy area and what impact might challenges have on the balance of competences?**

It is important that we input into the development of the MRPQ to ensure that any changes in educational requirements of healthcare professionals, such as the length of undergraduate study for a profession, do not cause issues for UK institutions.

**What are the main EU Treaty articles (what they mean in terms of the split of competences between the UK and EU); the key European Court of Justice case law and the major pieces of legislation applicable to this policy area?**

We are not aware of these details given that the Department of Health are in the lead with the EU law in the policy area.

**Have your team been involved in any stakeholder engagement or stakeholder events related to the Balance of Competences?**

We received a brief overview of the UK Government's work in a meeting with the Department of Health's Professionals Standards Team in late 2012.

**Are you aware of any of your stakeholders being involved in consultations, events or other activities organised by the UK Government?**

We are not aware of any other involvement by our stakeholders.

## Scottish Health Action on Alcohol Problems

SHAAP provides a coordinated, coherent and authoritative medical and clinical voice on the need to reduce the impact of alcohol related harm on the health and wellbeing of the people in Scotland. Our aims are:

- To raise awareness and understanding of the alcohol-related health problems with health practitioners, policy makers and the public
- To evaluate current research and identify strategies to reduce alcohol-related health damage based on the best available evidence
- To work together with key organisations in the alcohol field in Scotland, the rest of the UK and worldwide, in tackling alcohol misuse.

SHAAP was set up in 2006 by the Scottish Medical Royal Colleges, through their Scottish Intercollegiate Group (SIGA). We are governed by an Executive Committee made up of members of the Royal Colleges.

SHAAP welcomes the opportunity to contribute to the independent review of Drinkaware, though given the deadline there has not been adequate time to consult as we would wish with our representative Royal Colleges. We acknowledge that Drinkaware makes a contribution to raising public awareness of the risks associated with excessive alcohol consumption.

Our comments are made under the following headings:

- Alcohol-related behaviours amongst Drinkaware's target audience groups
- The role of the alcohol industry in positively changing public behaviour and the national drinking culture to help reduce alcohol misuse and minimise alcohol-related harm positively
- The Portman Group
- General comments about Drinkaware

### **Alcohol-related behaviours amongst Drinkaware's target audience**

Whilst we acknowledge that Drinkaware aims to produce helpful advice and information on 'safe' drinking levels and the impact on alcohol on the body, the organisation's focus on the 'individual' obscures and diverts attention away from the vital point that excessive alcohol consumption is a wider social and political problem which requires coherent population-level responses which can impact on supply and demand of alcohol. This includes the need for sustained action on pricing controls, sales and marketing. Our view is also that there should be a ban on all alcohol advertising.

Two measures of the social cost of excessive alcohol consumption are hospital admissions and drinking related illnesses. Although national data has shown a decrease in overall numbers of people affected, Scotland and the UK as a whole continue to have a poor track record compared to other European countries.

For example, in Scotland 2010/11 the alcohol-related acute hospital discharge rate (European Age Standardised Rate or EASR) was 696/100,000 population, a slight fall from the previous year (710/100,000 population). In 2010/11, rates for men were more than double those for women (1,021/100,000 population and 395/100,000 population respectively), consistent with the pattern in 2009/10.<sup>1</sup>

The Scottish Government<sup>2</sup> (2010) reported that alcohol misuse imposes a substantial burden on Scottish society, costing between about £2,476.6 million and £4,635.4 million per year at 2007/08 prices, with a mid-point of £3,555.7. Based on the mid-point of this range, 7.5% of costs are due to health service expenditure, 6.5% to social work services, 20.4% to crime,

24.3% to productive capacity, and 41.2% to wider social costs. In terms of the statutory agencies, alcohol misuse imposes the greatest burden on the health care system, followed by social care services.

### **The role of the alcohol industry in positively changing public health behaviour and the national drinking culture to help reduce alcohol misuse and minimise alcohol-related harm**

Evidence about alcohol-related harm is most reliable when it comes from independent organisations and professions directly responsible for dealing with the results of harmful drinking and when it is based on the best evidence available. Arguably, this is why efforts to reduce overall levels of alcohol consumption (such as the introduction of a Minimum Unit Price for alcohol) have been widely supported by the medical and nursing professions, the police, social work and public health consultants in Scotland.

Whilst the alcohol industry can and does commission public health research, it runs the risk of being perceived as potentially biased.

The alcohol industry does have an important role to play in areas where they have particular competencies such as providing information about alcohol sales, lowering the alcohol content of alcoholic drinks and labelling.

In summary, we would argue that the alcohol industry should not be responsible for public health information relating to alcohol, as this would most often be in direct conflict with their interests and responsibilities to their shareholders and employees.

For this reason, SHAAP has strong concerns about the degree to which Drinkaware can be genuinely independent from the alcohol industry interests. At the present time, five of the thirteen members of the Board of Trustees are alcohol industry representatives.<sup>3</sup>

The Health Select Committee has echoed these concerns, saying that there is a perceived lack of independence on the part of Drinkaware and that this review would be advised to entrench that independence.<sup>4</sup>

To address this conflict SHAAP suggests that Drinkaware is managed by a genuine 'blind trust'; that is governed by a Board of Trustees that does not include representatives from the alcohol industry. Such an arrangement would allow Drinkaware to continue to receive industry funds, provided that the industry had no involvement in how those funds were allocated or the content of Drinkaware's information and education campaigns.

1 Monitoring and Evaluating Scotland's Alcohol Strategy December 2012, ISD Scotland, p73

2 The Societal Cost of Alcohol Misuse in Scotland For 2007 (Scottish Government 2010), p2.

3 Health Committee Government's Alcohol Strategy; third reports of Session 2012-13, House of Commons Health Committee: Page 93

4 Health Committee Government's Alcohol Strategy; third reports of Session 2012-13, House of Commons Health Committee: Page 33

## Seafish

### **What advantages or disadvantages might there be in the EU having exclusive competence for negotiating trade agreements with third countries?**

- Inability for UK for promote goods on the basis of UK traditionalities or reputation.
- Food may be traded as 'product of EU' not UK
- Loss of flexibility to produce food to comply with third country Legislation, which is not in compliance with EU legislation. E.g. chlorine treatment for zero listeris required by US.

+ Opening up of new trade routes.

**How might the national interest be served by action on animal health and welfare being taken e.g. at regional or national level, in addition to or as an alternative to action at EU level?**

Where there is no infrastructure to be able to comply with the EU rules. alternative measures that can achieve the same outcome could be permitted e.g. disposal/use of animal by products.

**Does EU legislation on animal health and welfare provide the right balance between protecting animal and public health and the interests of UK businesses?**

In the UK welfare standards tend to be set higher than EU standards. EU standards are higher than some third countries. As there is no approved method to market products on improved welfare standards the cost of higher welfare cannot easily be passed on without being non competitive with imports.

EU welfare standards applied to food rather than just production facilities would ensure a level playing field within the EU. Third countries wishing to export to the EU would also need to comply if applied to the food product. This would remove the competitive advantage of poorer welfare standards.

**What future challenges or opportunities might we face on animal health and welfare and what impact might these have on the national interest?**

Challenge - extending of welfare requirements to fishing. It currently only included fish/shellfish farming or holding. the requirements on land are necessary to maintain quality so are not currently onerous. To apply standards for catching and slaughter of wild caught fisheries would place an unnecessary burden on industry.

**What impact might any future enlargement of the EU have on animal health and welfare?**

Transition periods given to new members allows unfair competition as new countries may not be applying the same standards. This is also misleading the consumer who might not wish to buy products made from animal raised in a lower standard than seen in the UK.

**What evidence is there that EU action to create the single market for food has been advantageous or disadvantageous for the UK?**

Advantages

No barriers to trade. No need for different packaging for different countries

Less delay at border ( incoming or outgoing).

In theory, in reality MS interpretation of requirements can cause refusal of entry. eg whether information should be on label or trade documents. Or whether consumer information needs to be on external carton as well as consumer label.

**What evidence is there that the national interest in terms of trade is best served by action at the EU level, national level or action being taken at a different level, e.g. in Codex Alimentarius?**

However in trading as part of the EU, the UK can lose its identity and reputation. Food may be marketed as a product of the EU and therefore the food standards will be judged with the food from other MS.

If there are food safety issues within sections of the EU, third countries may reject all of that product from the EU even if some MS are not affected.

**Has EU action in food law provided the right balance between protecting the consumer and protecting the interests and reputation of UK businesses?**

The EU sets rules to protect the consumer in terms of standards and safety. These apply across the EU to prevent different standards creating barriers to trade.

**Is there evidence that legislating for consumer protection at the European level has been advantageous or disadvantageous to the UK national interest?**

- EU wide standards should facilitate trade. But there are processes for prohibiting foods from being placed on the market on health grounds under 178/2002. Food can be judged unsafe based on the MS population. This allows trade to be blocked, it appears without much evidence to support claims.

- There can be multiple guidance from national and EU sources and inconsistency

- Lack of clarity in the detail, interpretation left to MS, Back to Directive type system. Regulations were intended to reduce MS interpretation of requirements

MS implement and enforce differently, MS authority implement above EU requirements and it is added to contracts of supply, therefore applying to other MS. This can also be used where a MS has a derogation but has to comply to supply to another MS. This is acting as a barrier to trade using contract.

There is a burden for small business to comply with EU law when it does not trade outside UK

The EU legislative process can be slow, lengthy and not transparent. Information is published too late to comment. Difficult for single MS trade body or business to become involved.

**What evidence is there that the principle of science based food legislation at the European level has served the national interest well? Are there any concerns about the principle and its application? Are there any examples of where it was not followed?**

EFSA are too remote from consultation with those affected. It does not always make recommendations that follow findings.

eg. EFSA report states ALA cannot be converted in the body for health benefits but still sets levels for a health claim

eg. When there is evidence that information is incorrect will not get involved in discussion eg. Application of average portion of shellfish at 400g which is clearly incorrect and could be used for estimating exposure to contaminants etc.

eg The scientific evidence points to an RDA of 450mg for Omega-3 which is recommended by FSA but EFSA recommended 250mg based on same evidence. Applying this level means most products containing Omega-3 can claim to be 'high' which doesn't allow the consumer to select products that confer benefits.

### **What impact has the EU taking on the representational role at the Coedx Alimentarius Commission had on the UK national interest?**

The UK cannot present its own views. The Commission will have to present the majority view of the EU

### **How might the UK benefit from the EU taking more or less action on food law in the future?**

UK could benefit from standards that raise EU to that of the UK on composition and welfare. Higher standards in the UK advantage MS with lower standards and mislead the consumer.

### **Could action be undertaken differently e.g. are there ways of improving EU food law?**

The change to Regulations has made more differences in legal requirements by MS. A return to Directives with more prescriptives outcomes may allow greater flexibility in achieving the aim.

A change to Directives would also speed up the legislative process as less debate would be needed on the detail. MS would be able to implement the Directive in the way best suited to their industry and infrastructure.

### **What future challenges or opportunities might we face in the area of food law and what impact might these have on the national interest?**

Compositional standards for foods traded across the EU would provide protection for consumers and business. Where foods can be said to have a customary name, minimum standards should be applied. This is seen in some products eg sausages but a system of standards applied to names similar to the PGI/PGO regime would help to maintain quality standards.

These standards would only apply to a particular name for a product. lower quality products can be traded but must be labelled clearly to inform the consumer.

### **The Portman Group**

We are aware of the activities of the Portman Group and that its voluntary regulatory code of practice on the naming, packaging and promotion of alcoholic drinks is supported throughout the industry, including producers, importers, wholesalers, retailers and trade associations. The major alcohol producing companies and retailers stress vigorously their commitment to encouraging responsible drinking through their marketing and sales practices and their CSR activities.

However, along with others in the public health community, we would regard the Portman Group essentially as an effective lobbying group for the alcohol industry (Baggott 2006). 5lts success

in lobbying against public health interests have been cited (Room 20066) as including persuading the UK Labour government to renege on its 1997 commitment to reduce the blood-alcohol level (BAL) for driving from 0.8 per mile to 0.5 per mile as, then and now, recommended by the EU. It has also been argued (Drummond & Chengappa 20067) that the Portman Group has previously offered money to established academics to criticise WHO alcohol reports while remaining anonymous.

5 The discursive constitution of the UK alcohol problem in *Safe, Sensible, Social: A discussion of policy implications* (Baggott et al 2006)

6 Room R. *Advancing industry interests in alcohol policy: the double game*. *Nordic Studies on Alcohol and Drugs*. 2006;23:389–392.

7 *Alcohol industry and alcohol policy in the United Kingdom* *Nordic Studies On Alcohol And Drugs V O L . 2 3 . 2 0 0 6*

8 Hastings, G & Angus, K. 2009, *Under the influence - the damaging effect of alcohol marketing on young people*, British Medical Association, London.

### **Drinkaware**

The British Medical Association (Hastings & Angus 2009)<sup>8</sup> in particular has argued that seemingly ‘pro-health’ messages such as “Drink responsibly” subtly advance industry’s sales and public relations interests. For example, when Drinkaware asserts on its website:

*We promote responsible drinking and find innovative ways to challenge the national drinking culture and tackle alcohol misuse*

It is argued that the idea of ‘safe limits’ is reinforced rather than relative risks and the impression is erroneously given that problems only arise when the product is used in specific ways, for which it is not intended. 5

BMA concludes:

*It is clear then, that while alcohol industry- sponsored marketing seems like a good idea, its public health value is questionable, and given its stakeholder marketing agenda, the effects are likely to be counterproductive. Such activity also focuses attention on individual rather than population level solutions, and can delay more effective statutory measures (Hastings & Angus 2009, p.40).*

In line with the BMA (Hastings & Angus 2009), we believe that there should be:

- A ban on all alcohol marketing.
- Introduction of minimum pricing.
- An increase in excise duty and a direct link between duty and units of alcohol.
- A reduction in licensing hours for on and off licensed premises.
- The commissioning of further research about sales practices to strengthen current regulations.
- Action to ensure that the density of alcohol outlets is taken into consideration in planning or licence applications.
- An assesent of the impact on public health of any changes to licensing legislation.
- An audit of the market and consider ways to prohibit the most harmful drinks or those which appeal particularly to young people.
- A compulsory levy on the industry to fund an independent public health body to oversee research, health promotion and policy advice. The levy should be related to current expenditure on alcohol marketing.

## Seakens Solicitors

As a lifelong smoker, albeit on a modest scale, I have welcomed the introduction of e-cigarettes as a method by which I can reduce my intake of tobacco and harmful chemicals whilst retaining the pleasure I obtain from smoking.

I was therefore appalled to read that the EU are proposing a Directive to tax and control e-cigarettes thereby nullifying any incentive to change to a less harmful product.

This appears to be lunacy on a grand scale and I urge you to reject these siren calls and allow ordinary common sense to prevail by leaving well enough alone.

## Senior European Experts Group

### Background

The Senior European Experts group is an independent body consisting of former high-ranking British diplomats and civil servants, including several former UK ambassadors to the EU, a former Secretary-General of the European Commission and other former senior officials of the institutions of the EU. A list of members of the group appears in the Annex.

SEE has no party political affiliation. As an independent group, it makes briefing papers on contemporary European and EU topics available to a number of organisations interested in European issues, drawing on the extensive knowledge and experience of its members.

Several members of the group have particular expertise on agriculture and food policy issues having worked for or as the UK Representative to the EU, or in the parts of the Commission dealing with these issues or in the relevant UK departments.

### General Points

#### Benefits of Membership

We consider the effectiveness of the single market in food and livestock products is entirely dependent upon the exercise of EU competence in animal health and welfare and food safety policy. For cross-border trade in these goods to flourish, the UK needs common, EU-wide rules that (a) give confidence to consumers that their food is safe to eat whatever its provenance, (b) prevents other countries from applying separate rules on food composition, quality and labelling and (c) ensures protection against the spread of animal diseases, especially those transmissible to humans. This could not be achieved without extensive action at Community level.

As the Defra/FSA paper makes clear, the UK's participation in the single market for food brings it major benefits, with total trade in 2011 reaching almost £39 billion. British consumers have become used to being offered a vast range and variety of quality foodstuffs from across the EU that was simply unavailable before the single market. At the same time competition from Europe has stimulated growth, innovation and export orientation amongst many farmers and UK food companies in what remains the UK's largest manufacturing industry.

This however is a policy area highly vulnerable to protectionism: history is replete with examples of countries seeking to protect their own national food cultures<sup>69</sup>, and other examples of countries rapidly closing their borders to imports when safety problems arose in a neighbour, whilst taking disproportionately long to lift them again. Our involvement in the single market provides the mechanisms to ensure both that our consumers (and animal health) are protected when food safety or disease threats develop elsewhere in the EU and that our export interests are not subjected to unjustified restrictions following incidents here.

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<sup>69</sup> It is no surprise that the seminal *Cassis de Dijon* and *Reinheitsgebot* cases, which concerned attempts by one Member State to protect its industry from competition from imports, were both in the food sector.

There is widespread evidence of this latter point. For example:

- Following the BSE crisis, EU legislation was adopted in 2006 to reopen the UK's beef export markets worldwide. When one Member State (France) declined to implement this law, it was taken to the ECJ and forced to apply it. By contrast Russia only lifted its ban some 6 years later, in late 2012, and the US market is still effectively closed;
- The EU's rapid alert mechanisms ensured that the UK authorities were immediately alerted when, for example, e-coli was discovered in food in Germany in 2011 so that national, and then EU, safeguard measures could be put in place;
- The EU is itself capable of protectionist action against third country exports: thus, for example, chicken imports from the US are banned due to cleaning processes that appear to carry no health risks. As an insider, the UK is invulnerable to such action.

In respect of animal welfare, the benefits to the UK of EU competence derive from spreading good practices in an area to which the British public attaches importance, as well as helping to ensure a level playing field for our own farmers. We recall that the main protagonist for including references to animal welfare in the Treaties has been the UK itself.

However, whilst the benefits of EU competence in this area are readily apparent, it is equally clear there is scope for improvement in the detailed regulation. Opportunities to achieve this will arise in the coming years, as the Defra/FSA paper indicates. The key will be to ensure that future regulation is effective, proportionate, risk-based and outcome focused.

## Questions

### A) Animal health and welfare

*Q1 What evidence is there that EU action on animal health and welfare benefits or disadvantages the UK? Q2 How might the UK benefit from the EU taking more or less action on animal health and welfare in future? Q3 What advantages or disadvantages might there be in the EU having exclusive competence for negotiating trade agreements with third countries?*

For the reasons outlined above – ensuring consumer confidence and disease control, thriving trade and rapid action in response to emergencies within the single market – we regard EU action on animal health and welfare as largely beneficial to the UK. We would see no merit in reducing EU action in the areas critical to maintaining cross-border trade and consumer protection, though there may be scope for greater flexibility in the rules applying solely to production for local consumption. On animal welfare, given that the UK will normally want to raise welfare standards, doing this at EU level will help to safeguard our farmers' competitive position vis-à-vis those in other EU countries.

As regards external trade agreements, the evidence generally is that the UK benefits significantly from the EU's competence to negotiate with third countries, and this should in theory apply in relation to veterinary issues too. There would moreover be potential efficiency savings from having a single, rather than 27, body of negotiators on these issues. It would be essential however to ensure the Commission was given all the necessary veterinary and scientific expertise to carry out this work effectively as it does not appear to have this currently.

*Q4 How might the national interest be served by action on animal health and welfare being taken e.g. at regional or national level, in addition to or as an alternative to action at EU level?*

As argued above, the core elements of EU activity on animal health - ensuring consumer confidence and disease control, thriving trade and rapid action in response to emergencies – are essential to the functioning of the single market in food. It follows that such activities could not be replaced by national action without major disadvantage to UK interests. There is however ample scope to supplement these core activities by national and regional action – for example in relation to the less highly transmissible and non-zoonotic diseases – which successive Governments (and the devolved administrations) have utilised.

The UK already has competence to act on animal welfare to supplement EU law, reflected in its comprehensive animal welfare legislation. It will generally be in the UK interest to persuade the EU to adopt our own standards, as we have successfully done over e.g. sow stalls and tethers where our standards were higher than in other Member States.

*Q5 Does EU legislation on animal health and welfare provide the right balance between protecting animal and public health and the interests of UK businesses? Q6 Could action be undertaken differently e.g. are there ways of improving EU animal health and welfare law, for example, to focus more on required outcomes using a more evidence and risk-based approach? Would this deliver more in the national interest?*

History – most dramatically the BSE crisis – shows that high standards of regulation and enforcement are in the interests of food businesses, as maintaining consumer confidence in the safety of their products is critical to their prosperity. Nevertheless, the EU has traditionally operated prescriptive and highly risk averse regimes, e.g. on slaughterhouse regulation, which can impose undue or disproportionate costs on operators. Whilst the Commission has been seeking to pursue more risk-based and outcome focused approaches recently, there is still much to be done, not least with certain other Member States and the EP, before the right balance is achieved for UK businesses and consumers alike. All that said, EU rules have in the past provided a welcome incentive to improve the hygiene and safety standards in UK slaughterhouses which were previously inadequate in a great many plants but which had proved notoriously difficult for the Government to tackle alone.

*Q7 What future challenges or opportunities might we face on animal health and welfare and what impact might these have on the national interest? Q8 What impact might any future enlargement of the EU have on animal health and welfare? Q9 Are there any general points you wish to make which are not captured above?*

The threat of disease outbreaks and spread is ongoing, so vigilance must be maintained. In terms of opportunities, the forthcoming Commission proposal on a new Animal Health law provides the occasion for the UK to press for a significantly improved EU legislative framework which meets our key criteria as set out above. An ongoing threat to UK interests is the continuing reluctance of at least some Member States and MEPs to embrace evidence- and risk-based policy making in this area, combined with protectionist instincts and highlighted by the debate on products from cloned animals and their descendants referred to in the Defra/FSA paper.

## B) Food safety, labelling, food quality and compositional standards

*Q10 What evidence is there that EU action to create the single market for food has been advantageous or disadvantageous for the UK? Q13 Is there evidence that legislating for consumer protection at the European level has been advantageous or disadvantageous to the UK national interest? Q11 What evidence is there that the national interest in terms of trade is best served by action at the EU level, national level or by action being taken at a different level, e.g. in Codex Alimentarius?*

As argued above (under General Points), the creation of the single market for food has benefited UK consumers and businesses greatly. The existence of two way trade of £39 billion per annum and the immense variety of foods available to today's consumers are, in our view, compelling evidence of the value to the UK of the single market in food. Moreover, the emphasis on mutual recognition (rather than the earlier vertical compositional Directives) supported by clear labelling rules and EU-wide limits for additives and other safety-related issues is the right approach to promote innovation and competition.

In general, legislation applying to the operation of the single market needs to be made at EU level and this is especially the case for food law. The alternative of having 27 sets of rules on e.g. food composition, labelling, additives etc would be highly disadvantageous for our exporting food businesses, disruptive of the single market and expensive in terms of additional bureaucracy. The *Codex Alimentarius* is a useful forum for agreeing standards (albeit very slowly as it requires unanimity) but is not a substitute for enforceable legislation.

*Q12 Has EU action in food law provided the right balance between protecting the consumer and protecting the interests and reputation of UK businesses?*

As regards food safety, the comment at Q5 above applies and we repeat it: "History – most dramatically the BSE crisis – shows that high standards of regulation and enforcement are in the interests of food businesses, as maintaining consumer confidence in the safety of their products is critical to their prosperity." We are not aware that the food industry regards EU food law overall as unduly burdensome even if some elements of it (alcohol labelling for example) have required significant compromise. Indeed, their main collective interest is that there is a consistent and clear set of rules that responds to consumers' requirements and avoids barriers to intra-Community trade.

*Q14 What evidence is there that the principle of science based food legislation at the European level has served the national interest well? Are there any concerns about the principle and its application? Are there any examples of where it was not followed?*

Basing EU food legislation on science has been a cornerstone of UK policy under successive Governments. Such an approach ensures consumer safety, encourages innovation and (combined with appropriate labelling rules) maximises consumer choice. The UK has frequently been successful in negotiating science based EU rules, to the benefit of UK consumers and businesses. Implicit in such rules are judgements about what levels of risk are appropriate and in the main EU safety levels are (rightly) cautious. But in some areas, especially at the forefront of technological development, science has been set aside in favour of overly restrictive measures, ostensibly designed to respond to "social" considerations. Implementation of the framework legislation on GMOs in food and feed is one example (an issue causing even greater problems in the environment chapter, on which we will comment in due course). Marketing of products from cloned animals and their descendants promises to be another.

An example of spectacular UK policy success based on science has been the rules on Pet Travel. When the single market was first created, there was a tension between the goal of

giving travellers freedom to cross EU internal borders with their pets and our (and Ireland's) desire to keep rabies out of our territory. The initial goal of the other Member States was to give priority to the freedom of movement arguments and therefore to force us to abolish our strict quarantine arrangements. The UK was also under some internal pressure, not least from some senior diplomats, to relax the rules. But deploying scientific arguments about the rabies threat and the possibility of eradication, the UK persuaded the EC instead to embark upon a programme of eradication of rabies from its territory as a prior condition for relaxing our rules. As this programme became progressively successful in eradicating the disease, the UK introduced the Pet Travel Scheme, including pet passports and micro chipping of pets, in the late 1990s (much of which was then adopted throughout the EU). Now, with the risk of rabies being imported via pet movements reduced to insignificance, the UK's regime is harmonised with the rest of the EU based on regular vaccination, pet passports and microchips. Thus both policy objectives – protection from rabies risk and freedom for travellers with pets to cross to and from the continent with minimal difficulty<sup>70</sup> – have been achieved.

*Q16 How might the UK benefit from the EU taking more or less action on food law in the future? Q17 Could action be undertaken differently e.g. are there ways of improving EU food law? Q18 What future challenges or opportunities might we face in the area of food law and what impact might these have on the national interest? Q19 Are there any general points you wish to make which are not captured in any of the other questions?*

Broadly we consider the EU work on food law is in the right place and serves the UK well. The main ongoing challenge will be to continue to resist pressure for protectionist or anti-innovation measures, by insisting on maintaining a science based approach. Strengthening the quality and credibility of scientific support to the Commission and to the Member States in this area would be in the UK's interest. A further challenge may well be to ensure that food law is appropriately aligned with environmental legislation. One obvious area of major current concern is food waste, to which the EU's rules on "Best before" and "Use by" dates are a contributor.

## **Annex**

### Sir Michael Arthur

Director-General Europe, FCO, 2001-3; British High Commissioner to India 2003-07; British Ambassador to Germany 2007-10.

### Graham Avery

Director, European Commission, 1987–2006.

### Sir Colin Budd

Chairman of the Joint Intelligence Committee 1996/97. British Ambassador the Netherlands, 2001-05.

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<sup>70</sup> Some specific rules remain to ensure dogs imported to the UK (and several other countries) are free from tapeworm

Sir Michael Butler

British Permanent Representative to the European Communities, 1979-85.

Lord Butler of Brockwell

Secretary to the Cabinet and Head of the Home Civil Service, 1988-98.

John Cooke

Member of the UK Permanent Representation to the EC 1969-73 and 1976-77. Under-Secretary, International Trade Policy Division, DTI, 1992-96. Chairman, OECD Trade Committee 1996-97

Sir Brian Crowe

Director-General (External & Politico-Military Affairs) Council of the European Union, 1994-2002. Previously Deputy Under-Secretary for Economic Affairs, FCO.

Sir David Elliott

UK Deputy Permanent Representative to the EU 1982-91. Director-General (Internal Market), Council of the European Union, 1991-95.

Sir Michael Franklin

Deputy Director-General (Agriculture) European Commission 1973-77; Permanent Secretary, Ministry of Agriculture, Fisheries & Food, 1983-87.

Lord Hannay

UK Permanent Representative to the European Communities 1985-90 and to the United Nations, 1990-95.

Lord Jay of Ewelme

Permanent Under-Secretary of State, Foreign & Commonwealth Office, 2002-06.

Lord Kerr of Kinlochard

UK Permanent Representative to EU 1990-1995; Permanent Under-Secretary of State, Foreign & Commonwealth Office, 1997-2002.

Andy Lebrecht

UK Deputy Permanent Representative to the EU, 2008 – 2012.

Sir Emyr Jones Parry

UK Permanent Representative to NATO, 2001-03 and to the UN, New York 2003-07. Political Director and previously EU Under-Secretary at FCO. Now President of Aberystwyth University.

Sir Nigel Sheinwald

UK Permanent Representative to EU 2000-03. Prime Minister's Foreign Policy & Defence Adviser, 2003-07. British Ambassador to the United States, 2007-12.

Sir Stephen Wall

UK Permanent Representative to EU 1995-2000. Head, European Secretariat, Cabinet Office, 2000-04.

Michael Welsh

Member of the European Parliament for Central Lancashire, 1979-94.

Lord Williamson of Horton

Deputy Director-General (Agriculture) European Commission 1977-83. Cabinet Office 1983-87. Secretary-General, European Commission, 1987-97.

## **IMPACT ON THE NATIONAL INTEREST**

EXPECTED INCREASE IN NUMBERS OF OVERSEAS VISITORS TO THE SOUTHEND AREA IN VIEW OF THE FOLLOWING:

- EXPANSION OF SOUTHEND AIRPORT – PASSENGER NUMBERS PREDICTED TO RISE TO 2 MILLION BY 2020. WE HAVE ALREADY SEEN NUMBERS OF OVERSEAS VISITORS TO THE TRUST INCREASE SINCE SOUTHEND AIRPORT INTRODUCED DIRECT FLIGHTS TO AND FROM EEU/EEA COUNTRIES
- NEW £1.5 BILLION SUPER CONTAINER PORT TO OPEN IN GRAYS IN 2013 HANDLING 1.6 MILLION SHIPPING CONTAINERS PER YEAR
- PORT WILL BE 717 ACRES – TWICE THE SIZE OF LONDON
- THE NUMBER OF EU/EEA PATIENTS TO THE HOSPITAL HAS DRAMATICALLY INCREASED AND FAR OVERTAKEN THOSE PATIENTS WHO ARE SUBJECT TO IMMIGRATION CONTROL (VISAS)

## **FUTURE OPTIONS AND CHALLENGES**

THE EHC SYSTEM IS DIFFICULT TO PROMOTE AS THERE IS NO FINANCIAL INCENTIVE FOR THE TREATING HOSPITAL TO OBTAIN THE RELEVANT INFORMATION TO PUT THROUGH THE DWP PORTAL.

MORE EFFORT NEEDS TO BE PUT INTO EDUCATING ALL EU/EEA NATIONALS THAT WHEN VISITING THE UK THEY MUST HAVE THIS CARD WITH THEM AND PRODUCE IT IN THE EVENT THAT THEY ACCESS TREATMENT. SO MANY EU/EEA NATIONALS THAT WE SEE HAVE NO IDEA WHAT AN EHC CARD IS.

UK GOVERNMENT (DoH) NEED TO START A NATIONAL ADVERTISING CAMPAIGN (PRESS AND TELEVISION) TO MAKE IT CLEAR THAT NHS HOSPITAL TREATMENT IS NOT FREE FOR EVERYONE. THIS CAMPAIGN IS LONG OVERDUE AND SHOULD ALSO INCLUDE GP SURGERIES, WALK IN CENTRES, CLINICS AND AIRPORTS.

HOSPITALS TREATING EU/EEA VISITORS SHOULD BE REIMBURSED DIRECTLY THROUGH THE EHC PORTAL FOR THE TREATMENT THEY PROVIDE RATHER THAN THE AMOUNT CLAIMED GOING BACK INTO THE NHS POT. THIS WOULD ENABLE OVERSEAS VISITORS MANAGERS TO HAVE A CREDIBLE ARGUMENT WHEN ENCOURAGING STAFF TO ASK FOR VISITORS FOR THEIR EHC DETAILS. AT THE MOMENT THE SYSTEM IS RELYING ON GOODWILL ALONE. THIS ARRANGEMENT WOULD PROVIDE MUCH NEEDED ADDITIONAL INCOME TO INDIVIDUAL TRUSTS.

ALL NHS TRUSTS SHOULD BE MADE TO PRODUCE ACCURATE AND AUDITED FIGURES RELATING TO TREATMENT PROVIDED TO OVERSEAS VISITORS. THE PROCESS FOR IDENTIFYING AND CHARGING NEEDS TO BE THE SAME FOR EVERY TRUST, RATHER THAN INDIVIDUAL TRUSTS DOING DIFFERENT THINGS. IT NEEDS TO BE MADE VERY CLEAR WHO IS ENTITLED TO HAVE FREE HEALTHCARE AS THE REGULATIONS ARE EXTREMELY COMPLICATED, PARTICULARLY WITH REGARDS TO EU/EEA.

I HAVE VISITED OUR LOCAL JOBCENTRE TO SPEAK WITH A SENIOR MEMBER OF STAFF REGARDING AN INDIVIDUALS ENTITLEMENT TO JOBSEEKERS ALLOWANCE.

I WAS ADVISED THAT NO ONE COULD QUALIFY FOR JSA UNTIL THEY HAD PAID NATIONAL INSURANCE CONTRIBUTIONS FOR A TOTAL PERIOD OF TWO YEARS. THIS MEANS THAT AN INDIVIDUAL MUST HAVE BEEN WORKING FULL TIME (OVER 16 HOURS PER WEEK). HOWEVER WE SEE MANY PATIENTS WHO HAVE ONLY BEEN LIVING IN THE UK FOR A MATTER OF MONTHS WHO HAVE BEEN AWARDED JSA AND HOUSING BENEFIT ALMOST IMMEDIATELY HAVING PAID NO NATIONAL INSURANCE CONTRIBUTIONS AT ALL.

CLEAR AND FIRM GUIDELINES NEED TO BE ISSUED TO EACH CHIEF EXECUTIVE IN EVERY TRUST ENSURING THAT AN OVERSEAS VISITORS MANAGER IS IN EVERY HOSPITAL. APPROPRIATE TRAINING NEEDS TO BE PROVIDED TO OVM'S AS STAFF ARE DEALING WITH EXTREMELY COMPLEX LEGAL ISSUES AND HAVE LITTLE OR NO EXPERIENCE IN HOW TO DEAL WITH THOSE SITUATIONS.

THE GENERAL OPINION FROM OVERSEAS VISITORS IS THAT THE UK IS A PROVIDER OF FREE HEALTHCARE TO ALL AND THE MESSAGE NEEDS TO BE MADE ABUNDANTLY CLEAR THAT THIS IS NOT THE CASE. PATIENTS AND HOSPITALS SHOULD BE ISSUED WITH CONCRETE RULES SURROUNDING WHO IS ENTITLED TO WHAT WITH REGARDS TO EU/EEA NATIONALS AND PATIENTS NEED TO BE MADE AWARE THROUGH A NATIONAL ADVERTISING CAMPAIGN THAT THEY WILL BE EXPECTED TO PROVE THEIR ENTITLEMENT TO QUALIFY FOR FREE HOSPITAL TREATMENT. SO MANY TIMES WE HEAR FROM PATIENTS WHEN CHALLENGED THAT "WE ARE FROM THE EU/EEA, THEREFORE WE ARE ENTITLED". THE PERCEPTION IS THAT BECAUSE THEY HAVE THE RIGHT TO RESIDE AND WORK IN THE UK, THEY ARE ENTITLED TO EVERYTHING ELSE TOO (I.E. BENEFITS AND HEALTHCARE) WITH IMMEDIATE EFFECT.

GPS SHOULD HAVE A LEGAL OBLIGATION TO INFORM HOSPITALS, WHEN THEY REFER, IF THAT PATIENT IS A VISITOR TO THE UK. AN NHS NUMBER IS AUTOMATICALLY GENERATED FOLLOWING REGISTRATION AND THIS ESSENTIALLY ALLOWS THE INDIVIDUAL TO UNLIMITED ACCESS TO ALL OTHER PRIMARY CARE, I.E. DENTIST, OPTICIAN, FREE PRESCRIPTIONS. WE SEE MANY PATIENTS WHO HAVE RECENTLY ARRIVED IN THE UK AND HAVE, IN THEIR POSSESSION, AN NHS EXEMPTION CERTIFICATE. THE ASSUMPTION IS THAT THIS ENTITLES THEM TO ALL HEALTHCARE FOR FREE. THE DIFFERENCE BETWEEN PRIMARY AND SECONDARY CARE MEANS NOTHING AND ESSENTIALLY ANYTHING CARRYING THE NHS LOGO IS DEEMED TO BE COVERED. IT WOULD BE INTERESTING TO CALCULATE HOW MANY OVERSEAS VISITORS WHO ARE CHARGED ARE IN POSSESSION OF A VALID NHS NUMBER.

IT IS ESSENTIAL THAT CURRENT CHARGING PRINCIPLES FOR SECONDARY CARE BE EXTENDED TO INCLUDE PRIMARY CARE. THIS WOULD CREATE A FAR MORE ROBUST METHOD OF SECURING THE RECOVERY OF TREATMENT COSTS TO HOSPITALS.

THE CURRENT SYSTEM PUNISHES NHS TRUSTS FINANCIALLY FOR FOLLOWING THE OVERSEAS CHARGING REGULATIONS. IF A PATIENT IS IDENTIFIED AS CHARGEABLE AND THEY DO NOT HAVE THE MEANS TO PAY THE TREATING HOSPITAL WILL RECEIVE NO FUNDING FOR THAT PATIENT AND THIS WILL BE A

FINANCIAL LOSS FOR THE TRUST. WE ARE IN A SITUATION WHEREBY FINANCIAL PRESSURES COULD DICTATE HOW EFFECTIVE THE MANAGEMENT OF THE OVERSEAS VISITORS SERVICE WE ARE LEGALLY OBLIGED TO PROVIDE, SHOULD BE. HOSPITAL TRUSTS SHOULD BE FUNDED FOR ALL EMERGENCY AND NECESSARY TREATMENT AND A STABILISE AND DISCHARGE POLICY SHOULD BE PUT IN PLACE IN EVERY HOSPITAL. (THIS WOULD BE SANCTIONED BY THREE CLINICIANS). THIS SYSTEM IS IN PLACE AT WEST MIDDLESEX HOSPITAL AND HAS PROVED EXTREMELY EFFECTIVE.

WITH THE NUMBER OF EU/EEA NATIONALS CHOOSING TO MOVE TO THE UK ON THE INCREASE, ROBUST MEASURES NEED TO BE PUT IN PLACE TO SECURE THE FINANCIAL FUTURE OF THE NHS.

### **Nutritional Information**

Sugar Nutrition UK fully supports a unified European approach to food labelling legislation, to provide both a level and consistent playing field and prevent barriers to trade. Legislation at a national level can result in inconsistencies across Europe and can in some instances be a significant barrier to trade.

**Regulation (EU) 1169/2011 on the provision of food information to consumers (FIR)** is beneficial in respect to its consolidation of the general food and nutrition labelling legislation. A single regulation is preferable as it improves understanding and supports the consistent application of the legislation across the breadth of the European Union. However to date guidance on the interpretation and implementation of the legislation has not provided the clarification in respect to nutrition labelling required by businesses for its implementation. This therefore is an area of concern; without timely and detailed information, unintended inconsistencies in labelling could occur when companies have to make their own interpretations of the FIR due to insufficient guidance.

The use of Front-of-Pack nutrition labelling has been increasing across Europe with companies using consistent labelling mechanisms on products sold across multiple countries. The use of a monochrome Guideline Daily Amounts system is widespread across the UK food market and is also seen in many other EU countries. Thus this provides consistent, clear and at-a-glance nutrition information to consumers across the EU. The flexibility of the regulation to authorise the continued use of this scheme on a voluntary basis is beneficial to the UK and supports the move towards greater penetration of consistent labelling across Europe. The provision to enable per portion labelling to continue is also beneficial to the consumer in making food choices. However concerns do exist in respect to possible national schemes in labelling. The development of a separate UK national front-of-pack hybrid labelling scheme which incorporates the use of traffic light colours and GDA's is of concern - given the lack of robust scientific evidence to underpin this proposal. Furthermore, this approach not only lacks a solid nutrition basis, but also fails to take into account any of the possible unintended consequences which could be detrimental to public health. If Member States develop national labelling schemes this can be both a costly and burdensome barrier to trade for companies that operate across the EU; different countries may require differing labels. It may also result in increasing the inconsistency in nutrition labelling between countries, as opposed to reducing it. Legislation at an EU level could therefore be beneficial in supporting a unified approach to nutrition information and labelling, but it should not prevent the provision of areas of good practices devised by individual Member States, such as allergen boxes.

Currently the FIR does not permit the labelling of calories without the co-labelling of kilojoules. This EU legislation is not beneficial to the UK consumer. In the UK the understanding of calories is not yet universal, but it is well known to consumers and comparison between products possible. The addition of a term (kJ) on the label that is unfamiliar to the vast majority of the population is not beneficial to consumer understanding. It can create confusion and thus negatively impacts on the goal of the food label achieving its intended purpose of providing easy to use information. In addition the required change from GDA to Reference Intake (RI) is not beneficial to UK consumers, as the term (RI) is uncommon to the UK consumer and therefore will result in confusion. However the definition of nutrient terminology and the setting of RI

values at an EU level is beneficial in providing consumers across the EU with consistent information.

Legislation at the EU level is beneficial to the UK consumer in the arena of nutrition and health claims. We therefore support **Regulation (EU) 1924/2006 on nutrition and health claims made on foods**, as this provides consistency across the EU in reassuring consumers that nutrition and health claims are scientifically substantiated. This is particularly important to UK consumers, due to the increase in distance purchasing and online advertising.

However proposals by the EC to amend Regulation (EU) 1924/2006 in 2012 to enable "now contains x% less" claims to be made "if the amount of energy of the product bearing the claim is equal to or less than the amount of energy in a similar product", are not in the interest of the UK population. This amendment would allow claims to be made even when the reduction was just a single calorie or even when there was no caloric reduction at all. This has been shown in research by Leatherhead Food Research to be misleading and deceiving to the consumer\*. UK consumer perception of products carrying 'reduced sugars' claim is that they expect this to be accompanied by a similar reduction in calories. Allowing sugars reduction claims when the reduction of the sugars content in a product leads to no or little change in energy content can mislead consumers, whilst at the same time not reflecting nutritional benefit to the consumer. There are numerous examples on the UK market of products that have met the current European legislation requirement of a >30% reduction in sugar content to make a reduced sugars claim, and yet have no significant calorie reduction, or even in some cases a higher calorie content than the original. Thus this highlights that the claim is not being used for nutritional purposes in these cases, but purely as a marketing aid. Sugar Nutrition UK therefore supports the MEP's veto of this revision, but also feel that the legislation could go further and state that sugar reduction claims can only be made when they are accompanied by a significant reduction in calories, as this would have then been beneficial towards the UK public health goals of reducing caloric intake.

\* Patterson NJ *et al.* (2012) Consumer Understanding of sugars claims on food and drink products. *Nutrition Bulletin*. 37: 121-130

## The Freedom Association

### Introduction

This paper seeks to examine the effectiveness of the European Union's Health strategy (with specific regard to funded EU health awareness campaigns) in comparison to UK national health strategy. An investigation of the following EU Health organisations and issues will be addressed: High Level Group on Nutrition and Physical activity<sup>71</sup>; HIV/AIDS Think Tank (working group with Member States)<sup>72</sup>; sexual health awareness; EU Health Policy regarding smoking. Discussion will focus on the effectiveness of initiatives when compared at national levels both within and outside the EU, this will look mainly at the cost effectiveness and the internal reach of EU health programmes and to what extent (if at all) EU Health strategy hampers UK Health strategy.

Following the conclusions gained from looking at the above Health discussion, this paper will apply lessons learned towards the future of the EU Health programme and how funding should be altered to focus on value for money and return on investment.

Conclusions will be drawn as to the effectiveness of previous EU health programmes and the likely comparable success of the future of EU health. Furthermore a brief analysis will be conducted on the streamlining and potentially conflicting nature of EU funding.

### HIV/AIDS & Sexual Health projects

The EU has invested considerable resources in the fight against HIV/AIDS. Using member state resources the EU allocates funding to successful project tenders. It is submitted this process should be reworked and become more accountable for the failures which it presides over.

EU statistics show that overall, the new surveillance data demonstrates no decline in HIV transmissions across Europe. However the number of new infections has remained stable in the European Union - between 27,000 and 29,000 new HIV cases per year in 2006-2011.

In order to attempt to stem the tide of infection the EU has funded the projects shown below (amongst many others).

### Sample EU Sexual Health projects

HIV in Europe Copenhagen 2012 Conference (HIV in Europe 2012)<sup>73</sup>

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71 [http://ec.europa.eu/health/nutrition\\_physical\\_activity/high\\_level\\_group/index\\_en.htm](http://ec.europa.eu/health/nutrition_physical_activity/high_level_group/index_en.htm)

72 [http://ec.europa.eu/health/sti\\_prevention/hiv\\_aids/think\\_tank/index\\_en.htm](http://ec.europa.eu/health/sti_prevention/hiv_aids/think_tank/index_en.htm)

73 <http://ec.europa.eu/eahc/projects/database.html?prjno=20114202>

Cost 100,000.00€

Boys and Girls - An interactive web-based series to promote healthy lifestyles among European adolescents (Boys and Girls)<sup>74</sup>

Cost 529,898.82€

Support to EATG in promoting UA in the New Member States and New Neighbourhood countries (Support to EATG)<sup>75</sup>

Cost 706,890.00€

Young and HIV: European network to arrange an innovative prevention campaign and to exchange good practices - experience in Europe" (SUNFLOWER)<sup>76</sup>

Cost 250,000.00€

Looking at the sample EU HIV/AIDS – Sexual Health campaigns we can see areas of ineffective spending.

The above campaigns show a lack of inclusiveness (the Copenhagen Conference had a target of only 300 attendees) – the focus largely being on the bureaucracy and not on results and value for money. Resources should be focused on quantifiable projects with real impact. Looking at the United States the International AIDS Conference<sup>77</sup> is funded by non-government enterprise – a similar approach should be taken towards 'conference' projects that have little positive impact little real effects on HIV/AIDS prevention.

Expenditure on ambiguous awareness projects is rife within the EU.

The 'Boys and Girls' web based series has been an outright failure – at a cost of over 500,000€ the entire web series has achieved only 8 subscribers and 2,385 views on YouTube<sup>78</sup> with fewer than 5 daily visits recorded to its website, This represents a dismal return on expenditure. The extent to which these types of project affect EU citizens is largely unquantifiable and the goals and steps taken are ambiguous – this failure could have been prevented with a more accountable planning process.

This poor performance is replicated by the Young and HIV (Sunflower) prevention campaign that only achieved 323 Youtube views and no subscribers – as a branded awareness project this low amount of interaction shows poor execution in expenditure.

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74 <http://ec.europa.eu/eahc/projects/database.html?prjno=20091203>

75 <http://ec.europa.eu/eahc/projects/database.html?prjno=20091217>

76 <http://ec.europa.eu/eahc/projects/database.html?prjno=2007305>

77 <http://www.safaids.net/content/xix-international-aids-conference-aids-2012-washington-dc-usa>

78 <http://www.youtube.com/user/BoysandGirlsLabs?feature=watch>

Yet again the (Support to EATG) - which has created [www.safesexedu.com](http://www.safesexedu.com) and several safe sex guides for the mobile phone – has been met with limited success at best, achieving only 38 website views per day<sup>79</sup> at a cost of 706,890.00€.

Looking to UK projects such as The National AIDS Trust we can see this successful nation-based campaign has achieved 57,779 Youtube views – showing what is possible with a planned approach. It is the ambiguous nature of EU health awareness campaigns which is at the heart of their failure. With little to no money raised through the private sector, no return is mandatory.

Acknowledging these large expenditure failures explains why the EU HIV/AIDS figures have been largely stagnant and show these campaigns to be having limited success at best. We would submit that, the value for money these projects represent is not sufficient to warrant continued resource allocation in the current EU manner.

### The UK Sexual Health & HIV/AIDS

Since the 1980s the UK has been fighting to stop the increase in HIV/AIDS infection. Recent figures show that in 2011 the total HIV/AIDS diagnoses per year has decreased since 2010 and continues the year-on-year decline from the peak of 7,820 diagnoses reported in 2005<sup>80</sup> The Department of Health has suggested that HIV prevention programmes have been effective according to a number of outcomes, amongst them:

- Awareness of the availability of post-exposure prophylaxis (PEP) following potential sexual exposure to HIV increased from 22% before the CHAPS campaign to 56% after the campaign 142; and
- Preliminary analysis of data suggested that between 2001 and 2008 there was a fall in the number of sexual partners among MSM.143.<sup>81</sup>

These figures suggest that national campaigns run by the UK chosen by the UK have a higher incidence of success. Indeed the UK has a history of awareness campaign success starting in 1986. The world's first major government-sponsored national Aids awareness drive appeared on UK television in 1986 – it is today hailed as the most successful. Its tactics were imitated around the world. France, Spain and Italy were all slower to react, the Terrence Higgins Trust (THT) has noted. Each of those countries has around twice the number of people with HIV as the UK, where there were an estimated 86,500 in 2009, according to the trust.<sup>82</sup> These figures

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79 <http://www.worthofweb.com/website-value/http://www.safesexedu.com/>

80 <http://www.hpa.org.uk/hpr/archives/2012/news1612.htm>

81 <http://www.publications.parliament.uk/pa/ld201012/ldselect/ldaids/188/188.pdf>

82 <http://www.bbc.co.uk/news/magazine-15886670>

show that by allowing the EU to largely take charge of HIV/AIDS awareness, they have taken money away from the UK government to continue to fund nationally effective campaigns, replaced instead by poorly conducted campaigns mimicking the style of successful 'early reaction' countries such as the UK and USA.

The effect here on the UK is a drain of national resources away from previously successful national projects towards largely unsuccessful European-wide projects. Furthermore, many of the health awareness projects funded by the EU (such as the Sunflower project above) have target groups that do not include the UK, meaning that, to some extent, the UK is damaging its ability to engage in successful health campaigns, as a result of funding being used in other EU member states. Meaning in some part the UK is damaging its ability outright to engage in successful health campaigns due to funding being used in other EU nation states.

### High Level Group on Nutrition and Physical activity

This group funds projects with the aim of stemming the rise of obesity across Europe as well as tackling blood pressure, cholesterol, Body Mass Index, inadequate fruit and vegetable intake, physical inactivity and alcohol abuse. The European Commission advocates an integrated approach, involving stakeholders at local, regional, national and European levels. However, as shown below (as seen in sexual health), projects are funded that have significantly less impact than their nation-based counterparts. It is submitted that this ineffective overlap is not only a waste of resources but also a barrier to UK national campaigns that would be able to receive extra funds were it not for our EU contribution.

Two examples of poorly performing projects are:

European Physical Activity Promotion Forum (MOVE)<sup>83</sup>

Cost: 676,020.00€

Action for Prevention (PREVACT)<sup>84</sup>

Cost: 75,624.00€

The European Physical Activity Promotion Forum (MOVE), despite 676,020.00€ in funding, has poorly performed in obtaining any meaningful following or traction. With only 11,807 YouTube views<sup>85</sup>, 1,594 Facebook likes and 424 Twitter followers<sup>86</sup> it has failed to create a true impact in comparison to national initiatives such as 'Change4Life'. Again, as seen with sexual health initiatives, we see resources being allocated ineffectively. Looking to the UK and the 'Change

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83 <http://ec.europa.eu/eahc/projects/database.html?prjno=20101206>

84 <http://ec.europa.eu/eahc/projects/database.html?prjno=20100002>

85 <http://www.youtube.com/user/ISCAchannel>

86 [https://twitter.com/ISCA\\_tweet](https://twitter.com/ISCA_tweet)

4Life' programme the statistics show an impressive impact with over 171,809 Facebook likes<sup>87</sup>, 32,357 Twitter followers<sup>88</sup> and 61,893 YouTube views<sup>89</sup>. This indicates again that UK campaigns are more effective and industry-leading than their EU counterparts. By supporting EU Health programmes such as 'Move' we take resources away from decision makers in the UK and allow projects that are unable to tap into national sentiment, due to their required 'EU Focus', ultimately failing to deliver value for money.

Furthermore, many funded projects such as Action for Prevention (PREVACT) – as with Sexual Health – are based on ambiguous goals such as, “bringing together leading European stakeholders with a common objective, will provide Member States and other stakeholders with a forum for sharing information, resources, best practise and expertise”<sup>90</sup>. These forum providing goals are costly at over 75,000.00€ funding for a conference attended by only 200 delegates – of which substantial cost was incurred having 72 participants' travel and accommodation costs covered. These types of project are simply not as effective as nation-based initiatives such as 'Change4Life' and represent frankly reckless spending, providing 72 participants with a full expenses-paid conference trip.

## The UK: Nutrition and Physical Activity

According to the 'Change4life' tracking study, over 1 million mothers within the first year of the programme already claim to have made changes to their children's diet or activity levels as a result of Change4Life. Looking to the change between 2009 and 2010 data<sup>91</sup>, about 180,000 more mothers now claim their families have adopted all eight of the Change4Life behaviours<sup>92</sup>. Analysis of actual sales data provided by commercial partners suggests that Change4Life may already be having a positive impact on the types of food that families are purchasing. They have been working with other government departments, with industry and with a leading academic to underpin these early positive indications with more robust evidence of behaviour change.

This success is illustrated in the large online footprint the organisation has and how truly engaged and involved it is with the UK populace. In stark contrast, far from providing ancillary support in this area, many funded EU projects such as the above do not provide the results, value for money or impact that UK-based organisations have been able to achieve. These inefficient EU projects represent a misapplication of resources for the UK and potentially take money away from nation-based projects that are likely to be more successful.

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87 <http://www.facebook.com/change4life?ref=stream>

88 <https://twitter.com/change4life>

89 <http://www.youtube.com/user/change4life>

90 <http://ec.europa.eu/eahc/projects/database.html?prjno=20100002>

91 [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_115511.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_115511.pdf)

92 [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_115511.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_115511.pdf)

## EU smoking policy and the UK

The EU-wide campaign, Ex-smokers are unstoppable (2011-13) focus on encouraging Europeans to stop smoking. It shifts the focus from the dangers of smoking to the positive benefits of quitting, highlighting the inspirational achievements of ex-smokers and offering practical tips on quitting. This campaign has been met with some success. It should be commended for its positive outlook campaign. However, successful as they may be, when compared to UK national campaigns, yet again the campaign fails to accomplish what a nationally focused project can achieve.

With 73,754 Facebook likes<sup>93</sup> and 253 Twitter followers<sup>94</sup> the 'Ex-smokers are unstoppable' campaign has met with some success. However, comparing this to the UK-driven NHS Smokefree programme which has garnered 144,382 Facebook likes<sup>95</sup> and 464 Twitter followers<sup>96</sup> we can see the differences in success. Money spent in conjunction with the strong NHS framework has clearly outperformed the EU-backed campaign. As with the previous areas yet again we see evidence of nationally-based campaigns that are able to tap into existing frameworks and national demographic trends, outperforming EU projects. Continuing to fund projects which largely overlap the existing role national projects have is a misapplication of resources; the money spent could achieve a better return and greater economies of scale were it not used to fund brand new projects which already cover areas the UK government has addressed.

### Internal EU conflicts: Smoking vs. Big Tobacco

A serious issue that must be addressed within the EU as a whole and within EU Health policy, is the focus of EU funds in the same direction. Recently, MEPs on the European Parliament agriculture committee have been looking to reintroduce the tobacco subsidy. When the old system was finally phased out in 2010, tobacco farmers in 12 EU countries, including Bulgaria, Greece, Romania and Italy, were typically receiving £260million in subsidies<sup>97</sup>. The scrapping of the subsidy prompted a decline in tobacco farming across the EU, which producers will now hope to reverse.

This potential reinvestment in tobacco is not only hurting the EU's own anti-smoking campaign (Ex-smokers are unstoppable) a £27million campaign in itself; it will also damage the UK's national health interest. By reversing the declining trend in tobacco farming, the EU is directly funding a market which it is actively attempting to eradicate. It shows that the EU lacks a fundamental focus on health, that different internal bodies are not co-operating and ultimately it represents a conflict of funding.

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93 <http://www.facebook.com/Unstoppable.uk>

94 <https://twitter.com/ExSmokersEU>

95 <http://www.facebook.com/NHSSmokefree>

96 <https://twitter.com/nhssmokefree>

97 <http://www.telegraph.co.uk/news/worldnews/europe/9844395/MEPs-plan-tobacco-subsidies-as-Brussels-fights-smoking.html>

The UK should have no hand in directly affecting a negative health market such as tobacco and is being harmed by having to hand over resources to fund less successful campaigns that cover largely identical areas.

## Conclusion

Throughout this paper it has been shown that EU awareness projects in particular consistently fall short of their UK national counterparts. It is submitted that the EU has erred in funding many of the Health projects associated with EU Health Policy. The targeted projects above have represented considerably bad value for money.

In future, it is suggested that the EU should fund tangible programs with quantifiable results. EU health policy has shown that it is largely incapable of running consistently successful awareness campaigns and that it largely mis-spends resources on conference event expenses that cater for a small community with results that are difficult to gauge. Focusing on awareness projects that have tangible results is going to yield better results on a value for money basis. Health campaigns, and conferences should be severely limited in light of the below average performance of such EU-funded projects. The result would be better allocation of resources and a more valuable EU health policy.

Finally, the EU should take a 'one common path' approach to its wider policy area decisions. As shown, the conflicting nature of funding anti-tobacco campaigns, whilst also funding EU tobacco farmers, is something that must be addressed. It represents a breakdown in communication and hampers the effectiveness of not only the EU but the UK and other nation states that are actively and successfully conducting national anti-smoking campaigns.

## The Medical Schools Council

Thank you for asking the Medical Schools Council to comment on what the UK's membership of the EU means for the national interest in the context of health.

The Medical Schools Council represents the interests and ambitions of UK medical schools as they relate to the generation of national health, wealth and knowledge through biomedical research and the profession of medicine.

As an organisation it occupies a unique position embracing medical undergraduate education, the entirety of health related research and a critical interface with the health service.

Overall we judge the impact to be positive: the considerable spending on research and innovation benefits UK universities which are world leaders in the bio-medical field and do well in competitive tenders.

The initiative around rare diseases will benefit from the establishment of Academic Health Science Networks in England and from the effective collaborations and partnerships already established in Scotland.

There are concerns about current moves in Europe around data protection and it will be important to ensure that the use of anonymised patient data for health research continues to be permissible. We welcome recent moves to simplify the EU Clinical Trials Directive, which has been a major barrier to the conduct of research in Europe. As the new regulation is implemented it is essential that it takes existing Member State processes into consideration in order to avoid the duplication of effort.

We are concerned that the free movement of healthcare professionals has not always been to the benefit of the UK. Approaches to medical education in some parts of the EU are not as patient-centric as they are in the UK. There is evidence that the practical clinical communication skills of some EU doctors are sub-optimal and patient care suffers as a result. The UK is a popular destination for many EU doctors resulting in competition for posts and the possibility that UK graduates might not be able to obtain full registration with the GMC. The current suggestion from some EU states that medical education ought to be of 6 years' duration is unacceptable. The UK is introducing a new Prescribing Skills Assessment for all final year medical students. Unfortunately the requirement for the mutual recognition of professional qualifications means that we are unable to require EU medical students applying for the UK's Foundation Programme to take the same assessment as part of the selection process.

As individuals, members appreciate the benefits of the European Health Insurance Card.

## The National Pharmacy Association and the Pharmacy Forum NI

The National Pharmacy Association and the Pharmacy Forum NI closely monitor and seek to influence EU developments through the Pharmaceutical Group of the European Union (PGEU). PGEU is the voice of community pharmacy in Brussels, engaging, informing and influencing stakeholders on behalf of 400,000 pharmacists and over 160,000 pharmacies across the EU. Our organisations, along with the Royal Pharmaceutical Society, form the UK delegation to PGEU.

We are pleased to respond to the “Review of the Balance of Competences” consultation and outline the impact of the EU on community pharmacy in the UK. We set out below a broad overview of the EU’s impact on pharmacy, which highlights advantages and disadvantages of EU actions.

### Free movement of people

Pharmacy is defined as a sectoral profession within the Professional Qualifications Directive. Therefore pharmacists are entitled to automatic recognition of their qualifications when moving to other member states of the EU. There has been a net movement of pharmacists into the UK, providing pharmacy employers with greater access to professionally qualified staff. This has been helpful, although the total numbers are small and so the overall benefit has been limited. This system has provided challenges, with a lack of clarity over healthcare regulators’ powers to test the language skills of transferring healthcare professionals. The ability to communicate with patients is a fundamental skill for a healthcare professional, and it has been concerning that regulators have not tested this skill before placing a registrant on the register. It is to be hoped that the revised version of this Directive empowers healthcare regulators to test language skills and only register those with the necessary aptitude.

In the upcoming Council of Ministers votes on the Professional Qualifications Directive, we urge the Government to support amendments which will give greater clarity on the ability of healthcare regulators to test the language skills of healthcare professionals. In the same Directive, we also urge the Government to support amendments which seek to update the description of the activities of a pharmacist.

### Free movement of goods

EU treaties permit the movement of medicinal products across national boundaries within the EU. This has been very beneficial for the UK tax payer, as medicines can be procured much more cheaply from, for example, Italy, Greece and Spain. The imported medicines are equivalent to the UK-marketed product – in most cases these medicines were manufactured and packaged within the same factory. Over the years, many millions of pounds worth of savings have been made this way for UK taxpayers.

At the same time, there is a demand from high-cost markets such as Germany to acquire cheaper stock which has been put onto the UK market. Pharmaceutical companies respond to this trade by limiting the stock available on the UK market. This results in quotas being applied on individual pharmacies, often resulting in a pharmacy being unable to obtain the medicines it needs for its patients. We have found evidence of significant patient distress resulting from these supply problems. We note that the EU’s own effort to ensure sufficient supply (Article 81 of Directive 2001/83) has proved impotent. However, the free trade principles have been repeatedly defended by the Commission and the European Courts.

We urge the Government to engage more fully in the findings of a recent Parliamentary inquiry into this problem (Report of the APPG inquiry into medicines shortages).

### Falsified Medicines Directive

Tackling the global problem of counterfeit medicines is one of the strongest examples within the health sector of an issue which can be handled most effectively at EU-level. Because medicines are manufactured and shipped all over the world, and criminals target the supply chain, an EU-response, ideally coordinated with other political blocks around the world, is the only effective way to protect the UK patient. We are supportive of the Directive's intention to combine a number of different strategies to reduce the incidence and therefore impact of these dangerous products on UK patients. We are concerned that the MHRA has failed to acknowledge the need for all prescribable medicines to be barcoded in its response to the Commission's consultation on implementation of this part of the Directive.

In on-going discussions about the delegated acts under the Falsified Medicines Directive, we urge the Government to recognise that barcoding all prescription medicines rather than a selection of POMs would be the more efficient and effective implementation of this Directive within community pharmacy.

Manufacturers, wholesalers and pharmacy have been working together through our respective EU representative organisations to establish the most efficient and cost effective way of implementing the safety features element of the Directive. We strongly believe that this pan-industry stakeholder model is the best way to deliver the additional security envisaged in the Directive, whilst avoiding unnecessary bureaucracy and cost.

In on-going discussions about the delegated acts under the Falsified Medicines Directive, we urge the Government to support the European Stakeholder Model, as the most efficient way of delivering the infrastructure required to deliver the EU-wide medicines anti-counterfeiting system.

### Pharmacovigilance Directives

We note the recent Pharmacovigilance Directives, which have sought to enhance the post-marketing monitoring of prescription medicines. These Directives recognise the important role of the pharmacist in pharmacovigilance, and improve information sharing between regulators. Better information on medicine safety, drawing on the experiences of hundreds of millions of patients across the EU, is clearly beneficial to UK patients. Pharmacovigilance is an area where EU solutions are particularly helpful.

### Taxation

Pharmacy has changed over the past few decades, with the delivery of clinical services (most often associated with promoting adherence to medicines) now core to the profession's role. The UK has been at the forefront of this change. Some pharmacy services are held back by the different tax rules that apply to more established providers.

Some health providers (doctors and dentists) benefited from zero-rated VAT on prescribing services (the supply of qualifying goods to an individual for his personal use when they are dispensed by a registered pharmacist on a prescription), whereas pharmacists acting as prescribers were subject to VAT. The UK Government previously acknowledged the inequity of

this arrangement, but felt unable to act due to previous agreements with the EU not to extend zero-rated VAT. This was finally rectified in 2009 when the Government changed the legislation so that supplies dispensed to an individual on the prescription of non-medical prescribers including nurses and pharmacists also became zero-rated.

#### Opportunities for greater involvement of the EU

We also believe that there are a number of areas in which the EU could potentially play a greater role:

Standardisation of coding systems for healthcare services and medicines

Interoperability standards for electronic prescriptions

#### UK interpretation of EU law

We have examples of situations in which certain practices that are common place in pharmacies across Europe, including this country, are suddenly deemed to be non-compliant with EU law by regulators in the UK. Safe and established practices are then put to a stop in the UK, whilst our colleagues in other countries carry on unimpeded. It may that in some situations rather than EU law creating bureaucracy, it is the way that Departments and agencies interpret it that is actually the issue.

#### EU institutions awareness of UK community pharmacy

Over the past few decades the practice of pharmacy has advanced significantly in the UK, with pharmacists now taking on a significant role educating patients about their medicines and promoting adherence to therapies. Some pharmacists have obtained an additional qualification which permits them to prescribe. Key players in the EU who make regulations that affect UK community pharmacy should have an up-to-date understanding of our sector, and we do not believe that they do. We recently issued an invitation to all of the UK's 73 MEPs to visit a community pharmacy in their constituency to learn first-hand from a pharmacist about their role. Not one MEP has responded to our invitation. It is of particular concern that the European Medicines Agency appears to have little understanding of the value of the pharmacist's role.

#### Wider collaboration

The increasing influence of EU law on pharmacy practice has necessitated much closer working between pharmacy associations across Europe. We do this through the Pharmaceutical Group of the European Union, which has member associations from the vast majority of EU states. There are significant benefits to this close working, with excellent communication of professional developments. The recent Falsified Medicines Directive has resulted in greater pan-European cooperation across the medicines supply chain. Representatives of branded manufacturers, pharmacy, wholesalers and parallel traders have come together to form the European Stakeholder Model which is an efficient and cost-effective way of implementing the Directive's requirement for safety features to facilitate authentication. This collaboration is the first of its type in our sector.

## The Wellcome Trust

### Key Points

- Effective engagement with the European Union on issues of health and medical science is vitally important given the increasingly global nature of research. This includes reaching a balance of competences between the EU and member states that is appropriate, proportionate to any risk, and evidence-based.
- Where the EU has a leading role in policy-making, this should be informed by appropriate and timely consultation, with adequate transparency and EU-wide harmonisation.
- It is important that the Department of Health works effectively with other government departments to ensure a joined-up approach to engaging with the EU on all issues, including health.

### INTRODUCTION

1. The Wellcome Trust is pleased to have the opportunity to contribute to this review. We consider engagement with the European Union to be of high importance for maintaining UK competitiveness, both within Europe and internationally, and science and innovation must be at the heart of this.
2. As a global charitable foundation and funder of medical research, we consider engagement with the European Union to be an increasingly important part of our advocacy work to secure the best environment for medical research in the UK and EU, particularly in light of the increasingly multidisciplinary and international nature of research. Our response focuses on those areas identified in the review which have direct relevance to the Trust's work, or otherwise impact on our activities.

### MEDICINAL PRODUCTS

3. European legislation on medicines has a particular bearing on our core activities, as a proportion of our funding goes towards supporting researchers in the development of new medicinal products, and so European legislation in this area, and its implementation in the UK, is of particular interest for us.

primary avenue by which we have engaged with the EU in this area is in legislation around clinical trials, particularly the Clinical Trials Regulation now passing through the European Parliament, and the preceding Clinical Trials Directive. Effective European legislation on clinical trials is important given the increasingly global nature of research and the increasing numbers of multi-national trials that are now taking place. Harmonised requirements for the approval and delivery of clinical trials are particularly important to achieve the goals of this legislation. We envisage this will provide significant benefits for multi-national trials of medicinal products for rare diseases where the patient population is spread across Europe. While the original Clinical Trials Directive was intended to harmonise requirements, it is widely acknowledged that the Directive was inconsistently implemented across Member States. We have welcomed the publication of the European Commission's proposal for a Clinical Trials Regulation, on the basis that it provides researchers and clinicians with an effective overall regulatory framework for testing the safety and efficacy medicinal products,

and aims for effective harmonisation across Europe. Once the Regulation is agreed it will be important for Member States to work together to ensure that it is consistently implemented across the EU, to avoid mistakes made in the implementation of the Directive.

5. The original Clinical Trials Directive, published in 2001, was highly criticised for its disproportionate and 'one size fits all' approach, resulting in an increased regulatory burden for researchers, contributing to a significant drop in the number of trials conducted in the UK. The UK and other member states raised these concerns with the EU commission, who responded effectively with the result that the Directive was revised and republished as the current Clinical Trials Regulation, which has made significant improvements and is currently under consideration. We are continuing to engage with the passage of the updated Regulation and ensure that it reflects the best interest of the research community.

## **MEDICAL DEVICES**

6. A significant proportion of the Wellcome Trust's translational funding portfolio is directed towards the development of medical devices to the point at which they can be successfully taken to market. The EU's regulation of this area is therefore another area of particular interest for us, with implications for the regulatory environment in which we operate, as well as the researchers and companies that receive our funding. We are monitoring the revision of the EU legislation on medical devices following the Commission's publication of its proposals for new Regulations on medical devices and *in vitro* diagnostic devices and we will continue to follow and engage with this process as it continues. Upon initial review, we regard the Commission's proposals as largely necessary, although we have highlighted areas in need of clarification.
7. We consider it necessary to take a balanced and proportionate approach to legislation in this area, which protects the interests and safety of patients while providing an effective legal environment for device companies to operate. A harmonised, pan-European approach is also necessary in order for the EU, and the UK as an EU member state, to compete effectively in an increasingly global marketplace.

## **HEALTH SECURITY**

8. While the EU has a valuable role to play in providing an early warning system and coordinating responses to cross-border health threats, we regard health as largely a member state competence. It is important that the Department of Health work effectively with other departments to effectively coordinate activities and ensure that policy decisions are informed by as wide a range of expertise and evidence as possible.

## **RADIATION**

9. We do not have a view on the Treaty to establish the European Atomic Energy Community. However, we have been engaging over the past several years with the redrafting and passage of the European Physical Agents (Electromagnetic Fields) Directive, which was intended to protect workers in the EU from risks arising from exposure to electromagnetic fields in the workplace. While the EU has an important role to play in this area in terms of providing consistent advice and harmonisation of standards across the EU, the original Directive suffered from a lack of adequate consultation and engagement with researchers

and the medical profession. This had the unforeseen effect of potentially seriously restricting the use of MRI for research and clinical diagnosis, because the use of MRI would have exceeded the safe limits set out in the Commission's proposal.

10. The Commission was responsive to these concerns when raised by a group of radiologists, research organisations and funders, including the Wellcome Trust, and a revised version of the Directive has now been published containing a derogation for MRI (although the revised Directive is still to be passed by the European Parliament). The development, subsequent withdrawal and revision of the European Physical Agents Directive illustrates the importance of timely engagement with expertise, adequate consultation to ensure any knock-on effects of legislation are identified and a responsive and evidence-based approach when drafting legislative proposals of this type.

## **RARE DISEASES**

11. We welcome the Commission's focus and activities on rare diseases, and previously responded to the Department of Health's consultation on the UK Plan for Rare Diseases<sup>1</sup>. The global occurrence of rare conditions means that pan-European and international approaches are increasingly important in this area. Within this, harmonisation and data sharing are ultimately necessary to compare, combine and make best use of the results, particularly as individuals with rare conditions may be distributed around the world. It is important for the UK to be fully engaged in this area, and with programmes such as the International Rare Diseases Research Consortium (IRDiRC) in order to maximise progress from international activity.

## **DATA PROTECTION**

12. There are other important areas of the EU's competence that impact on health. For example, the use of personal data concerning health for research is governed by European Data Protection legislation. Negotiations are currently underway on a Data Protection Regulation that would replace the current Data Protection Directive. The new Regulation will have a significant impact on health (and social) research. We welcome the provisions in the Commission's proposal for a Data Protection Regulation to support health research, which strike an appropriate balance between protecting the rights and interests of individuals and facilitating scientific research for public good. Some MEPs have proposed amendments that would significantly undermine Article 83 and the associated derogations that facilitate research. However, it is essential that these changes are resisted to continue to build on the UK's strengths in health research and capitalise on recent investments such as the Clinical Practice Research Datalink. It is also important for health research that negotiations on the Regulation result in a proportionate approach to the regulation of pseudonymised data (see also discussion of NHS and patient services below).
13. Where legislation is developed in another area of EU competence that has an impact on health – as is the case for data protection – it is important that the Department of Health works closely with the lead government department to ensure any health issues are fully taken into account in the UK's negotiating position.

## **NHS AND PATIENT SERVICES**

14. We are pleased to see the Commission has made eHealth a priority area. Appropriate use of and access to eHealth records are of significant importance in improving patient care and furthering important research. We are broadly supportive of the eHealth action plan. We have significant concerns however, that the currently proposed revisions to the Data Protection Regulation could have a devastating effect on the ability to carry out research using pseudonymised data, as highlighted above in the section on data protection. The issues raised by the Data Protection Regulation are a good example of why it is imperative that the Department of Health is able to work across government departments such as the Ministry of Justice and Department of Business Innovation and Skills to ensure UK interests are properly represented at the EU level.

1

[http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy\\_communications/documents/web\\_document/wtvm055494.pdf](http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/wtvm055494.pdf)

## The Wine and Spirit Trade Association

### **Introduction**

The Wine and Spirit Trade Association (WSTA) is the UK organisation for the wine and spirit industry representing over 340 companies producing, importing, transporting and selling wines and spirits. We work with our members to promote the responsible production, marketing and sale of alcohol and these include retailers who between them are responsible for thousands of licences.

We work with Government Departments such as Defra, the Food Standards Agency and BIS to ensure UK implementation of EU regulations is as smooth as possible for the alcohol industry.

We also work with our European colleagues through Comité Vins and Spirits Europe to ensure that existing and future European legislation relating to wines and spirits does not adversely impact businesses in our sector.

### **1/ Food safety and labelling**

The production and labelling of wines and spirits is governed by EU law. The EU's common market organisation for wines and spirits means that product labelling, descriptions and definitions are harmonised across all 27 member states and provide protection for EU product denominations.

This arrangement has facilitated trade between EU member states which has been broadly advantageous for the UK and its consumers.

However, the single market has in some instances created issues in relation to imports of some products from outside the EU which are not always compliant with EU standards, but many of these have been (or are being) dealt with via bilateral agreements between the EU and third countries.

**We therefore believe that it would not be possible or desirable for the UK to attempt to repatriate powers on specific legislation governing the production of wines and spirits and aromatised wines.**

### **2/ Consumer Protection Policy**

Consumer Protection Policy at EU level has been reviewed recently and a new Directive on Consumer Rights will come into force on 13 June 2014. While UK Consumer Protection Policy has always been relatively high compare to other EU member states, the new Directive will introduce improved consumer protection principles such as stronger withdrawal rights, increased clarity of prices and more transparency.

The Commission's efforts to harmonise Consumer Protection Policy across all member states will in time provide EU consumers with the needed guarantees and safeguards to have the confidence to shop across borders and, as such, should be welcomed.

According to a recent report for the European Commission, cross-border online shopping in the EU has increased from 6% to 11% between 2006 and 2011. This is in part due to improvements in EU Consumer Protection Policy. (ref: 'Consumers' attitudes towards cross-border trade and consumer protection", EC May 2012').

### **3/ Excise Duty**

Directive 2008/118 on the general arrangements for products subject to excise duty is the key directive governing the structure of excise duty across the EU. This sets the basis upon which excise duty is levied on alcoholic drinks.

The Directive allows EU member states to set their own rate of excise duty and also to charge a 'zero rate' on some products such as wine where for instance 15 out of 27 EU member states do not currently charge any excise duty at all.

Having an EU directive which sets the basis upon which alcoholic drinks are taxed provides certainty for operators who trade across borders, but within a single market, as they only have one taxation system for 27 member states.

**We believe it right for the UK to retain sovereignty over setting its own excise duty levels within the parameters of this Directive, but we believe the structure of excise duties (i.e. the basis upon which taxation is levied on alcohol) should remain under EU control.**

This is illustrated by several European Court of Justice cases which have been brought against some EU member states who were thought have set levels of excise duty on some products at a rate which was unfairly disadvantageous to other products.

One such case was brought against the UK in 1983 (European Commission vs UK, ECJ 170/78). The European Court of Justice ruled that still wine and beer were competing products and that taxing wine in excess of the equivalent rate of beer in a beer-producing and wine-importing country was against the Treaty of Rome, since it discriminated against products of other Members States. As a result of this ruling, the UK was required to bring wine and beer duty rates into line and rates for wine and beer have moved in parallel ever since.

#### **4/ Environmental Legislation**

Regulation aimed at 'greening' supply chains has not yet been adopted at EU level, but is under active consideration. Although the EU is the right level at which to address most environmental issues, a badly constructed EU Regulation based on poor evidence could prove excessively burdensome for business, especially SMEs and micro businesses, potentially leading to insolvencies and discouraging new start-ups.

Where a future EU Regulation is adopted, standards should be reasonable and adoption progressive; it should encourage efficiencies; and enforcement should be devolved to national level. Above all, new regulation should not be a barrier to international trade.

#### **5/ Working Time Directive**

Different sectors need additional labour at different times. For example, elements of the UK wine and spirit supply chains need extra hours in the run up to Christmas. **We believe that working time should be decided at national (or business) level and would encourage the UK government to negotiate removal of the Directive. At worst, the UK government must preserve its current 'opt out'.**

## UK Council for Health Informatics Professions

### UKCHIP preamble

The UK Council for Health Informatics Professions (UKCHIP, [www.ukchip.org](http://www.ukchip.org)) certifies individuals and publishes an open register of health informatics professionals. We have established standards for professional conduct and the continuing professional development of our registrants. The UKCHIP vision includes:

- Health informatics recognition as a valued profession in both the public and private health care sectors throughout the UK.
- All persons in the UK who spend a substantial proportion of their role or time working in health informatics to be registered and thereby certified as professionals who meet defined standards of professional conduct and competence.

This response identifies issues that impact on the health informatics professions, our registrant body, and does not address issues of these individuals in any other personal or business context.

### Impact on the national interest

1. How does the EU's competence in health affect your organisation
  - a. As mobility of both clinical staff and patients across EU (in and out of UK) increases, the pressure for fit for purpose clinical data to support patient care (both specific patient records and clinical evidence as reference information) increases. The requirement for quality patient data just in time and when and where needed for authorised, authenticated professional staff is extended. This requires that applications and solutions that provide such data need to be robust, interoperable, and interfaceable so that a contemporaneous holistic patient record is maintained; wherever the patient is to be treated. The EuroREC application system standards and Seals of accreditation which already have wide acceptability across Europe can contribute to this, as can multi-national research projects like ePSOS.
  - b. As the use of technology to deliver support to the health domain becomes more complex and trans-national, the apps / solutions and services must be operated and managed by recognised professionals in health informatics. Ideally they should be recognised by common standards of competence across the EU; or at minimum standards that can be cross-mapped without inconsistency, such that the handling of records (including generation, management, extraction, analysis, interpretation and presentation) does not introduce risk to patient safety. In addition to the competences of the health informatics specialists any clinician or manager involved with health or patient-related information sources or use should have the appropriate subset of the same competences embedded in their capability, through additions to the curriculum of their discipline or continuing professional development.
  - c. The UK Council of Health Informatics Professions has a wide-ranging set of standards already developed and in operational use to recognise professionals operating 'in and for' the UK health sector. The standards are being considered for deployment in Ireland and are now being recognised by the ProREC national centres within the EuroREC family. The standards have already been mapped to the requirements of many other professions who have information handling within their

job roles; and also being evaluated against the Modernising Scientific Careers requirements with a view to incorporation of health informatics as a health science and recognising health informatics within the over-arching quality scrutiny of the Professional Services Authority <check title>.

2. What evidence is there that EU action in health advantages or disadvantages :
  - a. The UK national interest
    - i. consistent recognition of UK health informatics professionals to standards that are widely accepted and understood internationally gives the UK staff potential increased mobility; conversely if the UK requires added capacity at any time, (for significant events like health and social care convergence) to be able to recruit to the national standard will result in that process identifying like-minded domain-sensitive professionals who can hit the deck running.
    - ii. UKCHIP also has an established course accreditation system (EQAS) by which both commercial and academic offerings are recognised against the health informatics standards. Thus, graduating students from EQAS-recognised courses can gain registration as 'fit to practice' in an efficient manner, having pre-compliance with existing development opportunities. This can affect both students and stimulate additional student enrolments onto UK courses.
    - iii. UKCHIP standards use could present a *fait accompli* restraint of trade or mobility barrier to non-UK students and non-UK active personnel wishing to get jobs in health informatics, IF UKCHIP was not taking steps through working with and informing other countries and nationals of the standards content and processes of registration and certification to facilitate replication and roll-out across Europe.
  - b. Business and Industry –
    - i. Improved mobility for recognised professionals, knowledgeable about the domain and working to a consistent code of conduct – can provide an additional quality resource capacity for systems development and service provision,
    - ii. Such a resource can contribute to improved input of UK workforce into EU projects and, vice versa additional registered resources can enhance the attractiveness of UK participant organisations (SME, operational, academic or corporate) into multi-national EU-funded research
  - c. Patients and citizens –
    - i. UK patients benefit from effective, efficient, efficacious electronic patient records solutions developed by a professional workforce
    - ii. The UK public benefit from professionally-produced population indices, clinical evidence databases and functionality; in terms of well-defined population demand management systems and analytics, fast response to epidemic / pandemic situations and efficient health facility management

- iii. Adherence to a professional Code of Conduct (such as that of UKCHIP) can go some way towards reducing inappropriate personal information manipulation
  - iv. Health Informatics professionals can contribute to the provision of quality information handling solutions eHealth, telemedicine, mobile health and personal health apps for citizens
3. What evidence is there to demonstrate:
- a. The extent to which the EU's role in public health supports member state actions effectively and efficiently
    - i. Research-funded projects encourage contributions to consistency between operational health processes for example the EU-funded EuroREC ([www.eurorec.org](http://www.eurorec.org)) seals contribute to a process of harmonisation between EHR systems, favouring in Europe cross-border interoperability of those systems.
    - ii. The networking and responses of the eHealth Stakeholder Group have facilitated an extension to the agenda from solutions' interoperability to, as expressed in the EU:US Memorandum of Understanding (EU:US Memorandum of Understanding (the 'MoU') on Cooperation surrounding health-related Information Communication and Technologies (2010)). Policy commitments such as '*Strategies for development of a skilled health IT workforce and of eH/HI proficiencies in the health professional workforce such that clinicians can fully utilise the technology's potential to enhance their professional experience and performance*' address both HI specialists and those who require selective embedded skills in HI to carry out their daily work
  - b. The opportunities and costs for delivery of health and social care in the UK that flow from wider EU competences and policies such as the free movement of workers or the Single Market generally
    - i. The movement of professional health informaticians across Europe is constrained by the fact that the cross-recognition of qualifications applied to doctors, dentists, pharmacists, nurses, midwives, veterinary surgeons and architects qualifications does not apply to our discipline
    - ii. Shareable patient records developments may provide underpinning clinical information to contribute to safe and cost-effective management of clinical interventions, medical tourism, personal accidents abroad and disaster incident responses. Developments are ongoing including accrediting records' systems (EuroREC) to utilising the Cloud, making primary care records web-accessible.
    - iii. OJEU (formerly OJEC) procedures are in place to facilitate bidding by any qualified provider to develop patient records' applications and related systems / solutions
  - c. The extent to which EU competences and policies intend to allow EU citizens to access healthcare across the EU are effective and proportionate
    - i. Quality informatics solutions give controlled, secure, robust access to patient records, which can support increased workforce mobility and travel across the EU for pleasure purposes. As improved access to these systems is generated, this may stimulate more cross-border activity. The necessary solutions do have

to be designed, developed and delivered by domain-sensitive professionals and rather than evaluate competences on an individual basis, UKCHIP registration can provide confirmation for health informaticians involved in these processes

- d. The extent to which health objectives are effectively and proportionally taken into account in wider EU policies
  - i. UKCHIP involvement as a contributing member of the EU eHealth Stakeholders Group through EuroREC, majoring on workforce issues. It is evident that the principle of synergy and subsidiarity confuses the achievement of a clear view of health initiatives, as they are currently lead by different EU Directorates, there is NO diagrammatic representation of which unit is responsible for what areas and it is challenging to bring together policy and practice

### **Future options and challenges**

1. How might UK benefit from the EU taking more action in health?
  - a) If existing UK-created health applications solutions and services (including EHR, prescribing, telemedicine) are rolled-out to other EU countries and are accredited to existing EU (EuroREC, ISO and HL7 standards)
  - b) If UK qualified health informaticians are registered professionals and UKCHIP standards are adopted / adapted across EU
  - c) If the Cross-border accreditation of those in the health domain was extended to recognise health informaticians per se and health informatics competences where embedded in other medical / clinical and health management curricula
2. How might UK benefit from the EU taking less action in health, or from more action being taken at national rather than EU level
  - a) Clearer definition and delineation of responsibilities
  - b) At national level:
    - i) if the DH recognised health informatics as a health science
    - ii) confirms the need to have a health informatician (or someone with health informatics competences) at Board level to facilitate good information handling to support UK health care delivery and management
    - iii) takes steps to encourage a more open / wider market for products and services to generate informatics solutions and services to support the health market across the home countries; generating a benefit to UK markets, exploitation of UK products across Europe and improvements in the tools that support health in-house and stimulate greater citizen involvement in their own health and lifestyle management
3. How could action in this area be undertaken differently
  - a) Are there ways of improving EU legislation in health
    - i) Continue funding innovative cross-border health research and development projects
    - ii) Produce graphic representations of health legislation, actions and responsibilities by Directorate, and make these available openly

- b) Are there ways the EU could use its existing competence in health differently to deliver more in the national interest
  - i) As above in 3a)
  - ii) Resolve issues around telemedicine services, professional recognition, qualifications comparability and market eligibility for products
  - iii) Produce a clear glossary of terms to resolve confusion in cross-border use, as for example 'medical', eHealth, medical device, health technology are confused in our domain
- c) Action at WHO level, legislative / non-legislative action -- no comments at this time
- 4. How else could UK implement its current obligations
  - a) Review its cross-border capability, national capacity and carry out risk analysis re technology deployment and human resource availability to operate effectively in the EU space
- 5. What future challenge/opportunities might we face in EU health competence and what impact might these have on the national interest
  - a) Increased mobility for business and pleasure purposes will place a pressure on existing health information sources, services such as telehealth and workforce recognition, capability and capacity to respond (4a relates); conversely will provide extensive market opportunities for UK products and research deliverables
  - b) Increased citizen involvement in their own health and lifestyle management will put a tension on the provision of health histories wherever and whenever required on a cross-border and increasingly global basis
  - c) Future enlargement of the EU would require additional multi-national input / resource to achieve continued stability and quality of both products and workforce
  - d) The current EU:US Transatlantic eHealth/health IT Cooperation Roadmap (the 'Roadmap', draft Jan 2013), EU:US Memorandum of Understanding (the 'MoU') on Cooperation surrounding health-related Information Communication and Technologies (2010)) demonstrate formal interest in issues including workforce flexibility, recognition and mobility of the workforce. The UK needs to recognise the potential impact of such initiatives more clearly, and identify a strategic resource to monitor, inform and capitalise on such activities; which could prove positive or negative to the UK.

### **General Published Sources of Supporting Information**

UKCHIP website, [www.ukchip.org](http://www.ukchip.org)

UK Health Informatics Career Framework [www.hicf.org](http://www.hicf.org)

Roberts J, Reflections on right-sourcing in the health domain, commentary on health implications of Sparrow EA, A Guide to Global Outsourcing: Offshore outsourcing and other Global Delivery Models, [www.bcs.org/content/conWebDoc/3930](http://www.bcs.org/content/conWebDoc/3930) (2004)

NHS patient records to revolutionise medical research

<http://www.guardian.co.uk/science/2012/aug/28/nhs-patient-records-medical-research-revolution>

eHealth: Legal, Ethical and Governance Challenges Editors: Publisher Springer-Verlag Berlin Heidelberg ISBN 978-3-642-22473-7. (c) 2013.

Travelling Well: Essays in Medical Tourism, Transdisciplinary Studies in Population Health Series – Vol. 4, Iss.1, 2013. Ed. Ronald Labonté, Vivien Runnels, Corinne Packer and Raywat Deonandan.

Learning to Manage Health Information: a theme for Clinical Education (2012)  
[http://www.cln.nhs.uk/eice/images/learningtomanage\\_12.pdf](http://www.cln.nhs.uk/eice/images/learningtomanage_12.pdf)

## Very Low Calorie (VLCD) Industry Group

The Very Low Calorie Diet (VLCD) Industry Group is the trade body for manufacturers and distributors of VLCD products set up to campaign for appropriate policy and legislation for slimming foods. VLCD Industry Group members provide products for weight loss programmes designed for the very overweight and obese. Both Low Calorie Diets (LCDs) and VLCDs are formula food diet programmes that are nutritionally balanced with key vitamins, minerals and other necessary nutrients, and are designed to replace more traditional meals to facilitate maximum weight loss.

The VLCD Industry Group welcomes the opportunity to comment on the Defra's review examining the balance of competences between the UK and the European Union. In particular, the Industry Group's response will focus on Section B of the consultation document, as the area of food safety, labelling, food quality and compositional standards is of particular relevance for the activities of the Industry Group's Members.

### **1. What evidence is there that EU action to create the single market for food has been advantageous or disadvantageous for the UK?**

The VLCD Industry Group believes EU action aimed at creating a single market for food has been broadly advantageous for British businesses, facilitating the free movement of goods and providing them with the opportunity to take advantage from a certain consistency of provisions across Member States. While harmonisation and further integration in areas where Member States share common issues is certainly desirable, we believe that often patchy implementation of EU legislation at the national level has meant the aim of the single market has been achieved only partially.

In addition, we believe that the EU should not seek to achieve further harmonisation for its own sake and at all costs. In areas where Member States display significant differences in terms of market configuration, consumers' preferences and in general do not have the same characteristics, a push for harmonisation often result in negative consequences for businesses and consumers alike. In the case of Britain, businesses are often over-regulated or swamped by rules designed to address issues which are not directly relevant or applicable in the context of the British market.

### **2. What evidence is there that the national interest in terms of trade is best served by action at the EU level, national level or by action being taken at a different level, e.g. in Codex Alimentarius?**

Actions at the EU or international level are only opportune in specific areas where cross-border co-operation is identified as the most efficient and cost-effective solution to deal with particular problems. Such actions should however always be based upon thoroughly conducted impact assessments.

As an example, while it is beneficial for both consumers and businesses that the same food safety standards apply across the EU, it is also essential that food legislation takes into account the particularities and different consumer needs across the continent.

**3. Has EU action in food law provided the right balance between protecting the consumer and protecting the interests and reputation of UK businesses?**

The VLCD Industry Group believes EU action aimed at achieving further harmonisation and integration between Member States in the area of food law could be advantageous for British businesses, although only in areas where Member States experience similar issues. In these areas, EU action could be positive by ensuring that standards based on science are applied in the whole European territory. With competence in the areas of food safety, labelling and nutritional information, the EU is in a privileged position to exert a coordinating role where Member States experience similar issues, offering common solutions.

However, too often the EU seems to aim for harmonisation at all costs, causing the emergence of situations in which British businesses are over-regulated or swamped by rules designed to address issues which are not directly relevant or applicable in the context of the British market. In addition, EU regulations are often too complex and a significant burden for businesses, and we would urge the Government to redouble its efforts towards achieving greater simplification.

The Industry Group would also like to point out that the excessive complexity of EU regulations has other negative consequences, as it is a significant factor in the divergent interpretation and implementation of rules across the EU. Of course, when divergent implementation does not respond to the need to take into account national differences, but is caused by lack of clarity in the rules themselves, the result is an increased regulatory burden without the correspondent gain which should be provided by market harmonisation.

**4. Is there evidence that legislating for consumer protection at the European level has been advantageous or disadvantageous to the UK national interest?**

We believe that in the area of food law and slimming foods the legislative activity of the EU institutions has so far been positive for consumer protection. However, as the EU institutions plan to develop further legislation in this area – for example through the revision of the Framework Directive (39/2009/EC) on foods intended for particular nutritional uses – it is very important that over-regulation is avoided. Over-regulation is not only detrimental for businesses, but also for consumers as it causes confusion and often derives in different interpretations and implementation between Member States.

**5. What evidence is there that the principle of science based food legislation at the European level has served the national interest well? Are there any concerns about the principle and its application? Are there any examples of where it was not followed?**

The VLCD Industry Group greatly supports the principle of science-based food legislation at the EU level and would like to see it properly implemented in all occasions. Sadly, we believe that this principle has often been relegated to a second plan in favour of political considerations during negotiations of important pieces of legislation in the food policy area.

In particular, we would mention the example of the Nutrition and Health Claims Regulation (1924/2006/EC), which has seen the Commission rejecting a certain number of health claims based on political concerns rather than on science.

**6. What impact has the EU taking on the representational role at the Codex Alimentarius Commission had on the UK national interest?**

No comment.

**7. How might the UK benefit from the EU taking more or less action on food law in the future?**

The area of food law, as far as slimming foods are concerned, is already widely regulated by EU legislation and we believe that further action at EU level will only be necessary in areas where Member States share similar problems which could be resolved by taking coordinated action through the EU institutions.

**8. Could action be undertaken differently e.g. are there ways of improving EU food law?**

The responsibility to implement EU legislation in the area of slimming foods is left to the Member States and their competent authorities. This may lead to certain inconsistencies and divergent interpretations between Member States, something which make it difficult and costly for businesses to operate across borders. The EU could work to identify problematic and unclear provisions, providing relevant guidance before legislation is implemented.

In addition, we believe that enhanced cooperation between national competent authorities would go some way in reducing the negative consequences caused by inconsistent application of EU legislation, while also contributing to share knowledge and best practice resources in areas where there may be a lack of clarity regarding correct implementation.

Another area where the VLCD Industry Group believe action could be undertaken differently is that of pre-legislative scrutiny for new European laws. In particular, we believe that before a measure is considered at EU level, it should be suitably assessed through both national and EU-level impact assessments. Such a procedure would avoid the emergence of situations in which a piece of legislation adopted by the EU institutions turns out to have a number of unintended consequences, often negative, caused by the lack of consideration for national circumstances.

This is the case, for instance, with the Nutrition and Health Claims Regulation (1924/2006/EC), which has seen a vast number of long-established claims being rejected and others, including the only VLCD claim, still on hold. In addition, confusion and lack of coordination still persists in most Member States as to the exact rules governing the implementation of the positive list of general function (Article 13.1) health claims which entered into force in December 2012.

Finally, we believe that too often Government officials have not taken a sufficiently active role in negotiations between Member States in the area of slimming foods policy, failing to adequately

defend the positions of British businesses at crucial times. We therefore urge the Government to renew its efforts towards ensuring that it provides an effective contribution and plays a prominent part during future negotiations in this area.

**9. What future challenges or opportunities might we face in the area of food law and what impact might these have on the national interest?**

We understand that the Commission will shortly undertake work to establish specific compositional and information requirements for total diet replacements for weight control. This follows the recent compromise reached by the EU institutions over the Commission's proposal revising the current Framework Directive (2009/39/EC) on foods intended for particular nutritional uses.

This new piece of legislation will have a direct impact on British businesses which produce and sell slimming foods. It will be therefore crucial that these new rules are based on appropriate scientific evidence rather than political considerations.

In particular, we believe that the Government should closely follow the progress of work in this area, which will see a scientific assessment prepared by the European Food Safety Authority (EFSA) in the first instance. Following the completion of the scientific assessment, we believe the Government will need to actively participate in negotiations between Member States, to ensure that the rules finally set by the Commission are based on sensible scientific evidence rather than on political considerations.

**10. Are there any general points you wish to make which are not captured in any of the other questions?**

No comment.

## Welsh Government – Department for Health, Social Services and Children

The Minister for Health and Social Services for Wales has considered the call for evidence.

The overall view of the Welsh Government is fully supportive of the UK's full EU membership. In the health field there are good examples where action of the EU has been helpful to Wales, for example in facilitating working with other EU countries on healthy school development, which has seen Wales acknowledged as one of the European leaders in the field, Wales was also involved from the start in the Smokefree Class Competition which was developed at European level and allowed exchanges between Welsh and EU pupils.

In addition, the EU has created through its various initiatives opportunities for Wales to share and learn with other parts of Europe in tackling thorny issues such as health inequalities. An example here is the EU Joint Action on Health Inequalities (2011-2013), which aims to identify good practice, share learning and develop a multi-level approach to tackling health inequalities. The Welsh Government is a national partner in two workstreams: 'tools' and 'regions'. The 'tools' workstream aims to promote a health equity focus in policy making, supported through tools such as Health Impact Assessment. The 'regions' workstream aims to build sub-national and regional capacity to address health inequalities and to share experience, lessons learned and progress within and across member states.

A further area of co-operation is in developing new data sources that illuminate problems and performance in different countries. An example here is through the development of the [European Community Health Indicator set](#). This consists of common definitions of data that allow comparison and benchmarking with other European health systems. This is valuable in being able to assess levels of performance, provide an impetus for building relationships and drive greater work to improve and protect the health of citizens.

There are other important areas of engagement including work on the healthy ageing initiative.

A point of concern is that the competence of the EU is not extended in unexpected or burdensome ways. For example, decisions of the European Court of Justice leading to the development of the directive allowing patients to receive health care elsewhere in Europe at the cost of their home country, have gone against the understanding that management of health services is the prerogative of the member states.

The result is that all of the states are having to put in arrangements to address this and in essence are being drawn into a single EU health service. This goes against the idea of the NHS in Wales being organised around the needs of Welsh people and money being invested and reinvested in the NHS in Wales.

## West Hertfordshire Hospitals NHS Trust

Our Trust (West Herts) have discussed some issues which we believe has a huge impact on our hospital, the NHS countrywide and UK resources – please see attachment.

- UK population – increase in numbers of people living in the UK which is leading to overcrowded hospitals, lack of bed availability, lack of resources available in hospital settings. Also leads to a dramatic increase in waiting times for both hospital appointments, waiting lists, etc
- GP surgeries – longer waiting for GP appointments due to too many people registering with GP's
- Issuing of NHS numbers to EU Nationals & newborns – should be issuing temporary NHS numbers to avoid people leaving the country and being able to return months or years later to receive further treatment
- EU members arriving in the UK pregnant – often almost at term to deliver babies then claim to be permanent residents but lack of documentary evidence to confirm this. Unemployment, receive benefits as soon as they arrive (i.e. maternity exemption certificate, tax credit exemption, child benefit, job seekers, housing, etc) Also, not being asked to provide any documents to confirm their residency here whilst applying for benefits. (application forms for benefits)
- Schools/Education – EU member children being offered nursery/school places when there is already a lack of availability for children resident in the UK
- EU Nationals – should be chargeable for certain period i.e. 12 months from arrival – particularly for elective treatment
- Elderly relatives from EU member states – increase in elderly relatives coming to the UK claiming to be taking up permanent residency. However, they have made no contributions to the UK and do not have sufficient documents to prove their move to the UK. They live with relatives and end up being a burden on resources
- Interpreters – increase in the use of interpreters for EU patients. Not only do they receive NHS care/treatment but there is also the additional cost for interpreters
- EHICS – there still seems to be many patients who do not have or are not aware of EHIC cards to cover the costs of their emergency treatment in the UK
- Issue of British Nationals who have are living in other EU countries and returning to the UK specifically for treatment

York Health Economics Consortium Ltd

[http://www.audit-scotland.gov.uk/docs/health/2010/nr\\_100617\\_medical\\_locums.pdf](http://www.audit-scotland.gov.uk/docs/health/2010/nr_100617_medical_locums.pdf)

<http://www.nao.org.uk/report/improving-the-use-of-temporary-nursing-staff-in-nhs-acute-and-foundation-trusts/>

## Members of the Public

I have today watched the proceedings in the EU on the TPD debate and frankly I am appalled. That these uninformed individuals, using a poorly scoped sample of 'experts' are due to reach conclusions on what is a life and death matter for many beggars belief.

There is the potential for a life saving harm reduction approach which is being almost completely ignored probably due to ignorance of research or, and I do hope not but fear so, influence of pharmaceutical companies.

Please, will some sensible individuals look at the research on SNUS in Sweden and electronic cigarettes . These two items alone could cut smoking within the EU by unprecedented amounts and if the EU will not listen then the UK must make a stand alone.

I have long been a supporter of the need to deal with matters in the real world and failure to so will lead to millions of unnecessary deaths due to tobacco consumption.

Please read the peer reviewed research on e-cigarettes and snus.

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It is with alarm that I learn the EU plans to treat e-cigarettes as a 'medicinal product'. This is likely to involve regulations leading to higher manufacturing costs, and a consequent increase in price to the consumer.

It is vital that the price of e-cigarettes is kept competitive. I gave up smoking after smoking 20 cigarettes a day for 40 years, by switching to e cigarettes. They worked when all other options siuch as gum and patches had failed dismally. Many other long-term smokers have found the same.

I trust the British government will not allow the EU to interfere in this market, or do anything to increase the price and reduce the take-up of e-cigarettes. I believe it would be extremely damaging to public health.

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I write with respect to evidence of the EU Competencies regarding the Tobacco Products Directive.

In 1992 the EU banned the sales of snus – without full and proper research. There was no evidence that properly prepared snus created the major health risks of smoking, Sweden, refused to implement this law and as a result, has the lowest adult male lung cancer rates in the developed world.

The EU is now proposing to implement a similar ban/restriction on electronic cigarettes under the Tobacco Products Directive.

The main components of the vapour in electronic cigarettes are propylene glycol and / or vegetable glycerine - which typically account for 90% or more of the volume. Both these are known to be benign and are used, for example in inhalers and nebulisers produced by the pharmaceutical industry and in wide use. The third component is nicotine, typically at a dose of 12 mg/ml to 36 mg /ml. At these dosages the toxicity is low and as users are ex (or current) smokers with high tolerance ,the LDA levels for nicotine are not an issue. The forth

component(s) are flavourings and those produced by major flavour houses within the EU are tested for toxicity and potentially harmful materials such as diacetyl excluded or removed. The potential benefits of this emerging market are substantial – the health risks several thousand times lower than smoking. Additionally the products are self adopted, self purchased and self administered and proven to have a far more effective result at keeping users off cigarettes than any of the NRT products on the market and are far less dangerous to use than some of these. The EU proposes to remove the efficacy of these and hand the product over to the pharmaceutical industry to exploit.

It is difficult to see how this is either in the interest of the public or public health. The only beneficiaries will be the pharmaceutical companies that will, have an effective competitor for NRT removed and be free to adopt and develop the technologies to their own profitable ends. Users, meanwhile have indicated that their likely recourse if this takes place will be to return to cigarette consumption, increasing the health burden and presumably guaranteeing the pharmaceutical industry the market for COPD and cancer treatments that electronic cigarettes threatened to reduce.

The proposal under the Tobacco Products Directive can be seen to be against public interest, against public health and as illogical as the EU's earlier ban on snus.

As a user of a personal vaporizer (electronic cigarette) I have found many benefits – I have now ceased smoking and feel healthier. I had previously tried prescription and non prescription nicotine replacement therapies to little effect. Possibly the worst of these was varenicline (Champix) which made me feel miserable and led to some strange behaviour. In contrast the personal vaporizer (electronic cigarette) was easy to adopt and as I increased my usage, my desire for cigarettes fell. Over the next year I plan to reduce the nicotine levels I use overall. Having the freedom to control these is important – the most difficult cigarettes to eliminate were the work tea break ones and a high (relative) nicotine content solution (42 mg /ml) was the course to this, whereas in the evenings I found I was content with 12 mg /ml and a 24 mg /ml for general daytime use. Not only does the EU propose to deny me access to this device and the nicotine 'e liquids' I need to use it, it proposes to make the solutions available at such low concentrations that they will be ineffective.

I find the EU competence in this to be lacking. I question the motivation and given the recent levels of bribery and corruption within the Commission concerned, have to question whether there is a vested commercial interest behind this proposal. Electronic cigarettes may be good for the public and public health, but they pose a threat to the revenue streams of the pharmaceutical industry.

In contrast NICE has evaluated electronic cigarettes from the point of their risks, their relative risks in comparison to cigarette smoking and the potential role they could play in the Tobacco Harm Reduction strategy. It's findings are both credible and balanced and take into account the best public interest.

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I'm writing to you regarding a matter which is of a serious concern to me. I realise you are very busy so will try and be as concise as possible.

I have been a heavy smoker for over 30 years. I've attempted to stop by using every form of NRT available and failed every time.

Eighteen months ago I was introduced to the concept of the personal vapouriser, also commonly known as electronic cigarettes. This is a device like an aromatherapy vapouriser

which works with a glycerol liquid containing a small amount of nicotine - typically 18mg/ml. This simulates all the pleasure of smoking without the deadly effects.

There are many advocates of this form of harm reduction - notably Prof. Gerry Stimson (Addictions advisor to the WHO) and Clive Bates (former Director of ASH).

It's readily acknowledged that nicotine, like caffeine, isn't 100% safe, but it's certainly safer than smoking tobacco. What's more, e-cigarettes do not contain the 4000+ carcinogens which tobacco does.

By using e-cigarettes, I stopped smoking tobacco immediately, painlessly and without any effort at all. Given that tobacco kills 50% of its users, I don't think I'm exaggerating by saying that e-cigs have likely saved my life.

My point of concern is that the proposed changes to the EU Tobacco Regulations ([http://ec.europa.eu/health/tobacco/docs/com\\_2012\\_788\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/com_2012_788_en.pdf)) amount to nothing less than an effective ban on e-cigarettes at worst and, by reducing the nicotine content to 4mg/ml, making them as ineffective as NRT at best.

E-cigarettes are not a smoking cessation or medicinal product designed for people to quit smoking. They are a method of continuing to use nicotine with greatly reduced risk.

Attempting to classify and regulate these devices as a medicine when tobacco can still be bought over the counter is disingenuous at best and this policy -will- result in an unnecessary loss of life.

I'm sure you don't need me to tell you that continuing to sell tobacco in corner shops while legislating against a proven reduced-harm alternative is both immoral and absurd.

I trust that you will consider what I've written and look forward to your reply.

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Please do not adhere to or implement any EU or other regulations which inhibit or regulate electronic cigarettes – they are fantastic and have stopped my smoking.

I believe an assault on these will drive people towards smoked cigarettes (and if these are increasingly taxed, dangerous counterfeit ones).

I know the EU is subsidising Romanian and Bulgarian tobacco farmers, but we don't need to maintain their industry further by making e-cigarettes restricted.

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I am submitting my views though I doubt very much they will be listened to as it seems that the unelected powerhouse, otherwise known as the World Health Organisation has already decided that no one should be allowed the freedom to choose whether they wish to smoke or not! So much for democracy, exactly when did democracy die?

It is well known that e-cigarettes are infinitely better for the consumer and it is also well known that many hundreds of thousands of people have weaned themselves off cigarettes thanks to the e-cig, so why are the EU in motion to ban e-cigs? As a non smoker who has lost nine (yes 9) family members to various cancers, even though none of them ever smoked, it seems to me that to have such devices regulated via a medical means only fuels the flames of discontent

insomuch that all these ridiculous smoking bans are clearly emplaced to benefit the big pharmaceutical giants. Why else would regulation be needed?

This EU motion also goes directly against the principles of free trade, something the EU is seemingly 'hot on' having seen the minimum pricing farce in Scotland totally scorned by that same EU!

The whole thing is very unsatisfactory, people will never stop smoking for the simple reason that they obviously enjoy smoking! Also, note the Danish study which clearly found against non smoking longevity in financial terms-where is our now impoverished Welfare State fund going to find all the £bns needed to finance all these people that are supposedly going to live longer? We have 10,000 centenarians already-how are we going to afford another 10,000?

For the love of God and all his subjects, be they smokers or non smokers, leave smokers and their enjoyment alone for no one has proved that SHS has actually killed any one and it certainly hasn't been proven that the smoking ban has extended one single persons lifespan as yet-and never will !

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I am writing this letter because I want to make clear to you firstly, how the new directive of the European Parliament regarding the manufacture, presentation and sale of tobacco products will affect me personally as a user and a voter. And secondly just to inform you, if you don't know already, exactly what a personal vaporiser (or electronic cigarette / eCig) is.

I live in Woolacombe, North Devon, and will be turning 23 this month. I started using electronic cigarettes November last year. So I have been using them for about three months. Before that I smoked up to 50 traditional cigarettes (or analogues as we call them) a day. I had tried other forms of nicotine replacement. And they just did not work. And at that time I didn't want to give up smoking tobacco. But as soon as I tried a eCig I instantly realised that not only did it satisfy my cravings. But it was more pleasurable than tobacco. And to a smoker the enjoyment is what matters most. this is what nicotine replacement can not give you. It is important to have the freedom to find a style that suits you be it flavour, strength, look, feel, and so on.

Since I have converted the first thing I have noticed is that my sense of smell has returned. I no longer wake up in the morning with my lungs feeling like they are on fire. I can breath clearly. And I don't stink.

I do not want to give up nicotine. I find it calms me, helps me concentrate and focus on my goals. I do not consider myself to have a disease, therefore I do not need medicine. Electronic cigarettes are not intended to help you with nicotine dependency. They are only a healthy way if getting nicotine into you're body. Which means if they were to be regulated as a medicine, and justified on the therapeutic value in helping with nicotine dependency. Then they would not be accepted by the medical community. And I am certain that my doctor will not be willing to prescribe me something that will not help with what he/she considers to be the problem, which is my dependency on nicotine. So the idea that they will be available on prescription after the regulations are put in place in a myth. But if they were, then it would only be for a period in which my doctor felt I needed to give up nicotine completely. Possibly a maximum of a year. And as I intend to live for at least another 50 years. You can see how this would not be a solution.

When I first started the safety of eCigs was a concern. So I took it upon myself to research the issue thoroughly before I started. There a few different base liquids to choose from when buying

liquid for electronic cigarettes. The most common of which is Propylene glycol (PG). The term PG refers to a family of organic compounds which are used in anything from pharmaceutical and personal care products to antifreeze. And the type of PG used in eCigs is the same as that used in fog machines. So if you have ever been to a disco then I'm sure you have already felt the effects of inhaling large amounts of PG. And it is certainly considered safe for DJs, bar workers, theatre workers, and even children to work around the substance for long periods of time.

"propylene glycol was classified by the U. S. Food and Drug Administration as "generally recognized as safe" (GRAS) for use as a direct food additive."

Wikipedia

there is also an alternative to PG called Vegetable glycerine (VG) I personally only use 100% VG in my liquid because not only do I prefer it. But there is no known health concerns with it. some people prefer PG because it gives what they call a 'throat hit' as to say it feels more like tobacco smoke as it goes down the throat. Where as some people like me prefer VG because it produces a bigger and fluffier cloud of vapour when it is exhaled. And some people use a mixture of the two. an option would be to possibly allow VG while more studies are conducted with PG, if it were shown to be absolutely necessary.

Now to say that we don't know what is in eCigs is at best a bending of the facts. The list of ingredients that I have on my bottle of liquid here is certainly more extensive than what you would get on a packet of cigarettes. But it is impossible to know much more than 99.9% of the content of any consumer product. Like frozen beef burgers. However as a user I am not concerned about a possible risk of 0.1%. if however there were a risk of the content being misrepresented. And a harmful substance was put onto the market my some shady company. Then this is where I certainly would say that regulation is necessary. Recent events have highlighted how important it is to consumers that we know what is in what we are buying. But banning or over regulating the whole category into obscurity is simply overkill.

Now the suggested amount of 4mg of nicotine per ml of liquid in 1ml doses is, as any eCig user will tell you completely unworkable. Allow me to use my own habits to illustrate why. As I have said, before I started using eCigs I smoked roughly 50 analogues a day. So 2-3 per hour. And yes I was very addicted. And it had a major impact on my health. An accurate figure of how much nicotine is in a cigarette is 1-3mg. Now the cigarettes I used were very strong so I think it is safe to say each one contained 3mg. Now with my eCig I use refillable cartridge. And I buy the liquid separately to refill them which it makes it much much cheaper for me. And cost is my a major concern . The liquid I use contains a concentration of 36mg of nicotine per ml of liquid. And a cartridge will hold roughly 1ml. At a rate of about 1 puff per minute. this will last me about 4 hours. So to summarise with the electronic cigarette I consume 12 cigarettes worth of nicotine in the time I would have had 12 cigarettes. If these regulations were put in place, simple maths would show you that I would have to puff once about every 5 seconds, and a cartridge would last about 10 minutes. And I would need nearly 100 cartridges a day. With a 1ml limit that would only allow for the sale of pre filled cartridges that cannot be refilled. And as a cartridge could not possibly cost less than £1 due to cost of production. that would make it impossible for me to use them. As what now costs me roughly £5 a week would then cost me £700 a week. I would have no choice but to go back to tobacco.

I want to make it clear that I am not against smoking lit tobacco. And am not supporting this from an anti smoking point of view. I think informed adults should be able to do what they want with there bodies. And I myself very occasionally will have one traditional cigarette, say every couple of weeks. But I am so happy that I no longer have to rely on something that is so detrimental to my health to get that nicotine.

However I think that young people should not have access in any way to addictive substances. Although all vendors have entered in an agreement that they will not sell to persons under 18. it is at the moment not illegal for young people to buy eCigs in this country. I think this is wrong. And again I think that this is a case where strict regulation is needed. But banning a substance has not been shown as a good way to stop it getting into the hands of young people. From my experience as a youth worker. It is easier for a young person to acquire cannabis than alcohol. This is because the person selling cannabis is already a criminal. And has nothing more to lose by selling to a child. But an alcohol vendor is accountable. And could lose there licence. It is as simple as that.

So to summarise. This directive would spell the end of electronic cigarettes. And force me and many people like me to go back to smoking tobacco. And killing ourselves. eCigs have saved my life. They are not a fad, but a new lifestyle. And now you know this, I hope you will use this knowledge and communicate it to you're peers. And allow us to access to a healthy alternative to tobacco which I am sure will save many lives

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1. **Summary.** In summary, this submission proposes that competence to ban or to allow oral tobacco ('snus') to be placed on the market should rest with member states, not the EU. However, where member states do allow it, the concepts of the single market should apply and product quality regulation should be harmonised to secure a high level of health protection.

2. **Subject for realignment of competence: oral tobacco.** I would like to draw your attention to one area of policy that causes harm to health by virtue of European Union level competence. That is the policy regarding 'oral tobacco' (tobacco for oral use that is not inhaled or chewed), often known as snus. Oral tobacco is banned throughout the EU, with the exception of Sweden, under Article 8 of Directive 2001/37/EC and would remained banned under the Commission's proposed revision to the Directive COM(2012) 788 final - Article 15.

3. **Evidence.** There is no justification for this ban on scientific, ethical or legal grounds (see my review [Death by regulation: the EU ban on low-risk oral tobacco](#)). Sweden has the lowest smoking prevalence by far in the EU (13% vs 28% average - Eurobarometer 2012 survey), and has the lowest rates of smoking related disease as a result. The risk reduction associated with snus is use exceeds 90% and it is likely that the low-nitrosamine version of this product carry minimal cancer, cardiovascular and lung risk - certainly far lower than cigarette smoking. It is clear beyond doubt that in Sweden, oral tobacco displaces cigarettes use and facilitates smoking cessation. There are no signs of significant 'gateway effects'. The effect of snus in Sweden, and in Norway, is unambiguously positive for health. Yet through EU decision-making, this product remains subject to an unjustifiable ban. I attach letters from scientists making the case for lifting the ban and replacing this with a regulated market.

4. **Reason for the ban.** The reason for the ban is essentially political - all other attempts at justification have been quite convincingly dismissed. For countries where there is no history of this product, where it is hard to envisage its beneficial effect, or where decision-makers simply don't want to take on the reputational risk, lifting a ban on a tobacco product comes with political cost and no obvious political gain. The real-world effect of this is to give greater weight to

looking tough on tobacco than to real health outcomes and to the rights of consumers to have access to safer alternatives to cigarettes where such alternatives exist. Whilst that is an explanation, it is not a justification. The current balance of competencies allocates competence to the European Union - but the effect of that is to lock in a ban and prevent any country that does see the advantage of a harm reduction strategy based on oral tobacco outvoted by those that do not.

**5. Opportunity to do better by realigning the balance of competencies.** However, it is not impossible or implausible that a 'harm reduction' market in oral tobacco could develop in some Scandinavian, North European or Baltic states, where the product is more familiar and where decision makers are closer to the experience of Sweden and Norway and have a better instinctive grasp of the benefits. Why should they be prevented from doing this, because the idea does not find favour in Spain, Italy or Germany? We should also consider the possibility that the UK will adopt a more robust evidence-based approach to tobacco harm reduction at some point in the evolution of its tobacco policy - perhaps recognising that certain groups have particular needs for alternatives to cigarettes (ageing low income smokers, people with psychiatric conditions etc). It should not require the re-opening of an EU directive and securing a qualified majority for UK ministers to decide that this product should be available in some form in the UK - no other member state would be harmed or affected at all if they were to do this, yet there could be significant health benefits in the UK.

**6. Proposed realignment of competencies.** A split competence is proposed for oral tobacco:

(1) allow members states to take the decision on whether to ban or allow oral tobacco - this would determine the geographical extent of the single market in oral tobacco and would in effect allow members states to opt-in to the exemption that Sweden already has, though via a different mechanism. As with Sweden, members states where the product was permitted would still have the obligation to prevent sales in members states where it is not. It does not, therefore, create significant new points of principle or practice.

2) Once the geographical extent of the market is established by member states, then the European Union should impose a harmonised regulatory standard for those countries where the members states have opted in to allowing sales of oral tobacco. The standard could be that proposed by the WHO's TobReg Committee, a variant on the voluntary 'Gothiateg' standard, an existing member state standard such as that used in Germany or a newly defined EU standard drawing on these.

This would support the development of the internal market with a high level of health protection, but only in those countries where member states wished to have a market like this. It would not permit, but not require, the UK to allow sales of oral tobacco, and so return powers to UK ministers. It would also provide a basis for other member states to consider whether to lift the ban and increase experience in the introduction of low risk alternatives to cigarettes.

I attach three files to support this case:

1. Letter from 15 international experts to Commissioner Dalli in 2011, calling for lifting of the ban on oral tobacco
2. Letter from sic experts to Sweden's health minister in February 2013, calling for her to champion lifting the ban through allowing member states discretion, as envisaged above.
3. Some supporting data on the health benefits of oral tobacco in Sweden

I would like to add my comments as I am electro-hypersensitive (EHS).

My symptoms: Agitation; burning sensations all over; head , neck and shoulder pains; fatigue; difficulty concentrating. From the start of exposure these symptoms can appear within minutes or may take 20 minutes or so. Symptoms may take up to an hour to disappear after exposure has stopped. Long term exposure lead to extreme fatigue and bad head aches – diagnosed as M.E. (chronic fatigue syndrome) by my G.P.

Causes: Exposure to microwave emissions from mobile phone masts, cordless (DECT) phones, Wi-Fi, smart phones etc. Also power lines (pylons).

Quality of life limitations:

- Isolating because of difficulty in visiting other people's homes (most have DECT phones and many have Wi-Fi).
- Unable to visit most cafes (free WI-Fi) and many hotels (I do not take holidays anymore).
- Dread of having to go into hospital – my nearest large hospital has many masts on its roof and I have already experienced the effects.

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I live in county Kilkenny, southern Ireland. There is no equivalent review taking place in southern Ireland that I know of, so in the absence of same I would still like to give evidence and participate, so that my relevant story can add to the pool of knowledge and evidence, and might benefit others.

If, being slightly outside of the UK rules me out, I would ask that the close geographical proximity of Ireland to England will allow my evidence to go forward, because this is ultimately about the health of our children, all our children, and in such a case boundaries and borders are irrelevant.

### My Story

In 2004 I worked full-time as a Resource teacher in a local primary school in the village of Piltown in southern Kilkenny. It was a pensionable job and I was guaranteed an income for the rest of my life. I was a single parent with 2 children aged 17 and 10 yrs. Being a qualified teacher I had a reasonable standard of living and financial independence and security. This mattered because my former partner in the UK has never supported his children, and my attempts to seek maintenance ended in failure. I intended to be there to help my children through college and give them whatever financial support they needed, a helping hand financially as any good parent would.

I had a small mortgage on a cottage ( where I still live) and a mortgage free site out in the country. Despite briefly putting the site up for sale during that summer, when I got a buyer I realised I did not want to sell afterall, and I reverted back to my original 4 yr plan which was to keep the site and build on it, and selling the cottage would fund the build so that I would be mortgage free. I realised that the cottage was in a bad location for anti-social behaviour and for various reasons that anti-social behaviour was set to get a great deal worse. I really needed the site to move and build a house big enough for the three of us as the cottage had only one proper bedroom. At the beginning of October 2004 I contacted an archtitect to start the process of applying for planning permission. I already had house plans. He was on holiday and could not be contacted until he returned on the first week in November. I left a message that I would contact him again in November.

Meanwhile in October, in the middle or towards the end of the month, I started having big problems sleeping. I needed sleep in order to teach but I was unable to sleep despite being totally exhausted. When I would finally fall asleep I woke up with sickening 'sunburn' headaches as if the inside of my forehead, in a tight band across the front of my brain, was badly sunburned. The pain would last for several hours, sometimes into late afternoon. After approx 2 weeks I mentioned it to my daughter one morning. She said that she too was getting headaches, like me the pain would be there when you'd wake up. She was also getting abdominal pains which she could not explain. My son wasn't getting any regular headaches like these. We were mystified as to the cause. Then I started getting severe pain in my eyes and eye inflammation. My doctor sent me down to the eye clinic - tests proved nothing. The inflammation recurred. That first christmas we had no christmas dinner as I had to stay in a darkened room and my children tried their best to cope - I was sleeping with painkillers and my children were worried sick as none of us knew why this was happening. Weeks turned into months and I kept having to go up and down to eye casualty with eye pain and inflammation. Then I noticed a large breast lump visible through my clothes around February. I had a cancer scare as once again I ended up down at the hospital where 16 breast cysts were suddenly discovered. I had to wait for 14 days to see if the biopsy proved cancerous. I still wasn't sleeping and still had severe recurrent eye inflammation, plus things were going badly wrong in my workplace as I lacked the energy/health resources to deal with conflicts arising with colleagues. The ability to do my job properly was impaired as concentration, organising thoughts, planning, writing assessments and reports et al went down the pan. I couldn't think straight, couldn't remember, and cried frequently. Fibromyalgia flare-ups - muscular pain - ( started 1997 from car accident - previously successfully managed) happened more often and got out of control.

Sometime at the start of November 2004 I received a phone call from a buyer wanting to buy the site. I refused the offer explaining that I was not selling. Inexplicably, a few days later, when I was due to ring the architect, I rang back this prospective buyer and agreed to sell the site because I had changed my mind. In making this life-changing decision I sealed my fate, not realising that I was dooming me and my 2 children to 3 years of irradiation and the hell of 11 years of non-stop anti-social behaviour. In retrospect I realise that the chronic lack of sleep, the constant headaches often lasting all day, and the eye inflammation on top of all this, seriously affected my decision making ability. Had I not had radiation polluting my home 24/7 there is the possibility that I would not have sold my site and I would not be submitting evidence to you today. Selling the site meant I had to stay put. In December 06 in desperation I tried selling my house but I failed. The site was too far out in the country for me and - if I hadn't had irradiation from the mast and constant anti-social behaviour I would have been happy to stay in the cottage, maybe selling the site at a later stage but the decision I made in November 2004 to sell it when I did was definitely influenced by my state of mind - frazzled by non-stop irradiation from the Vodafone mast.

Three pet cats started to bleed from between their toes/claws, and all 3 started to bleed from their eyes. I later realised that the male/son cat had gone blind in one eye. The mother cat lost a lot of fur and her skin seemed a yellow colour. All 3 animals developed bleeding lesions, they were scabby with triangular shaped tops, domes like triangles all over their bodies. The male cat disappeared and the other 2 were rehomed as I was unable to look after them. Previously the garden was full of birds. All the birds left, only a few visited from time to time. I found a dead bat in my garden and a dying bat on the small bridge beside my house. In spring/summer the bees in my garden seemed disorientated, drunk, and dying. I contacted various wildlife organisations - they all said that microwaves were fine. My vet said my cats were fine. He said I was imagining things like John Hanrahan - the man whose farm animals were poisoned by

chemicals from the Merck Sharpe & Dome factory. He said that he was one of the attending vets and that man's animals were all fine. He didn't know that I had seen the documentary on the BBC and I had seen the deformed animals being born, with 2 heads, 3 legs and no spine - the same as John Ryans animals in Tipperary. Microwaves from the Vodafone mast had caused the same deformities as chemical poisoning.

A lesion appeared on my upper chest and on my daughter's face, still there now. This mark weeps and burns when radiation levels high. It has grown in size. Another mark appeared on my son's face, intermittent, appeared 3 times.

In April 2005 discovered a Vodafone antenna mast 20 yards from bedroom walls of my house on roof of Glanbia building next door. Neighbours say it went up end of August 2004. I did not notice it. Over the next 2 and a half years I begged Glanbia, Vodafone and local and national politicians and the council and every government agency to remove it but I was ignored.

There were many other symptoms, I gave a full list to the Irish Government - non-ionising radiation section, Dept. of the environment. and to the EU in a petition I sent to them. I will list them at the end of my story. On the 16.8.07 my eye doctor, Mr Tormey (now retired) of the Waterford Regional Hospital told me it would be likely that I would permanently lose my sight if the severity and frequency of the recurrence of the eye inflammation were to continue as it had been regularly happening every few weeks /months over the previous 3 years. Loss of sight would be sudden and irreversible as the cornea would stick to the lens. I contacted Glanbia and Vodafone yet again and begged them to remove the mast and stop the irradiation as having lost my job ( 06), my health and the enjoyment of my home I was now being told I would lose my sight. Weeks later John Moloney the CEO of Glanbia wrote back to say - in the spirit of good neighbourliness - the mast would be removed. On the 18th Sept. 2007 the mast was removed.

I thought then I could get on with my life however things got worse. On the 1.11.07 I developed severe lower jaw and chest pain - like a vice of pain connecting the two, plus a migraine at the same time and whole body shaking which I could not control. It started about 7 pm ( the shaking ) and lasted about 2 hours. I refused to go to hospital as I was frightened of going. On the 3.11.07 bad chest pain started again like a heart attack. It went on for a while and at 2am I called for an ambulance. Later my left arm started shaking I could not control it. I have had to run out of shops because I feel so unwell. I checked with IERVN as I couldn't understand why this malaise/feeling of dying was happening when in shops and around people who had mobile phones. Told I had developed a sensitisation to microwave radiation.

For past 8 years I have been unable to lead a normal life. I have been refused help by the HSE, and denied any access to redress. I feel I am being left to die as has happened to a fellow sufferer on the 19.5.08 and several others who are fighting cancer. Not only has all help and justice been denied but more irradiation is to start again in 3 months time. In April 2013 another microwave phone mast will be put up beside my house, stronger strength this time for a computer centre beside the house. The former CEO of Vodafone who oversaw the previous mast being put beside my house is Paul O'Donovan, now CEO of Eircom, who will supervise the siting of the new mast or disguised transmitter which will pollute my home with radiation once more. When this happens I will not live for much longer as it has already shortened my life. I will try and appeal it but I have no faith that my appeal will alter anything. I have lost faith in democracy.

Symptoms as follows - most if not all have been witnessed by GPs or hospital staff at A & E in Waterford Regional Hospital. Chest pain, shaking of body, both legs and arms and left arm only, bleeding into tissue, internal, contusions appearing for no reason and raised painful lumps of blood on fingers, esp. of left hand, on sole of left foot in middle, left ankle area swelling of ankle and left foot and turning purple and blue, peri-anal haematoma, rectal bleeding, left ear swollen red like sunburn, peeled 3 times over following week, eye pain and eye inflammation,

mostly left eye ( Blackrock clinic report by a Dr Moloney confirms that eye inflammation possibly caused by microwave exposure ) chest pains, pressure on chest difficulty breathing, sunburn headaches, depression, impairment of cognitive function, memory problems, inability to organise thoughts/ideas to write reports and carry out teaching duties, increased muscular pains due to fibromyalgia getting out of control, metallic taste in mouth, bladder problems, inability to hold urine for more than 1 hour and 40 mins max, vertigo, falling over, insomnia lasting up to 6 nights ( this can happen several times over course of year) tinnitus, hair loss, depression, fingernails turning yellow and soft, palm of right hand yellowing and itchy, toes all swollen ( fluid) and curling inwards, inability to drink water as it results in a sunburn headache the next day etc etc etc..

This list might not be complete as I can't remember everything and there is so much. A complete list with chronological recording of symptoms was sent as an EU petition a few years ago. I will try and attach it to this if I can.

Since August 2012 my heart is affected by electromagnetic fields, wi-fi on all buses etc. Arrhythmia and breathing problems at night after exposure, or immediately. At night lying down can go on for many hours. Chest pressure and stomach nausea started on buses during end of summer - previously just malaise and sick feeling in my head.

Finally may I add that I want an apology from the Irish Government and the EU Parliament for polluting my home with a radiation known to be toxic since 1924, and immediate medical and practical support, along with financial redress. Money is a paltry substitute for lost years and health but in the absence of anything else it has to do - and the characteristic of any civilised humane society is to ensure compensation for those whose health has been damaged as a result of a wilful ignoring of 88 years of medical and scientific evidence and resultant negligent policies which fail to protect health.

I hope this review furthers the process of allowing justice to those whose health has been damaged, which might go some small way to lessening the shame of those in power who authorised the pollution of family homes in the first place, with a radiation known to be carcinogenic and detrimental to health since 1924.

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As a mental health nurse working in the knowledge industry I am particularly interested in the social determinants of intellectual capacity in terms of national productivity. For instance, in relation to the UK's inclusion in the EU I seem to regularly be asking myself: Does bilingualism increase or decrease intellectual capacity? How do conflicts in cultural values impact on productivity and performance? How does 'reality' become stratified and fragmented across multi-cultural systems? Do any of these issues impact on the workforce's resilience to stress?

From an academic perspective most of these questions concern an interaction between individual and collective psychologies and should therefore be of concern to public health and community mental health workers working in the EU.

From a public health perspective the European Union has established a network for monitoring and coordinating action upon a number of known biologically communicable diseases ([http://ec.europa.eu/health/communicable\\_diseases/diseases/index\\_en.htm](http://ec.europa.eu/health/communicable_diseases/diseases/index_en.htm)).

However, from a mental health perspective, little is known about viruses that live in the nervous system (<http://www.stanleylab.org/>), and little control is exerted over the contagion of toxic

emotional states

([http://developingchild.harvard.edu/topics/science\\_of\\_early\\_childhood/toxic\\_stress\\_response/](http://developingchild.harvard.edu/topics/science_of_early_childhood/toxic_stress_response/)).

Thus, within an EU context many intangible psychological factors involved in the epidemiology of communicable diseases are largely being ignored. The public health implications of this are only clear if pathogens such as violent crime or sexual abuse are considered as the outcome of these omissions.

The impartiality of the EU could be of benefit in organising the scientific research and clinical responses of member states in these areas; however, where the EU is seen as exerting partisan political interests in these areas it is viewed as 'part of the problem not part of the cure'.

Thus, the role of the EU, it seems to me, should be in providing clinical guidance in the same way that NICE does at the moment.