Review of the Balance of Competences

Department of Health

REVIEW OF THE BALANCE OF COMPETENCES: HEALTH

Call for Evidence

November 2012

Contents

CALL FOR EVIDENCE ON THE GOVERNMENT'S REVIEW OF THE BALANCE OF COMPETENCES BETWEEN THE UNITED KINGDOM AND THE EUROPEAN UNION

HEALTH

Closing date: 28 February 2013, midday

Introduction

1.1. The Foreign Secretary launched the Balance of Competences Review in Parliament on 12 July 2012, taking forward the Coalition commitment to examine the balance of competences between the UK and the European Union (EU). The review will provide an analysis of what the UK's membership of the EU means for the UK national interest. It aims to deepen public and Parliamentary understanding of the nature of our EU membership and provide a constructive and serious contribution to the national and wider European debate about modernising, reforming and improving the EU in the face of collective challenges. It will not be tasked with producing specific recommendations or looking at alternative models for Britain's overall relationship with the EU.

1.2. As the Foreign Secretary further announced in Parliament on 23 October 2012, the review is broken down into a series of reports on specific areas of EU competence, spread over four semesters between autumn 2012 and autumn 2014. The review is led by Government but will also involve non-governmental experts, organisations and other individuals who wish to feed in their views. Foreign governments, including our EU partners and the EU institutions, are also being invited to contribute. The process will be comprehensive, evidence-based and analytical. The progress of the review will be transparent, including in respect of the contributions submitted to it.

The health review

1.3. The Department of Health is leading the review into competences related to health and is seeking views on their application. This call for evidence requests input from anyone with relevant knowledge, expertise or experience. You can submit evidence until midday on 28 February 2013. Following the call for evidence, we will publish a full report on EU

competence in health, providing more detailed legal analysis as well as taking into account the evidence presented.

1.4. This review links to the other balance of competence reviews over the four semesters. We will feed in evidence we receive from the health sector to other reviews where this is relevant. Full details of the other reviews and the programme as a whole can be found on the FCO website, via www.fco.gov.uk/en/global-issues/european-union/balance-of-competences-review

1.5. Whilst responsibility for health policy is a matter for individual Member States, the EU has an important role in various issues related to public health and healthcare. The health review is an opportunity to look at this role and to examine the evidence concerning the impact of EU competence on the UK's national interest with respect to health.

We would particularly welcome evidence addressing the following overarching questions:

- *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*
    - *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*
    - *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*

Section 21 at the end of this document includes the full set of questions and provides details about how to submit your response.

1.6. In terms of the scope of the review, we would wish to emphasise that:

- We are keen to engage stakeholders both on the general position around the EU's role and also in the specific areas outlined in this document, such as medicines and medical devices, public health, and nutrition and food labelling.

- This document deliberately does not list every area of health and social care policy – it focuses on the main areas of EU competence. There are some areas where the role of the EU is more limited, for example in social care, and we would welcome views on these areas too.

- The review clearly relates predominantly to areas where the EU's role is clarified through legislation, but includes other areas where there may be a more limited, non-legislative role for the EU. Views are welcome on both legislative and non-legislative EU work and the inter-relationships between them.

- We value responses on the inter-linkages between competences. The economic impact of the EU on healthcare is another area on which we will want to hear views from respondents.

- This is a UK wide review. We would like to encourage stakeholders in Scotland, Wales and Northern Ireland to contribute to the review.

- This review is not about making value judgments, but about using an evidence based approach to ascertain the impact of the EU's health-related activities in the UK.

1.7. Above all, we want to encourage everyone to engage in this review and help us build a full and accurate account of the EU's role in health and healthcare.

What is competence?

1.8. For the purposes of this review, we are using a broad definition of competence. Put simply, competence in this context is about everything deriving from EU law that affects what happens in the UK. That means examining all the areas where the Treaties give the EU competence to act, including the provisions in the Treaties giving the EU institutions the power to legislate, to adopt non-legislative acts, or to take any other sort of action. But it also means examining areas where the Treaties apply directly to the Member States without needing any further action by the EU institutions.

1.9. The EU's competences are set out in the EU Treaties, which provide the basis for any actions the EU institutions take. The EU can only act within the limits of the competences conferred on it by Member States as set out in the Treaties, and where the Treaties do not confer competences on the EU they remain with the Member States.

1.10. There are three types of competence: exclusive, shared and supporting, which are described in the diagram below. The areas that are covered by each competence are set out in Articles 3, 4 and 6 of the Treaty on the Functioning of the European Union (TFEU).

Exclusive	Shared	Supporting
Only the EU can act eg customs union & commercial policy	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) eg the internal market & energy	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 eg public health & culture

1.11. The EU must act in accordance with fundamental rights as set out in the Charter of Fundamental Rights (such as freedom of expression and non-discrimination) and with the principles of subsidiarity and proportionality. Under the principle of subsidiarity, where the EU does not have exclusive competence, it can only act if it is better placed than the Member States to do so because of the scale or effects of the proposed action. Under the principle of proportionality, the content and form of EU action must not exceed what is necessary to achieve the objectives of the EU treaties.

EU competence in health

1.12. Health is important for the wellbeing of individuals and society, but a healthy population is also a prerequisite for economic productivity and

prosperity. Member States in the EU are facing similar challenges in improving the health of their populations: the demands of an ageing population and increasing rates of chronic diseases, coupled with an economic climate resulting in pressure on budgets available to spend on healthcare systems. In the UK, healthcare expenditure accounted for 9.6% of UK Gross Domestic Product (GDP) in 2010.[1] Healthcare expenditure varies across EU Member States, which have the competence to allocate resources to their health systems as they see fit.

1.13. The Treaty on the Functioning of the European Union (TFEU) makes clear that in many areas of health and healthcare the EU plays a limited role. The EU is required in Article 168 of TFEU to respect the responsibilities of each Member State to define their own health policy and to organise, deliver and manage health services; as well as to allocate resources to their health systems.

1.14. However, there are certain areas where the EU does have competence to get involved in health issues, which impacts, directly or indirectly, on health in the UK. The legal basis of EU competence in health is outlined in the legal annex in paragraphs 1.6–1.15.

1.15. The European Commission ('the Commission') Health Strategy is designed to confront the challenges to the health of Europe's citizens, such as an ageing population or cross border health threats. The aim of the strategy is to strengthen in a single strategic framework, community cooperation where Member States cannot act alone, ensuring that health is better understood at European level, thereby securing a bigger role for health in all EU policies.

1.16. The strategy recognises that since health is determined to a large extent by factors outside the health area, an effective health policy must involve all relevant policy areas, such as social and regional policy or research. All EU policies are required by the EU treaty to follow this "*Health in all Policies*" (HIAP) approach.

1.17. Health is also an important element of many other areas of EU competence. For example, in employment policy, the Directive on the recognition of professional qualifications covers workers in many sectors of the economy, but a particularly high proportion of those affected work in the healthcare sector. Similarly, reciprocal healthcare arrangements are an important factor in ensuring the free movement of persons within the EU. These significant inter-relationships result in important links to the balance

[1] *Source: OECD Health Data 2012*

of competence reviews led by other departments, which are referenced throughout this document.

1.18. The rest of this document focuses on the areas of EU competence upon which we are primarily asking for evidence, although this is not intended to be an exhaustive list and we would welcome views on other aspects of EU competence in health, and on the overall impact upon the UK national interest, UK business and industry, and patients and citizens.

1.19. The legal annex provides a brief legal summary of the main Treaty Provisions and European legislation relevant to this paper. It provides a short overview and is not intended to be an exhaustive description or analysis.

Medicines and Medical Devices

This section covers EU competence as it relates to medicinal products and medical devices.

*The UK pharmaceutical sector has 365 companies, employing nearly 78,000 people and with a total annual turnover of over £31 billion.**

It accounted for 8% of the UK manufacturing sector in 2010 (by gross value added).

Pharmaceutical companies carry out more than a quarter of all industrial research and development in the UK. Around 20 per cent of the world's top 75 medicines were discovered and developed in Britain - more than any other country except the USA.

In 2011-12, nearly 600,000 patients were recruited to trials and other well-designed clinical studies and 1,307 trials and studies were entered onto the National Institute for Health Research Clinical Research Network (England) portfolio database.

Over 960 million prescription items were dispensed in primary care in England in 2011.

Source: OLS/ DH/ UKTI Bioscience and Health Technology database 2011

2. Medicinal products

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 and ensure a high level of patient safety.

2.1. The legislation:

- harmonises the pre-marketing authorisation requirements for medicines;
- harmonises how clinical trials are carried out in the EU (the Clinical Trials Directive - this is in the process of being revised by the EU);
- harmonises good manufacturing practice and good clinical practice across the EU;
- set up the European Medicines Agency, which authorises medicines for the whole of the EU (the so called centralised procedure);
- ensures the safety of medicines once they are on the market (which is known as pharmacovigilance);
- provides a regulatory approval process for herbal medicines in the EU and aims to protect public health
- prevents counterfeit medicines from being sold;
- sets minimum requirements for Member States to follow when they legislate on the prices of medicines (this is in the process of being revised by the EU);
- incentivises industry to research and develop medicines for children and for rare diseases.

2.2. In addition to legislation, there are a range of EU-led non-legislative initiatives aimed at supporting non-binding cooperation between the Member States, including discussing the implementation of legislation, exchanging information and experiences and fostering voluntary collaboration. For example, the Heads of Medicines Agencies brings together the authorities responsible for the regulation of medicines in each Member State four times a year. There are also plans to set up a voluntary network in the area of Health Technology Assessment.

2.3. Member States are able, under Article 5(2) of Directive 2001/83/EC, to temporarily authorise the distribution of unauthorised medicines in response to the suspected or confirmed spread of pathogenic agents

(which includes pandemic flu). This Article has also been used to cover shortages of non-pandemic related medicines caused by the impact of pandemic flu.

3. Medical devices

The EU directives on devices exist to allow medical devices to be sold and bought freely across the internal market of the European Union and ensure that devices perform to a high level of safety.

3.1. The legislation covers general medical devices, active implantable medical devices and *in vitro* diagnostic devices.

3.2. European legislation on devices is in the process of being revised. The aim is to address acknowledged weaknesses in the current regulatory system, including those which were brought to light during recent events with faulty breast implants and metal-on-metal hip replacements. The UK is negotiating to improve the quality and safety of devices by strengthening controls on the organisations which assess the safety of devices, increasing transparency and making the surveillance of the safety of devices once they are on the EU market more robust.

3.3. This competence is also exercised through a number of non-legislative initiatives. The authorities responsible for the regulation of medical devices in all of the Member States (in the UK, the Medicines and Healthcare products Regulatory Agency) meet twice a year to exchange experiences and discuss implementation of the existing directives on medical devices. In addition, the Commission drafts non-binding guidance documents in an effort to promote a common approach to the implementation of directives.

There are 22,000 medical technology companies in Europe.

There are around 500,000 medical devices available to healthcare professionals.

Source: www.eucomed.org/medical-technology/facts-figures

Public health

This section covers areas of EU competence related to public health.

4. Organs, blood, tissues and cells

The EU Blood, Tissue and Cells and Organ Directives set high standards for quality and safety that must be met when carrying out procurement, testing, storage, distribution and follow up activity involving blood, organs, tissues and cells for human transfusion/transplantation through a harmonised approach to regulation across the European Union.

4.1. The Tissue and Cells and Organ Directives set a benchmark for the standards that must be met when carrying out any activity involving organs, tissues and cells for patient treatment. The Directives also require that systems are put in place to ensure that all organs, tissues and cells used in patient treatment are traceable from donor to recipient and to ensure that action can be taken quickly to address severe adverse events or reactions.

4.2. The European Union Tissue and Cells and Organ Directives were transposed into UK law in 2007 and 2012 respectively. The aim is to bring all EU countries up to the same high quality and safety standards.

4.3. 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 complementary Joint Actions, such as the ACCORD programme agreed in 2011, which provides 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 programme.

4.4. EU Directives also set standards for the safety and quality of blood and blood components for transfusion. These include measure to ensure:

- that people do not donate if giving blood would harm them;
- that people do not donate when they have a disease or condition, or have received treatment, that might affect the blood they give; or when there is a risk that they might have an infection which could be passed on in their blood;
- that blood donors receive the information they need, and also that the right details about them are collected;

- that donated blood is thoroughly tested for the presence of possible infectious agents;

- that blood is handled and stored safely during collection, testing, processing and distribution;

In the calendar year 2011, more than 1.8 million units of red blood cells for transfusion were issued by NHS Blood and Transplant, which provides blood to hospitals in England and North Wales.

Source: NHS Blood and Transplant

- that proper records are kept so that, for example, blood can be traced and linked to both donors and recipients;

- that the regulators are notified of serious adverse reactions to transfusion;

- that the blood used for transfusions is safe and of a high quality; and

- that imported blood or blood components meet similar standards of quality and safety.

4.5. The UK operates a voluntary, unremunerated blood donation scheme, which is encouraged, but not mandated, by the Blood Directive 2002/98/EC. The Directive does not prevent Member States maintaining or introducing more stringent measures on their territory than those set out in the Directive, provided the national measures comply with the provisions of the EU Treaty. Blood and blood components for transfusion may also be imported from other Member States and purchased by health providers in the UK. Because of the Internal Market principles, any restrictions on these imports, relating to standards of safety and quality or designed to ensure stability of supply, would have to comply with Treaty provisions prohibiting quantitative restrictions on imports - details about which are given in the legal annex (paragraphs 1.13 and 4.2).

5. Nutrition and food labelling

EU legislation in this area sets out to regulate labelling of foods, including nutritional information and health claims, as well as the nutritional composition of certain foods.

5.1. EU competence in relation to food safety and food labelling will be considered by a separate review to be led by the Department for Environment, Food and Rural Affairs and the Food Standards Agency in the first semester (autumn 2012). We would welcome evidence from the

health sector about the impact of this EU competence through this call for evidence.

5.2. In the context of health, the EU regulates nutritional information and composition through a number of Directives and Regulations (set out in more detail in the annex): the voluntary addition by manufacturers of vitamins and minerals to foods (known as 'fortified foods'); the nutritional and health claims that are made for foods; food supplements; general nutritional labelling; and food for particular nutritional uses, such as infant formula. The legislation for this final specific area is currently under review by the Commission. A proposal for a regulation on food intended for infants and young children and on food for special medical purposes was submitted on 24 June 2011, and negotiations are ongoing.

5.3. There is also significant non-legislative action on nutrition. For example, the EU platform for action on diet, physical activity and health is a forum for European-level organisations, ranging from the food industry to consumer protection NGOs, which aims to tackle current trends in diet and physical activity. The idea is that, led by the Commission, the platform will provide an example of coordinated action on this problem by different parts of society that will encourage national, regional or local initiatives across Europe. An example is the work to reduce the level of salt in the diet.

5.4. The Commission has also developed a voluntary initiative to improve the nutritional quality of food and consumers' diets through the EU Framework for National Initiatives on Selected Nutrients. The first two elements of this work are reformulation of specific foods to reduce their salt levels by 16% by 2012, and in June 2012 work was agreed to help reduce consumers' intake of saturated fat. This incorporates reformulation activities and the promotion of lower fat foods.

6. Tobacco

EU competence on tobacco control is exercised with clear public health objectives, but also aims to avoid distortions in the internal market in tobacco products.

6.1. Tobacco has been one of the Commission's public health priorities in recent years. The EU currently exercises its competence in relation to tobacco control primarily through three Directives.

6.2. The Tobacco Products Directive sets down requirements in relation to the products themselves - their manufacture, presentation and sale. The aim is

to align the laws, regulations and administrative provisions of the Member States concerning, for example, maximum levels of tar, nicotine and carbon monoxide and the health warnings on packaging of tobacco products.

6.3. The Directive has remained largely unchanged for a decade and does not reflect the nature of tobacco products and markets in the EU as well as it once did. The Commission is expected to adopt a proposal for a revised Directive by the beginning of 2013, although this may be delayed.

Around 10 million people in the UK smoke.

Smoking is the biggest preventable cause of death in the UK, causing around 100,000 preventable deaths in each year.

Sources: Integrated Household Survey, ONS, April 2011 – March 2012
Statistics on Smoking 2012, Health and Social Care Information Centre
Tobacco and Health in Wales 2012, Public Health Wales Observatory
Ten year tobacco control strategy for Northern Ireland, Dept of Health, Social Services and Public Safety
Scotland Public Health Observatory

6.4. The second directive covers the advertising and sponsorship of tobacco products. It was designed to ban tobacco advertising in printed publications, in radio broadcasting and in information society services throughout the EU. It also bans the sponsorship of events involving several Member States.

6.5. The third directive prohibits television advertising for cigarettes and other tobacco products. It was later extended to cover other types of audiovisual commercial communication.

6.6. There is also a non-legally binding Council Recommendation on smokefree places. This was more relevant to countries with less developed smokefree policies than the UK.

6.7. The Commission has also been active in carrying out communications and marketing activities to reduce the number of smokers in the EU.

7. Alcohol

In public health terms, the EU's competence with regards to alcohol is to complement the action of Members States with the aim of addressing harmful and hazardous alcohol use.

7.1. The EU Alcohol strategy, which runs from 2007 to 2012, is soon coming to an end, and Commission officials are considering whether there is a need and support for a new strategy. The strategy aims to support Member States in their role of reducing alcohol related harm, through raising awareness of the impacts of hazardous alcohol consumption, and to develop a common evidence base. The Commission plans to publish evaluations of the impact of the current Strategy and of the work of the EU Alcohol and Health Forum in the near future.

7.2. The advertising of alcohol and the labelling of alcoholic beverages are regulated by EU legislation, as outlined in paragraphs 7.2 and 7.3 in the legal annex.

Alcohol is the third biggest lifestyle risk factor for disease and death in the UK after smoking and obesity with 1.2 million alcohol-related hospital admissions in 2010/11.

Over 9 million people in England say they drink above the alcohol guidelines.

NHS Information Centre Statistics on Alcohol: England, 2012

8. Health security

The EU's role in health security is to provide surveillance of communicable diseases. The current early warning system is to be extended to include other cross border heath threats.

8.1. The TFEU requires the EU to ensure a high level of protection of human health in defining and implementing its policies and activities (Article 9 and 168(1)). In addition, the Commission's health strategy, designed to confront the challenges to the health of Europe's citizens, addresses cross border health threats.

8.2. Member States have competence to take any measures that are necessary to safeguard public health in an emergency, for example as a result of terrorism. Emergency Powers under the Civil Contingencies Act 2004 could be enacted, in extreme circumstances, to provide the powers needed

to respond to an emergency, where they do not otherwise exist or cannot be brought into effect quickly enough.

8.3. In the UK, the Health Protection Agency (Public Health England in the future) works closely with the European Centre for Disease Control, in partnership with national health protection bodies across Europe, to strengthen and develop content wide disease surveillance and early warning systems. In doing so, the UK plays its part to develop authoritative scientific options about the risks posed by current and emerging infectious diseases.

8.4. A Decision focusing on serious cross border threats to health is currently being negotiated by the European Council. This Decision extends the existing systems of risk assessment, surveillance, monitoring and early warnings that are currently in place for communicable diseases, to other cross border health threats from events of biological, chemical, environmental and unknown origin. It also strengthens the EU response to cross-border health threats, and provides a platform for the co-ordination of preparedness and response planning across Member States.

8.5. The Decision is currently still working through negotiation in Council. The UK have a few remaining concerns although it now largely meets the concerns the UK had with the original text. It is concurrently proceeding in the European Parliament under co-decisions procedures.

9. Radiation

An EU Recommendation provides that Member States should keep public exposure to non-ionising radiation below international guidelines.

9.1. Ionising radiation comes within the Treaty establishing the European Atomic Energy Community (Euratom), which will be dealt with in a call for evidence to be launched by the Department for Energy and Climate Change next year.

10. Public health programmes

The EU public health programmes exist to implement the EU's strategy for protecting and improving human health, a competence under Article 168.

10.1. The current EU public health programme covers 2008-13. It has three main strands: health determinants, health security and health information. It provides funding to organisations such as voluntary sector

bodies, charities, NGOs and university departments for projects that provide EU added value.

10.2. The proposed EU Health for Growth programme recognises the importance of innovation to meet future healthcare needs across Europe, and of making the health field a significant area for economic growth. It supports key priorities of Europe 2020 – the EU's overarching strategy for smart, sustainable and inclusive growth. The general objective of the programme is to improve the health of EU citizens, protect them from cross-border health threats, encourage innovation in healthcare, and increase the sustainability of health systems.

10.3. The UK has supported the programme in principle but has sought:

- to reduce the budget for the programme
- to refocus it on prevention rather than healthcare
- to seek assurance that areas such as e-health and health technology assessment would remain matters of voluntary cooperation

10.4. Negotiations are currently taking place to agree the EU Health for Growth Programme, which should be completed by the end of 2013.

10.5. The Joint Action on Mental Health and Wellbeing was agreed under the current public health programme, and the UK is participating in two projects under this Joint Action. These projects are promoting mental health and preventing depression in children and adolescents; and mental health in all policies, which aims to strengthen the links between mental health and other policy areas.

10.6. In relation to public health aspects of drug misuse, the EU has exercised its competence through the Justice Programme. The European Monitoring Centre for Drugs and Drug Addiction, which supports public health measures through the collection, analysis and dissemination of information, was established under Regulation (EC) No 1920/2006. DG Justice has also operated a grant awarding scheme called the Drug Prevention and Information Programme. A new EU Drug Strategy for 2013-2020 is due to be agreed by the end of 2012. A shared responsibility for taking forward initiatives under the new Drugs Strategy across the Justice, Home Affairs and Health and Consumers Directorates General of the Commission is envisaged. In line with this, the Health for Growth programme will encompass public health measures in support of the Drugs Strategy.

11. Rare diseases

The 2009 EC Recommendation on Rare Diseases aims at introducing measures at European level to combat rare diseases. Member States are encouraged to adopt a plan or strategy under their respective social and health schemes by 2013.

11.1. Rare diseases were one of the priorities in the EU Public Health Programme 2003-2008. A rare disease is defined as one that affects fewer than 5 in 10,000 persons. On 11 November 2008, the European Commission published a Communication and proposal for a Council Recommendation on Rare Diseases. The Recommendation set out a number of actions placed upon Member States to take forward at national and community level.

11.2. The UK supports the Recommendation and its ambition for a global approach to improving coding and classification of rare disease, particularly if it helps secure a better understanding of data on an EU level. It is expected that the Recommendation will:

- improve the codification and classification of rare diseases
- improve the exchange of expertise on rare diseases which could enable more effective treatment of rare diseases in the UK and other EU countries
- encourage more EU level research on rare diseases

11.3. The Recommendation requires that national Plans should integrate all current and future initiatives at local, regional and national levels in the field of rare diseases. This will be the first time that the UK has developed a plan to tackle rare diseases and to help with the development of the Plan, the four nations of the UK undertook a full public consultation on a UK Plan for Rare Diseases.

NHS and patient services

The following issues are related to the NHS and the provision of services to patients.

12. Implications of employment policy

The EU has shared competence with Member States on employment policy, which impacts the whole UK economy including the health sector.

12.1. Employment policy will be the subject of a separate review to be led by the Department for Business, Innovation and Skills and the Department for Work and Pensions in the third semester (autumn 2013). We would welcome evidence from the health sector about the impact of this EU competence through this call for evidence.

12.2. EU employment policy has a particular impact on the health sector through the Working Time Directive, which sets down minimum EU standards for working time including minimum holiday and rest break requirements and a maximum working week. In the context of health, the Working Time Directive has implications for delivering the health service.

12.3. The impact of two European Court of Justice (ECJ) judgements has changed how doctors' time during on-call shifts is counted; and redefined when rest must be taken. The European Social Partners (who represent employers and employees across Europe) are currently in negotiations on proposals to amend the Directive and to resolve the issues caused by the ECJ judgements. They have until the end of December 2012 to reach an agreement. If this is not possible the Commission will issue a proposal to amend the Directive.

12.4. In the UK, the interaction between the Directive and the junior doctors' contract has operational implications. An independent review assessed the Directive's impact on doctors' training and recommended the contract be reappraised to support training. UK health ministers are considering options to renegotiate the contract.

13. Implications of free movement of persons: healthcare professionals

The EU acts under an Internal Market treaty base to enable the free movement of workers within the EU, including healthcare professionals.

13.1. The free movement of workers 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.

13.2. In particular, the Directive on recognition of professional qualifications aims to facilitate the free movement of regulated professionals around the European Economic Area (EEA). The Directive is relevant to the health review in the context of healthcare workers: it aims to ensure that regulated medical professionals can move between EEA countries, whilst also ensuring patient safety. It does this by ensuring that necessary checks on professionals from other Member States are carried out by the competent authorities at registration. For the health professions (doctors, dentists, nurses, midwives and pharmacists) minimum training has been harmonised to allow automatic recognition of the professional qualification throughout the EEA.

14. Implications of free movement of persons: coordination of healthcare provision

In order to provide for the free movement of persons, citizens within the EU are entitled to healthcare in another Member State under the coordination of social security rules. EEA nationals living in another member state but not covered by the coordination of the social security rules, may or may not be entitled to free healthcare in that member state, depending on what type of healthcare system it operates.

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.

14.2. EU citizens are entitled to healthcare under the EU coordination of social security rules. Health coverage is provided within this context as a benefit in kind to certain groups when moving around the European Economic Area (EEA), available to:

EHICs issued since their introduction	
Date	**EHICs issued**
Sep 05-Mar 06	5,592,334
Apr 06-Mar 07	7,189,876
Apr 07-Mar 08	4,160,935
Apr 08-Mar 09	4,172,428
Apr 09-Mar 10	4,540,813
Apr 10-Mar 11	5,819,861
Apr 11-Mar 12	6,903,507
Total	38,379,754

- state pensioners, and their dependents, who have moved abroad;
- temporary visitors, using the European Health Insurance Card (EHIC) (formerly known as the E111) for immediately necessary care;
- a worker posted to work in another EEA country by a UK-based employer;
- a person who has been authorised in the UK to undergo a planned medical treatment abroad (see section 11 below);
- a dependent who lives in another EEA Member State of someone from another EEA Member State working in the UK.

14.3. Under this legislation, such UK citizens are entitled to access state-provided healthcare in other EEA countries on the same basis as someone insured in that country. Applying the same principle, the UK has an obligation to provide NHS services to citizens in any of the listed categories who are in the UK from other EEA countries. In the same way that the UK pays other countries for healthcare provided to UK citizens, so we can claim back the costs of providing healthcare to EEA citizens.

14.4. There are clear linkages with the Directive on the application of patients' rights in cross border health care (the Cross Border Healthcare Directive) and it remains to be seen how the two legislative provisions will work together over the coming years.

14.5. EEA nationals, not just those covered by the coordination of social security rules, have a right of free movement around the EEA. Their ability to access free healthcare funded by the host member state will depend on the host member state's type of healthcare system.

14.6. Those who move their current place of residence to a member state with a residency based healthcare system, such as the UK, will be entitled to healthcare on the same basis as any other resident there. In the UK, a 'resident' is anyone who is simply here lawfully and is 'properly settled' for the time being. The NHS is free to all residents, therefore an EEA national

who moves here will receive free care, which may include pre-planned or high cost treatments that the person may not be entitled to in their home member state (by not having paid required contributions).

15. Implications of free movement of services: cross-border healthcare

The Cross Border Healthcare Directive clarifies patients' rights to access safe and good quality treatment across EU borders, and be reimbursed for it, subject to the same conditions that apply to accessing treatment at home.

15.1. While the reciprocal arrangements for healthcare in other EU Member States (as described above) have existed for many years, increasingly Europeans are accustomed to crossing borders with ease and being able to purchase goods and services from any part of the EU. Consequently, they are less willing to accept constraints on how and where they obtain their healthcare. This is often due to perceived advantages relating to quality, favourable cost, waiting times, the availability of different treatments or where citizens have close cultural or familial links in another country.

15.2. The Cross Border Healthcare Directive sets out the arrangements under which Member States provide treatment to citizens from other EEA states. It also clarifies the arrangements that a Member State must provide to allow its own citizens to access their rights to cross-border healthcare. In addition, it specifies the information they are required to provide to citizens of other states considering coming to their country.

15.3. The Directive clarifies the rules for patient reimbursement of eligible treatment costs and also confirms that it is always the home health system that decides which healthcare is available to its citizens, regardless of whether they are treated at home or abroad. Therefore, the Directive is not a way for citizens to gain entitlement to treatments that would not normally be available under their home health service. Member States are required to be clear and transparent about the entitlements to healthcare which home patients have within the national health system.

15.4. The Directive also requires Member States to accept and dispense prescriptions issued by prescribers from other Member States. For example, a UK GP can write a prescription that would be dispensed in another EU Member State for continuity of care purposes. However, this requirement does not affect any national rules that Member States have for prescription and dispensing.

15.5. To facilitate the dispensing of prescriptions, discussions have taken place on a core set of elements to be included on a prescription that allow for the authentication of prescribers; correct product/device identification and safe substitution practices; and for the information to be readily understood by patients. These requirements are expected to be mandatory only on those prescriptions intended to be dispensed in another Member State.

16. eHealth

The rationale behind EU action on eHealth is to help Member States facilitate the transmission of data and services in cross-border care scenarios.

16.1. In the EU context, eHealth is the combined use of electronic communication and information technology in the health sector and includes such things as development of electronic patient records, information sharing and ePrescriptions, telemedicine, and the electronic booking of appointments.

16.2. The Commission has made eHealth a priority area. There are a number of initiatives to encourage collaborative working, to improve eHealth deployment throughout the European Union, and to strengthen interoperability of eHealth across borders. There are a number of voluntary programmes of work, including a second eHealth Action Plan, which was consulted upon during 2012 and is due to be adopted by the Commission before the end of the year. In January 2012 the Commission formed a "voluntary" eHealth network, with the aim of advancing the implementation of eHealth across Europe.

17. Health research

The Framework Programme is the main mechanism used by the European Commission to fund research across Europe, including on health.

17.1. Research and development, including the Framework Programme, will be considered by a separate balance of competences review to be led by the Department for Business, Innovation and Skills 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.

17.2. The EU launched the 7th Framework Programme for research and technological development in January 2007. The programme will run for seven years and has a budget of €50.5 billion. Collaborative health research is funded through the Health theme. Framework Programme 7 replaced Framework Programme 6, which ended in December 2006.

In the 'Life sciences, genomics and biotechnology for health theme' of Framework Programme 6, the UK received €380 million, which was 16 per cent of the total available funds.

17.3. Negotiations for Horizon 2020 (which will replace Framework Programme 7) are ongoing.

Statistics

17.4. EU competence as regards statistics will be considered by a separate balance of competences review to be jointly led by the Cabinet Office, the Foreign and Commonwealth Office, the Ministry of Justice and the UK Statistics Authority in the fourth semester (spring 2014). We would welcome evidence from the health sector about the impact of this EU competence through this call for evidence.

17.5. In the context of health, Regulation 1338/2008 establishes a common framework for the systematic production of Community statistics on public health and health and safety at work. The aim is 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.

18. External representation

The EU exercises its external competence in the area of public health, for example through interactions with the World Health Organisation and international health agreements.

18.1. EU competence to act with regard to third countries and international organisations (external competence) will be considered by a separate review led by the Foreign and Commonwealth Office in the first semester (autumn 2012). There are a number of situations in the area of health where the EU exercises its external competence.

18.2. Article 168(3) TFEU states that the Union and Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

18.3. The EU exercises this competence in the area of health most significantly in its interactions with the World Health Organisation (WHO). The UK is an individual member of the WHO, like all other Member States. The nature of the EU's interaction with the WHO depends on its competence to do so on any given issue. The Commission works with EU Member States to prepare joint statements and to negotiate texts with third countries. In matters of EU competence, the Commission takes the floor. In addition, the Commission works with WHO and participates in the regular consultations that WHO organises on the health topics.

18.4. Both the UK and the EU are signatories to international health agreements developed under WHO – the Framework Convention on Tobacco Control (FCTC) and the International Health Regulations (IHR) (these are therefore termed mixed agreements).

19. Further legislation and case law

19.1. The Commission's health strategy recognises that health is determined to a large extent by factors outside the health area, including social and regional policy, taxation, environment, education and research. There is a large body of EU legislation that, whilst not directly related to health, has a significant impact on the health sector and the NHS. This includes, for example, environmental and energy efficiency legislation, health and safety regulations, internal market legislation including competition and procurement law, data protection, and case law arising from treaty articles on free movement of persons and freedom of establishment. This legislation does not relate to a specific EU health competence, and so will be the subject of other Balance of Competence reviews, to which responders to the health review may also wish to submit their views.

20. Non-legislative action

20.1. There is a significant amount of voluntary, non-legislative EU activity in the field of health and healthcare, some examples of which have already been outlined, but which is too numerous to cover exhaustively. We welcome evidence related to any such EU action.

20.2. The open method of coordination is a non-legislative tool that aims to encourage Members States to share and coordinate approaches and good practice that address common European challenges. Since 2006, the open method of coordination on social protection and social inclusion ('Social OMC') has included health and long-term care. The Social Protection Committee serves as the vehicle for cooperative exchange between Member States and the Commission in the framework of the Social OMC, as part of its remit to monitor the EU social situation

21. Your views

21.1. This public call for evidence sets out the scope of the review of the balance of competences in the area of health. We request input from anyone with relevant knowledge, expertise or experience. This is your opportunity to express your views.

21.2. We welcome views from a range of interested parties, and wish to hear about the impact of EU competence in health from diverse perspectives - from patients and citizens, the healthcare sector, voluntary organisations, and business and industry. We are keen to receive a broad range of evidence, including the following aspects:

- **Political** (for example, the extent to which the UK is able to have greater or less influence as a result of the EU competences in health);
- **Economic** (for example, the economic benefits of the EU's role in health compared to the regulatory or other costs to the UK);
- **Social** (for example, the extent to which the UK's social agenda is impacted by EU competence in health), and;
- **Technological** (for example, the impact of EU competence in health on the life-sciences sector).

21.3. Please send your evidence or related inquiries to balanceofcompetences@dh.gsi.gov.uk before the closing date of midday on 28 February 2013. We appreciate written feedback but will also be organising events to facilitate input to this call for evidence.

21.4. Your evidence should be objective, factual information about the impact or effect of the competence in your area of expertise. We will expect to publish your response and the name of your organisation unless you ask us not to (but please note that even if you ask us to keep your contribution confidential we might have to release it in response to a request under the Freedom of Information Act). We will not publish your

own name unless you wish it included. Where appropriate, we will also share evidence with the reviews led by other government departments.

21.5. Please base your response on answers to the questions below.

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*
    - *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*
    - *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*

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

Continued overleaf

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

LEGAL ANNEX

Introduction

1.1. The Treaty on the European Economic Community (EEC) was signed in Rome on 25 March 1957 – along with the Treaty establishing the European Atomic Energy Community (Euratom) – and entered into force on 1 January 1958. The EEC Treaty had a number of economic objectives, including establishing a European common market. Since 1957 there has been a series of treaties extending the objectives of what is now the European Union beyond the economic sphere. The amending treaties (with the dates on which they came into force) are: the Single European Act (1 July 1987), which provided for the completion of the single market by 1992; the Treaty on European Union – the Maastricht Treaty (1 November 1993), which covered matters such as justice and home affairs, foreign and security policy, and economic and monetary union; and the Treaty of Amsterdam (1 May 1999), the Treaty of Nice (1 February 2003) and the Treaty of Lisbon (1 December 2009), which made a number of changes to the institutional structure of the EU.

1.2. Following these changes, there are now two main treaties which together set out the competences of the European Union:

- The Treaty on European Union (TEU);
- The Treaty on the Functioning of the European Union (TFEU).

1.3. Within this document references to Treaty Articles are to the Articles in TFEU.

1.4. An explanation of what is meant by competence is given in the main call for evidence paper.

1.5. Article 288 TFEU provides that to exercise its competences, the EU shall adopt regulations, directives, decisions, recommendations and opinions. A regulation is binding in its entirety and is directly applicable in all Member States such that it can be relied upon without needing to be implemented by domestic legislation (although in the UK, national legislation is usually used). Directives are binding as to the result to be achieved so each Member State is required to implement them with national legislation. Decisions are also binding in their entirety. However, recommendations and opinions have no binding force.

Treaty Articles related to Health

1.6. Article 9 and Article 168(1) requires the EU to ensure a high level of protection of human health in defining and implementing its policies and activities.

1.7. Article 6 (a) specifies the protection and improvement of public health is an area where the EU only has supporting competence.

1.8. Article 168 provides more detail in respect of Union action in the field of public health. It states that Union action shall complement Member States' action and national policies (168(1)). It includes the requirement that Union action shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. The Article expressly recognises that the management of health services and medical care and the allocation of the resources assigned to them is the responsibility of the Member State (Article 168(7)).

1.9. In some aspects of public health the Union shares competence with the Member State and these are provided for in Article 4 and Article 168(4) and (5). There are two specified areas of shared competence which are relevant to the scope of this call for evidence:

(a) common safety concerns in public health matters (Article 4(2)(k) and 168(4) and (5)); and

(b) the internal market (Articles 4(2)(a), 26 and 114).

Common safety concerns and incentive measures to protect human health

1.10. Article 168 includes some limited derogations from the general principle that organisation of health services is a matter for the Member States. Article 168(4) specifies the areas in which there is shared competence for common safety concerns for the purpose of:

(a) setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives (Article 168(7) expressly recognises that these measures shall not affect national provisions on donation or the medical use of organs and blood);

(b) measures which have the direct objective of protecting public health in the veterinary and phytosanitary filed (which will be covered by the Animal Health and Welfare and Food Safety call for evidence led by DEFRA); and

(c) measures setting high standards of quality standards for medical products and medical devices for medical use.

1.11. Article 168(5) TFEU, whilst setting out a shared competence, only provides for the EU to adopt *incentive* measures designed to protect and improve human health and in particular to combat major cross border threats to health and measures to protect public health in respect of tobacco and the abuse of alcohol. The harmonisation of national laws is specifically excluded under this Article.

Internal market

1.12. The internal market of the EU is an area without internal frontiers designed to ensure the free movement of goods, services, capital and persons: the so-called Four Freedoms. In the broadest sense, around 80% of all EU legislation draws on some element of the Internal Market for its justification. The legal basis for the Internal Market is covered in Articles 26 to 66 and 114 to 118 of the TFEU.

1.13. A number of the Treaty Articles that deal with the Internal Market are 'directly effective' which means that national courts must not only apply the Treaty provision but must do so in priority over any conflicting provisions of national law. Some of these are relevant to this call for evidence, for instance:

- Article 34 prohibits all quantitative restrictions on imports (or measures having the equivalent effect). This can affect the health sector in a number of ways, for instance Austrian national measures putting conditions on the import of blood for transfusions have been held to be contrary to this Article (see section 4 below); and Article 34 has been used to challenge national measures on tobacco and alcohol control;
- Article 45 provides that the free movement of workers shall be secured and prohibits discrimination based on nationality, and is relevant to the coordination of Member States' health care benefits (see section 13); and
- Article 56, which prohibits restrictions on the freedom to provide services within the Union, has affected patient's rights to obtain health care services abroad (see section 14 below).

1.14. Article 114 provides a general legal base for harmonising Member States' laws by adopting measures which have as their object the establishment and improved functioning of the internal market. It is a far reaching power that can be used to harmonise national laws in a wide variety of areas and can be used to legislate for situations that would otherwise be wholly internal to a Member State. The Union is able to exercise this competence in relation to health matters where some Member States have introduced their own national measures so that disparities between states mean there exists an 'internal market barrier'. The Union can then introduce harmonising laws to minimise or eliminate those internal market barriers.

1.15. EU competence on the internal market is to be covered in detail by the reviews led by the Department for Business, Innovation and Skills. However, Article 114(3) states that the Commission should take as its base, a high level of protection in its proposals for Health. Article 114 is

used as the legal base for measures adopted in the areas of medicines and medicinal devices, food safety and labelling, cross-border health care, and tobacco control measures.

The following sections provide more detail on the legal basis for EU action in the specified areas and how that competence has been exercised.

Medicines and Medical Devices

2. Medicinal products

2.1. Measures in this area are adopted under Article 114 on the harmonisation of the internal market (which includes the internal market in medicines); and Article 168(4)(c) which specifies that measures *shall* be adopted by the Union setting high standards of quality and safety in medicinal products, as part of the shared competence on common safety concerns in public health.

2.2. The EU has exercised these competences through Regulation 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, which sets out the authorisation, supervision and pharmacovigilance of medicinal products for human and veterinary use.

2.3. Regulation 726/2004:

(a) establishes the European Medicines Agency and the Committee for Medicinal Products for Human Use; and

(b) provides for certain medicines to be subject to licensing by the Commission.

2.4. Directive 2001/83/EC on the Community code relating to medicinal products for human use, was made on the basis of what is now Article 114 (although recent amendments to it are made under both Article 114 and Article 168(4)(c)). This Directive provides for medicines which do not fall to be licensed by the Commission, to be licensed by Member States. It makes detailed provision in relation to placing on the market, production, labelling, classification, distribution, pharmacovigilance and advertising of medicinal products for human use. It has been amended many times.

2.5. Clinical trials are the subject of Directive 2001/20/EC on the approximation of Member States' laws relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. It has been amended by Regulation 1901/2006 and Regulation 596/2009. Directive 2001/20 makes provision for the

approval of clinical trials and for the manufacturing and importation of products used in clinical trials.

Other Directives include:

- Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use.
- Commission Directive 2004/24/EC provides a regulatory approval process for herbal medicines in the EU and aims to protect public health - the Directive was implemented in the UK in October 2005. Manufactured herbal medicines require an appropriate product licence before they can be placed on the market.
- Council Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems. This lays down minimum requirements for Member States to follow when they legislate on the prices of medicinal products.

3. Medical devices

3.1. Measures in this area are also adopted under the internal market provisions (Article 114) whereby the EU provides a regulatory framework for market access for medicinal products and medical devices; and, as with medicinal products, Article 168(4)(c) specifies that measures shall be adopted to achieve the setting of high standards of quality and safety in medicinal devices as part of the shared competence on common safety concerns in public health (Article 4(2)(k)).

3.2. The EU has exercised these competencies in three European Directives:

- Directive 90/385/EEC on active implantable medical devices (AIMDD);
- Directive 93/42/EEC on medical devices (MDD); and
- Directive 98/79/EC on in vitro diagnostic medical devices (IVDD).

3.3. These are implemented in the UK in the Medical Devices Regulations 2002 (S.I. 2002/618).

3.4. The Commission recently adopted two proposals to replace the existing three directives with two regulations. One regulation incorporated the MDD and AIMD and the second covered the IVDD.

Public Health

4. Organ, blood, tissue and cells

4.1. Article 168(4)(a) provides the EU with shared competence to adopt measures setting quality and safety standards for organs, substances of human origin, blood and blood derivatives. However, this competence does not affect national provisions on the medical uses of donated organs or blood.

4.2. Directive 2002/98 (see below) allows Member States to set more stringent protective measures than the requirements of the Directive. However, case C-421/09 *Humanplasma GmbH v Republik Osterreich* held that any national laws which prohibit imports of blood or blood components not complying with the state's more stringent national standards, must also be compatible with Article 34 TFEU (which prohibits quantitative restrictions on imports) as read with Article 36 TFEU (which allows restrictions on imports where the measures are a proportionate means of protecting the health and life of humans).

4.3. The relevant EU legislation in this area is:

- Tissues and Cells - Directives 2004/23/EC setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells; 2006/17/EC; and 2006/86/EC.

  Transposed into UK law by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (S.I. 2007/1523).

- Blood and blood components - Directives setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components; 2002/98/EC; 2004/33/EC; 2005/61/EC; and 2005/62/EC.

  Transposed into UK law by the Blood Safety and Quality Regulations 2005 (S.I. 2005/50), as amended.

- Organ Donation and Transplantation Directive 2010/53/EC.

  Transposed into UK law by the Quality and Safety of Human Organ intended for Transplantation Regulations 2012 (S.I. 2002/1501).

5. Nutrition and labelling

5.1. Fortified foods, nutrition and health claims, food supplements, and Foods for particular nutritional uses, fall within the scope of this call for evidence. Virtually all the legislation in the area of nutrition is created by the EU or is domestic legislation which either implements EU Directives, or creates criminal offences for breaches of EU Regulations.

5.2. The legal base in the TFEU for EU competence in this area is provided by Article 114 on the functioning of the internal market. Article 169, concerning consumer protection, is also of particular relevance to food legislation. Specific provisions under some EU legislation provide Member States with powers to maintain or create national measures, for example, in relation to alcohol related nutrition claims, the addition of some substances other than vitamins and minerals to food or the restriction of trade where there is a risk to public health.

5.3. The principal Directives of relevance to this call for evidence are Directive 1990/496/EEC dealing with nutrition labelling for foodstuffs and Directive 2000/13/EC on the approximation of laws of Member States dealing with the labelling, presentation and advertising of foodstuffs. Both of these are scheduled for repeal in 2014 under the new food information Regulation (see below).

5.4. Other EU legislation in this area is as follows:

- Regulation (EU) 1169/2011 is the new Regulation on the provision of food information to consumers which comes into force in 2014. It deals generally with the issue of food information, but creates specific provisions in relation to nutrition information in respect of foods, which replace those found in Directive 90/496/EEC. It applies, aside from transitional provisions, from 13 December 2014, although the nutrition provisions requiring a mandatory nutrition declaration do not come into force until 13 December 2016.

- Regulation (EC) 178/2002 which lays down the general principles and requirements of food law, establishes the European Food Safety Authority and lays down procedures in matters of food safety is also of relevance.

- Regulation (EC) 1924/2006 regulates nutrition and health claims in relation to foods.

- The relevant legislation regulating composition and labelling of Food Supplements is Directive 2002/46 EC.

- Directive 2009/39/EC is the principal “framework” Directive dealing with Foods for particular nutritional uses. (These are foods created to fulfil the specific nutritional needs of consumers with special nutritional requirements (for example, infant formula, gluten-free produce etc.) A number of subordinate Directives dealing with specific foods covered by the framework Directive have been made under it. At present, the current legislative framework for these foods is the subject of a Commission proposal which is being discussed and negotiated in

Europe. The proposal was precipitated partly by perceived difficulties in achieving market harmonisation and consistent enforcement across the EU.

- Regulation (EC) 1925/2006 regulates the foods to which vitamins, minerals and other permitted substances have been added (i.e. fortified foods).

6. Tobacco

6.1. Article 168 (5) TFEU provides, for the first time in the EU Treaties, an express reference to tobacco control stating that incentive measures may be adopted with the objective of public health regarding tobacco. However, this Article explicitly excludes the possibility of the EU harmonising laws under that provision.

6.2. Virtually all existing legislation on labelling, advertising and product regulation has therefore been enacted based on the internal market competence provided for in Article 114. The Union is able to exercise competence in this area where only some Member States have introduced certain tobacco control related legislation so that disparities between states' laws mean there exists an 'internal market barrier'. As stated above, Article 114(3) states that a high level of protection for health should be taken as a basis of any provisions under this Article.

6.3. The relevant legislation in this area is:

- Tobacco Products Directive 2001/37/EC which brings together provisions concerning the manufacture, presentation and sale of tobacco products. (It recasts and repeals Directives 89/622/EEC and 92/41/EEC.) It sets maximum limits for tar, nicotine and carbon monoxide yields of cigarettes, and industry reporting requirements. Health warnings have to appear on tobacco products and they must not contain descriptive elements suggesting that they are less harmful than others (e.g. "light").

- Directive 2003/33/EC has an EU wide ban on cross-border tobacco advertising and sponsorship in the media other than television. The ban covers print media, radio, internet and sponsorship of events involving several Member States, such as the Olympic games and Formula One races.

- Directive 2010/13/EU on the coordination of laws and regulations concerning the provision of audio visual media activities. This Directive relates to tobacco control in that it prohibits advertising promoting cigarettes and other tobacco products, including indirect forms of advertising, on all forms of audiovisual commercial communication. For this Directive the EU exercises its competence under Articles 53 and 62

TFEU regarding the right of establishment and free movement of services.

6.4. There is extensive domestic legislation on tobacco control but for the purposes of this review the main UK legislation implementing the EU directives is The Tobacco Advertising and Promotions Act 2002; The Tobacco Advertising and Promotion 2002 (Amendment) Regulations 2006 (S.I. 2006/2369); and the Tobacco Products (Manufacture, Presentation and Sale (Safety) Regulations 2002 (S.I. 2002/3041) as amended.

7. Alcohol

7.1. The European Union has competence and responsibility to address public health problems such as alcohol abuse, by complementing national actions in this field, under Article 168(5) TFEU, which has been used to develop the EU alcohol strategy.

7.2. Directive 2010/13/EU on the coordination of laws and regulations concerning the provision of audio visual media, sets out criteria that television advertising of alcohol must comply with. These include that the advertising must not be aimed at minors or depict minors drinking; it must not link alcohol with enhanced physical, sexual or social performance; and it must not encourage immoderate consumption. The EU competence for this Directive derives from Articles 53 and 62 TFEU regarding the right of establishment and free movement of services.

7.3. The labelling of alcoholic beverages as a foodstuff is impacted on by Directive 2000/13/EC, which is detailed in paragraph 5.3 above.

8. Health Security

8.1. Article 168(5) TFEU provides competence for the Union to adopt *incentive* measures to protect and improve human health in particular to combat the major cross border health scourges and measures concerning the monitoring, early warning of and combating serious cross-border threats to health.

8.2. This competence has been exercised in Decision 2119/98 to establish a network at Community level for the surveillance of communicable diseases and to provide an early warning system for the prevention and control of these diseases. The Decision requires Member states to provide relevant information to the Commission and other Member states and consult about their measures to control communicable diseases.

8.3. A new Decision on serious cross-border threats to health is currently being negotiated which provides for similar obligations on Member States to cooperate and consult on their preparedness plans but extends

the scope of the areas on which the procedures apply to cover cross-border threats to health arising out of other biological, chemical, environmental or unknown threats.

9. Radiation

9.1. For public exposures to non-ionising radiation the only EU pronouncement is Council Recommendation (519/1999) adopted under Article 168 TFEU that states that Member States should keep exposures to non-ionising radiation below ICNIRP (International Commission on Non-ionising Radiation Protection) guidelines.

9.2. The ICNIRP guidelines are the internationally recognised standards for non-ionising radiation. These standards are also used in the draft EU Physical Agents Directive which will apply to worker exposures. Public health issues are regulated under the Health and Safety at Work Act, which places the responsibility for public safety on the operator of a facility.

10. Public Health Programmes

10.1. EU competence in this area is shared and is derived from Article 168 TFEU. Article 168(1) states that a high level of human health protection shall be ensured in the definition and implementation of all Union policies. The Article directs Union action in particular at protecting people from health threats and disease, promoting healthy lifestyles and helping national authorities in the EU cooperate on health issues. It states that the Union shall complement Member States' action in reducing drugs related health damage.

10.2. 168(1) sets out a subsidiarity principle in relation to public health, such that EU action will complement National policies and the actions of Member States and will encourage cooperation.

10.3. The EU has exercised its competence in the area of Public Health chiefly by adopting programmes of community health. The current Decision is 1350/2007/EC on establishing a second programme of Community action in the field of health for 2008-2013. The key purpose of the programme is to provide financing for health projects in tandem with Member States, regions and stakeholders.

10.4. The third programme of EU action for the period 2014-2020 ("Health for Growth") is currently being negotiated. The Programme is intended to assist EU countries to respond to economic and demographic challenges facing their health systems and enable citizens to stay healthy for longer. The legal base for the Regulation is Article 168(5) which provides for the European Council to adopt incentive measures designed to protect and improve human health.

11. Rare Diseases

11.1. The Recommendation on an action in the field of rare diseases (2009/C 151/02) is based on article 168(5) TFEU which provides competence to adopt incentive measures designed to protect and improve human health. A recommendation is not legally binding (Article 288 TFEU), but carries a level of expectation that Member States will not ignore it.

NHS and Patient Services

12. Implications of employment policy

12.1. The Working Time Directive (2003/88/EC) was adopted under Article 153 (2) and relates to the field in Article 153(1) (a), which covers improvement of the working environment to protect workers health and safety. It lays down minimum safety and health requirements for the organisation of working time.

12.2. The Directive consolidates the former basic Council Directive 93/104/EC of 23 November 1993, as amended by Directive 2000/34/EC of 22 June 2000. It is designed to strike a balance between the principal objective of the health and safety of workers and the needs of a modern European economy.

12.3. Along with a number of other areas, doctors in training were exempt from the original 1993 Directive, but were brought within its scope in an amendment agreed in 2000.

12.4. The Directive is implemented in the UK by the Working Time Regulations 1998 (S.I. 1998/1833). Doctors in training were subject to a transitional provision to allow a higher average working week rather than the 48 hour week. The working week limit was gradually phased in for doctors in training from 1st August 2004 and applied in full from 1st August 2011.

12.5. The Directive is currently being negotiated by European Social Partners.

12.6. There are two key ECJ cases which significantly affected the scope of the law in this area and had a particular effect on doctors' working time:

- C-303/98 *Sindicato de Médicos de Asistencia Pública v Conselleria de Sanidad y Consumo de la Generalidad Valenciana*. The SIMAP judgment defined all time when the worker was required to be present on site whilst on call as actual working hours for the purposes of work and rest calculations.

- Case C -151/02 *Landeshauptstadt Kiel v Norbert Jaeger (Jaeger).* The Jaeger judgment confirmed that time spent on call at a place of

work was work, even if workers could sleep when their services were not required. It also held that where compensatory rest was due because the daily/weekly rest requirements cannot be met, it must be taken immediately after the end of the working period. The result is that it will not be sufficient to aggregate the rest available to an individual over a period.

13. Implications of free movement of persons: healthcare professionals

13.1. Article 46 TFEU requires the European Parliament and the Council to issue directives or make regulations to facilitate the free movement of workers; Article 53 TFEU requires the European Parliament and the Council to issue directives for the mutual recognition of diplomas, certificates and other evidence of formal qualifications; both articles are part of the shared competence on the internal market under Article 4(2)(a).

13.2. The EU has exercised this competence through Directive 2005/36/EC which requires the mutual recognition of professional qualifications either through the 'automatic system' or 'general system'. The automatic system requires the automatic recognition of qualifications relating to the following professions: doctors, dentists, nurses, midwives, pharmacists, veterinary surgeons, and architects; which all have harmonised minimum training requirements. Other professions benefit under the general system where qualifications and experience are assessed and where necessary compensatory measures may be imposed. The Directive is implemented in the UK by the European Communities (Recognition of Professional Qualifications) Regulations 2007 (S.I. 2007/2781).

13.3. In December 2012, the European Commission issued proposals to amend the Directive and the UK Government are currently in negotiations in respect of those proposals.

13.4. Prior to Directive 2005/36/EC, there were various directives which provided for mutual recognition of professional qualifications on a piecemeal basis. The purpose of the 2005 Directive was to consolidate and harmonise those directives under a single directive.

14. Implications of free movement of persons: coordination of healthcare provision

14.1. It is recognised that in order to secure the free movement of persons, citizens and their families who are living, working or temporarily visiting another Member State (e.g. as a tourist or for study or business) must have their health care benefits coordinated to allow proper access to medical treatment. The EU has competence in this area on the basis of Article 48 TFEU which directs that the Union shall adopt measures in the

field of social security (which includes health care) as are necessary to provide freedom of movement for workers.

14.2. The key Union provision in this area is Regulation (EC) No. 883/2004 on the coordination of social security systems. From 1st May 2010 Regulation 883/2004 replaced Regulation (EEC) No. 1408/71 which in its turn replaced Regulation 3, drawn up in 1958. Regulation 3 was one of the earliest Regulations as coordination of social security was seen as essential for the free movement of workers even at that early stage.

14.3. The United Kingdom has applied Regulation 1408/71 since 1st April 1973 when the UK acceded to the European Economic Community.

14.4. Originally, Regulation 3 was limited to wage earners and assimilated workers. Regulation 1408/71 was also limited to this category but was extended to cover the self-employed and then students. Now, Regulation 883/2004 is not limited to the economically active population; it applies to nationals of a Member State[2], stateless persons and refugees[3] residing in a Member State, their families and survivors. But for the Regulation to apply the person must be or have been subject to the (social security) legislation of one Member State and have moved to or be visiting another Member State.

14.5. Article 3 of Regulation 883/2004 provides a list of the branches of social security legislation to which the regulation applies. This includes sickness and maternity benefits including what is termed 'benefits in kind', which are to supply (or pay for the cost of) medical care and products – in the UK this is done through the NHS.

14.6. Both Regulation 1408/71 and its replacement Regulation 883/2004 give individuals certain rights to obtain health care in another Member States. The main examples of this are as follows:

- The most widely known benefit is for visitors using the EHIC (the European Health Insurance Card) which covers medically necessary treatment needed during a holiday, business trip or longer course of study.

- A patient's "home" State can authorise a patient to go to another Member State for specific planned treatment (Article 22(1)(c) of Regulation 1408/71 now replaced by article 20 of Regulation 883/2004) – See section 15 below.

[2] This includes the European Economic Area states Iceland, Liechtenstein and Norway, (as the Regulation is incorporated into Annex VI of the EEA Agreement) and Switzerland (Regulation 883/2004 is incorporated into the EU-Switzerland Agreement).
[3] It was confirmed in the case of Khahil C95/99 ECR I-7413 that Article 48 TFEU was a sufficient legal base to include refugees and stateless persons in the Regulation.

- Where an individual receives a pension under the legislation of one Member State but lives as a habitual resident in another Member State, health care is provided to the pensioner and members of his family by the Member State in which the pensioner is living on behalf of, and therefore reimbursed by, the State that pays the pension (article 24 of Regulation 883).

14.7. The cost of benefits in kind provided by one Member State in the situations above are to be reimbursed by a citizen's home (or competent) Member State (Article 35 of Regulation 883/2004). The reimbursements are determined and arranged in accordance with administrative arrangements set out in the Regulation 987/ 2009 which lays down detailed provisions for the implementation of Regulation 883/2004.

14.8. On the basis of the rules set out in the EU Regulations, workers (employed and self-employed persons) are generally subject to the social security legislation of the country where they actually work, regardless of where they live or where the employer is based. In these circumstances, the principle of non-discrimination contained in Article 4 of Regulation 883/2004 applies and they are entitled to receive healthcare on the same terms as other nationals in the state where they work. Therefore the cost of health care for workers is met by the State in which they work. This is not the case for 'posted' workers who remain subject to the legislation of the state from which they are posted, meaning that this state is responsible for their healthcare costs.

15. Implications of free movement of services: cross-border healthcare

15.1. The ECJ has recognised that the freedom to provide services extends to those receiving the services[4]. Over a number of years, judgments of the ECJ that looked at the need for authorisation to obtain medical treatment abroad under Regulation 1408/71, established that an individual could purchase health services in another Member State and seek reimbursement of their costs from their national system of health care under what is now Article 56 TFEU on the free movement of services[5]. In Case C-120/95 Decker and Case 158/ 96 Kohll the Court of Justice found that a national condition requiring prior authorisation to do this was, in some cases, contrary to Article 56 TFEU (although such a condition could be capable of justification where necessary for maintaining a balanced medical and hospital service).

[4] Joined Cases 286/82 and 26/83 Luisi and Carbone

[5] See in particular Case C-157/99 Geraets-Smits v. Stichting Ziekenfonds VGZ and Peerbooms v. Stichting Z Groep Zorgverzekeringen; Case C-385/99 Müller-Fauré/van Riet; Case C-56/01 Inizan v Caisse Primaire d'Assurance Maladie des Hauts de Seine ; *Case C - 512/08 Commission v France*

15.2. A key case for the NHS was Case *C-372/04 The Queen on the application of Yvonne Watts v Bedford Primary Care Trust and the Secretary of State for Health* where the ECJ held that the right to reimbursement for the cost of services obtained aboard applied to a system such as the NHS - a residence based system providing free hospital treatment funded out of general taxation (rather than insurance based healthcare systems common in other Member States). The Court also held that refusal to grant prior authorisation could not be based merely on the existence of waiting lists without carrying out an objective medical assessment. This key ruling led to the National Health Service (Reimbursement of the Cost of EEA Treatment) Regulations 2010 (S.I. 2010/915) which amended the National Health Service Act 2006 so as to impose a duty on the Secretary of State to reimburse the cost of treatment provided by an authorised provider in another EEA Member State to a patient who is ordinarily resident in England, subject to certain conditions and limitations.

15.3. The numerous piecemeal ECJ judgments led to the development of Directive 2011/24/EU on the application of the patients' rights in cross border health care which was adopted on 9 March 2011. It clarifies the rules and procedures on patients' access to cross-border healthcare and provides EU citizens with better information on their rights. Member States are required to transpose the Directive into national legislation by 25 October 2013.

15.4. The legal base for this Directive is Article 114 (except in relation to Articles 12 and 14 of the Directive where the legal base is Article 168) because the predominant purpose of the Directive is to remove obstacles to the internal market for health care services. The Government's proposals for implementation will be the subject of consultation in due course.

16. eHealth

16.1. eHealth deployment falls under Article 168(7), which states that Union action shall respect the competence of Member States to organise and deliver health services and medical care.

16.2. However, to encourage eHealth use throughout the EU, the supporting competence of Article 168(1) and (2) TFEU are often used to in respect of incentive measures to support, facilitate and encourage voluntary co-operation between Member States on eHealth deployment in cross border care and also to support funding and policy direction.

16.3. Article 14 of Directive 2011/24/EU on the application of patients' rights to cross border health care provides for Union action to support and facilitate a voluntary network of national authorities on eHealth. Under

this provision the European Commission formed an eHealth network in January 2012, in order to advance implementation of eHealth in Europe at a co-operative level. The Network connects national authorities to help Member States facilitate the transmission of data in cross-border care scenarios.

16.4. Article 12 of that Directive provides for Union action to support Member States in the development of a European reference network between health care providers and centres of expertise particularly in rare disease. Participation is voluntary.