Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

A guide to what is a medicinal product

MHRA Guidance Note 8

March 2016

A guide to what is a medicinal product

MHRA

151 Buckingham Palace Road

London

SW1W 9SZ

Published by MHRA 2016

Applications for reproduction should be made in writing to:

The Copyright Unit

Her Majesty's Stationery Office

St Clements House

2-16 Colegate

Norwich

NR3 1BQ

Contents

		Page
	Introduction	5
1.	What are Borderline Products?	5
2.	MHRA policy and practice	5
3.	How does the MHRA determine as to whether the product is a medicinal product	6
4.	What is a medicinal product?	6
	• Definition • Meaning of Disease	
5.	Advertising	7
	• Regulations • Internet advertising	
6.	Deciding factors when determining the regulatory status of a product	8
7.	Products that are not classified as medicines under the “functional” limb of the definition of a medicinal product	10
8.	Is my product a herbal medicinal product?	11
9.	Is my product a homeopathic medicinal product?	11
10.	What claims can I make for my product?	12
	• Claims to treat or prevent disease • Claims to “maintain” health • Cosmetic claims • Food claims	
11.	Products judged to be non-medicinal	13
12.	Borderline Interface with other regulatory frameworks	14
	• Medical Devices • Cosmetics • Aromatherapy • Biocides • General Product Safety Directive	

- Food including food supplements
- Food Supplements – Application of Mutual Recognition
- Misuse of Drugs Act 1971 and amendments
- UK Anti-Doping

13. Miscellaneous 19

- Sports supplements
- Topical anesthetics (Numbing Gels/Creams)
- Weight loss Products
- Nitrous Oxide
- What to do if you are still unsure of the status of your product
- Marketing Authorisations

14. A summary of case law that is relevant to decisions concerning borderline products 21

Appendix 1 Words and phrases

Appendix 2 Useful addresses

Appendix 3 Statutory Determination Procedure

Appendix 4 Guidance Note on Smoking Cessation Products and Alternatives to tobacco products

Appendix 5 Guidance Note on Chlorhexidine for a medical purpose

Appendix 6 Guidance Note on Topical Products

Appendix 7 Guidance Note on Hangover Preventives and Cures

Appendix 8 Guidance Note on Headlice

Appendix 9 Guidance Note on Internet Advertising

Introduction

To protect public health, and on behalf of the UK Licensing Authority, the Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicinal products for human use in accordance with the European Community's medicinal products directive (Directive 2001/83/EC, as amended, "the Directive") and UK law. The MHRA may be asked to give an opinion on, or make a formal determination on whether a product is or is not a medicinal product. This is a specialist function carried out by classifiers in the MHRA's Medicines Borderline Section. If a classifier does decide that a product is a medicinal product, then unless an exemption applies, it will be subject to the Human Medicines Regulations 2012 [SI 2012/1916] ("the Regulations").

The person or company marketing a product has a responsibility to do so in accordance with the law. The Regulations provide that, unless exempt[1], any medicinal product placed on the UK market must have a marketing authorisation (MA), traditional herbal registration (THR) or certificate of registration as a homoeopathic product granted by the European Commission or by the UK Licensing Authority. A marketing authorisation or registration is only granted for a medicinal product which meets statutory standards of safety, quality and efficacy, whilst products registered as traditional herbal medicines or as homoeopathic medicines have to meet statutory standards of safety and quality. Traditional herbal medicinal products are required to demonstrate plausible efficacy alongside other criteria. See Section 9 of this guidance note for further information on this aspect.

1. What are Borderline Products?

The regulatory status of products on the borderline between medicinal products and food supplements, biocides, cosmetic products, medical devices or 'general products[2]' may not be immediately obvious.

This Guidance explains how, and on what basis, the MHRA decides whether products are medicines or not and clarifies the MHRA's position on traditional herbal medicinal products.

2. MHRA policy and practice

European Community legislation on medicinal products is not fully harmonised and products are classified under national regulations. For this reason, it is possible that a product classified as a medicine in the UK may be classified as, for example, a food in another Member State. However, when reaching decisions on the status of products each Member State is obliged to abide by the judgments of the European Court of Justice.

The MHRA classifies products on a case by case basis. Final determinations issued by the Medicines Borderline Section provides brief details of the determination for the product at the time it was investigated and where relevant refers to product ingredients. These final determinations are available using the link https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/404785/Final-determinations-Vol4_1_.pdf.

Further information regarding the statutory determination procedure can found in Appendix 3.

---

[1] *Human Medicines Regulations 2012 – Regulation 3(9) states "This condition is that the medicinal product is not manufactured or, as the case may be, assembled-*
(a) on a large scale; or
(b) by an industrial process."

[2] General Products Safety Directive (EC Directive2001/95/EC)

Where medicinal claims are being made for example for foods or cosmetic, there may be occasions where the MHRA may regard it to be more appropriate for local trading standards officers to advise in relation to compliance with the Food Information to Consumers Regulation (Regulation (EC) No.11/69/2011) In such circumstances, Appendix 1 can be used to assist in deciding whether the claims may be regarded to be medicinal. In cases of doubt the MHRA can assist the relevant trading standards officer as required.

The MHRA, on behalf of the UK Licensing Authority, determines (subject to review by the courts), whether a product is a medicinal product. The MHRA's power to determine the status of a product as a medicinal product has been confirmed following a judgment of the Court of Appeal (R. v. Medicines Control Agency ex parte Pharma Nord (UK) Limited 1998). The Court ruled that it was acceptable for the Licensing Authority to determine whether or not a product is a medicinal product, having expert knowledge, the decision of the Licensing Authority being subject to review by the courts. This authority is also cited in subsequent litigation cases. The judgment noted:

"The approach of the European Court is equally consistent with the initial decision being made by the licensing authority and that decision being reviewed by whatever are the appropriate courts within a particular member state."

3. How does the MHRA determine whether a product is a medicinal product

The MHRA reaches a determination on whether a product is or is not a medicinal product on a case by case basis, and in the light of:

- the definitions of a medicinal product
- following an assessment of all the available evidence
- relevant ECJ and domestic Court precedents.

When considering that evidence, and determining whether a product comes within either limb of the definition, no single factor or combination of factors will necessarily be conclusive, or more or less important than others. But in relation to particular products, a single factor or combination of factors may be more important than others, and may even be conclusive.

A minority of products may potentially satisfy the definition of a medicinal product and the definition of another type of product. The MHRA will decide whether to classify such a product as a medicinal product on a case by case basis, taking into account all relevant factors in relation to its presentation and function. However, in accordance with Article 2(2) of the Directive, where doubt remains as to its classification as a medicine or another type of product, it will be classified as a medicinal product.

4. What is a medicinal product?

Definition

Article 1 of Directive 2001/83/EC as amended defines a "medicinal product" as:

> *"Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; [the first/presentational limb]*

Any substance or combination of substances which may be used in, or administered to, human beings, either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis" [the second/functional limb]

Medicinal products may well fall under both limbs of the definition but the European Court of Justice (ECJ) has confirmed that falling under either limb is sufficient to classify a product as a medicinal product[3].

Meaning of Disease

Regulation 8 of the Regulations states *"disease" includes any injury, ailment or adverse condition, whether of body or mind"*

When considering borderline products the MHRA considers the following examples to be medicinal claims:

- references to all medical conditions major to minor including colds, headaches, cuts and bruises, spots, smoking addiction, obesity, arthritis, depression, stress and all childhood disorders and serious diseases.
- references to condition of the mind such as depression, addictions, attention deficit/hyperactivity disorder.
- references to treatment or alleviation of adverse conditions including decongests, relieves pain, reduces inflammation, calms, stops itching, cures insomnia, reduces blood pressure, reduces sugar levels.
- References to the symptoms of disease such as pain, inflammation etc.

5. Advertising

Regulations

"Advertisement" is defined broadly in Regulation 7 of the Regulations and includes any published materials or any other activity which are designed to encourage the purchase and use of medicines by the general public, generally by means of highlighting qualities of the medicine (product claims).

Regulation 279 of the Regulations states:

"A person may not publish an advertisement for a medicinal product unless one of the following is in force for the product-

(a) marketing authorisation;
(b) a certificate of registration;
(c) a traditional herbal registration; or
(d) an Article 126a authorisation. This refers to an authorisation granted by the licensing authority under Part 8 of these Regulations".

[3] [Upjohn 1989 C-112/89]: *"Directive 65/65 (now Directive 2001/83) provides two definitions of the term "medicinal product": one relating to presentation, the other to function. A product is medicinal if it falls within either of those definitions."*

Forms of marketing MHRA consider may suggest to a consumer that a product is properly classified as a medicinal product:

- references to medical conditions
- comparison with licensed medicines
- references to interference with the normal operation of a physiological function
- product names which refer to adverse medical conditions
- references to medical and / or clinical research and testing
- references to the health risks of not taking a particular product
- editorial medicinal claims
- recommendations by Doctors/health professionals
- testimonials that include/imply medicinal claims
- graphics that imply medicinal uses
- references to or reproduction of "generic" information
- juxtaposing with any examples of the above
- inclusion of details in an Ailments Section.

Internet advertising

Information on the internet about a product and its uses is not excluded from the definition of the term 'advertisement' in Regulation 7 of the Regulations. Where a product is sold on or has links to a website which presents that product as a medicine, the website will be used by the MHRA as evidence in the determination process. Similarly, where a customer is directed from a website selling a product, to another website for more information about the substances contained in a product and their uses, this may also be used by the MHRA as evidence in the determination process. To help companies avoid bringing unlicensed products within the definition of a medicinal product further information can be found in Appendix 9.

6. Deciding factors when determining the regulatory status of a product

What factors does the MHRA take into account when determining the product under the 'first/presentational limb'?

The second limb of the definition is concerned with the *presentation* of the product. A product may be determined by the MHRA as a medicinal product *solely* under the first limb of the definition. In assessing whether a product is *"presented as having properties for treating or preventing disease",* the MHRA considers, in context, any claims (implicit as well as explicit) which are made for it, and the characteristics of its presentation as a whole.

The MHRA considers the following factors:

- all claims made for the product, both explicit and implicit, including any made on websites, linked helplines, testimonials or in linked publications. Implicit claims may include product names
- the context in which the claims are made, and the overall presentation
- how a product appears to the public, or to those to whom it is promoted
- the labelling and packaging/package inserts including any graphics
- the promotional literature, including testimonials and any literature issued by the person placing the product on the market or on their behalf

- advertisements, including those appearing in “advertorials”, on television, other media and the Internet
- the product form, (capsule, tablet, injection etc.) and the way it is to be used
- any particular target of the marketing information/advertising material, for example, population groups with, or particularly vulnerable to, specific diseases or adverse conditions.

What factors does the MHRA take into account with determining the product under the ‘second/functional limb’?

The first limb of the definition is concerned with the *function and intended use of the product*, that is, whether the product *“may be administered…..with a view to”* achieving a medicinal purpose.

The factors which are relevant in determining whether a product falls within the second limb of the definition have been considered by the following ECJs:

The judgment in HLH Warenvertriebs, 2005 (C-211/03) says:

“…for the purposes of determining whether a product comes within the definition of a medicinal product ‘by function’ within the meaning of directive 2001/83, the national authorities…must proceed on a case by case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological properties, to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail.

The pharmacological properties of a product are the factor on the basis of which the authorities of the Member States must ascertain, in the light of the potential capacities of the product, whether it may, for the purposes of the second subparagraph of Art 1(2) of Directive 2001/83/EC, be administered to human beings with a view to…restoring, correcting or modifying physiological function in human beings.”

Commission of the European Communities v Federal Republic of Germany (C-319/05) says:

“… the definition of medicinal product by function is designed to cover products whose pharmacological properties have been scientifically observed and which are genuinely designed to make a medical diagnosis or to restore, correct or modify physiological functions.”

The judgment in Hecht-Pharma GmbH, 2009, (C-140/07) says:

“... a product cannot be regarded as a medicinal product within the meaning of that provision where, having regard to its composition – including its content in active substances – and if used as intended, it is incapable of appreciably restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action. The capacity to restore, correct or modify physiological functions should not lead to the classification as medicinal products by function of products which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions.”

The MHRA can consider the following factors (non- exhaustive list):

- the pharmacological, immunological or metabolic properties of the ingredient(s) and any significant effect(s) the product will have on physiological function in humans, or in the case of a product which satisfies the definition of a traditional herbal medicinal product in Directive 2004/24/EC where the pharmacological, immunological or metabolic effects or efficacy are considered plausible on the basis of long standing use and tradition
- the composition of the product
- the manner in which the product is used
- the product promotional literature, including testimonials and any literature issued by a third party on behalf of the person who places the product on the market
- the familiarity of the product to consumers and the extent of its distribution in the UK
- the product form, (capsule, tablet, injection, etc.) and the way it is to be used
- the presence of essentially similar licensed, registered or exempt medicines on the UK market
- the risks which use of the product may pose.

7. Products that are not classified as medicines under the "functional" limb of the definition of a medicinal product

The MHRA only classifies finished products and not individual substances and ingredients. A product will not be classified as a medicine solely on the basis that it may be unsafe for human use. A product must be intended for, or be capable of performing, a medicinal function before it can be classified as such.

Products containing chemicals or substances that were primarily developed for non-medicinal purposes, such as for industrial (e.g. chemical) processes or agricultural use, and which have no valid use in clinical practice are unlikely to fall within the function limb.

The Judgment in the joined cases Markus D (C-358/13) and G. (C-181/14) concerns the classification of substances that are not intended to be consumed for a medical but for a recreational purpose. For products to fall under the Directive 2001/83/EC the ECJ Judgment states:

"…for the purpose of determining whether a product falls within the definition of a medicinal product for the purposes of Directive 2001/83, the national authorities, acting under the supervision of the courts, must decide on a case-by-case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological, immunological or metabolic properties, to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail (the judgments in Upjohn, EU:C:1997:147, paragraph 23, and BIO Naturprodukte, C-27/08, EU:C:2009:278, paragraph 18)";

The Judgment concluded that *"Article 1(2)(b) of Directive 2001/83 must be interpreted as not covering substances, such as those at issue in the main proceedings, which produce effects that merely modify physiological functions <u>but which are not such as to have any beneficial effects, either immediately or in the long term, on human health, are consumed solely to induce a state of intoxication</u> and are, as such, harmful to human health."* [Emphasis underlined.]

8. Is my product a herbal medicinal product?

There are many herbs with known medicinal uses and at the same time uses as either foods or cosmetics. When considering the status of a herb that does have various uses the Agency will make a judgment as to which is the dominant function and pays particular regard to the purpose of the herb's inclusion in a product. In very general terms the Agency does not usually regard products containing culinary herbs to be medicines unless included for their medicinal properties, or claims to treat or prevent disease are made for them. Some herbs, however, have well-known medicinal effects and would usually only be found in products for a medicinal purpose.

A significant number of Herbal medicines or remedies sold or supplied in the UK are controlled under Part 7 of the Regulations for which herbal medicinal products can receive a traditional herbal registration instead of a marketing authorisation.

A European system for regulating herbal medicinal products is now fully in force. The scheme is limited to herbal medicinal products for minor health conditions where medical supervision is not required, for example, symptomatic relief of hay fever, rhinitis, muscular pain and stiffness including backache. In order to qualify applicants' will be required to show evidence that the herbal medicinal product has been traditionally used to treat the stated condition for a minimum of 30 years, 15 years of which must have been in the European Union. Registered products have the requirement for efficacy replaced by a requirement for plausible effect on the basis of long standing use and experience.

Guidance on how to apply for a traditional herbal registration (THR) and to market a herbal medicine (remedy) in the UK and permitted indications is available on the website. https://www.gov.uk/apply-for-a-traditional-herbal-registration-thr.

9. Is my product a homeopathic medicinal product?

While a product described as "homeopathic" will effectively fall within the first limb of the definition of a medicinal product since the practice of homeopathy is only concerned with medicine all homeopathic products must comply with the definition given in the EU Directive 2001/83/ EU.

Homeopathy is a system of medicine which involves treating the individual with highly diluted substances, given mainly in tablet form, with the aim of triggering the body's natural system of healing. In the UK there are two regulatory schemes for homeopathic medicines; a simplified registration scheme and the national rules scheme. Depending on which scheme you apply for will determine if indications are permitted.

Under the simplified scheme you will be required to submit data on the quality of the product and show that it is dilute enough to guarantee safety. This scheme does not allow indications. Under the national rules there is no restriction on the first dilution to be authorised or the pharmaceutical form.

This scheme will allow you to claim that your product is used within the homeopathic tradition for the relief or treatment of minor symptoms and conditions which do not require the supervision of a doctor. You will be required to submit data that demonstrates quality, safety and use within the UK homeopathic tradition, including details of your labelling and product literature as part of your application.

Guidance on the legislation which controls homoeopathic medicinal products and on the registration scheme is available on the website https://www.gov.uk/search?q=mhra+homoeopathic.

10. What claims can I make for my product?

The MHRA is committed to considering each product individually, and it is not possible to produce more than an indicative list of the kind of claims that the MHRA may decide are presenting the product as treating or preventing disease. However, it may be helpful to refer to the words and phrases listed in Appendix 1. The MHRA has previously decided that, in context - for example, when used in relation to a disease, illness or specific adverse condition - claims which included words like these were presenting products for treating or preventing disease, and accordingly could be classified as medicines.

Claims to treat or prevent disease

A product which claims to treat or prevent disease falls within the first limb of the definition of a medicinal product. Claims to relieve symptoms, or to cure, or to provide a remedy or heal a specific disease or adverse condition of body or mind will also be regarded as medicinal claims. In context, stress, anxiety and nervous tension can be adverse conditions of the mind, and claims to cope with or manage those conditions can be regarded as claims to treat or prevent disease.

Again in context, and particularly in the case of products on the borderline between food and medicinal products, claims to “protect” or “avoid” may be perceived by consumers as having much the same meaning as “prevent”. For example, a product may be presented to “protect” a consumer against a specific disease or adverse condition in such a way that consumers would believe that the product could “prevent” it. Saying that a product “may help with” an adverse medical condition implies to the averagely well-informed consumer that the product is a treatment and such claims will bring the product within the first limb of the definition.

Claims to “maintain” health

The MHRA view is that claims to “maintain” or “help to maintain” or “support” health or a healthy lifestyle, can be approved under food law, and would not normally regard such claims to be medicinal. Nor, if such claims are clearly made in relation to healthy bodily functions or organs, is the MHRA likely to consider them as presenting the product for treating disease. In general, the MHRA is only likely to consider “health maintenance” claims as medicinal if they suggest or imply that a product may prevent disease or, where targeted on a vulnerable section of the population, may restore, or help to restore, a specific bodily function or organ to a normal healthy state.

Cosmetic claims

Cosmetic claims should emphasis the *cosmetic* use of the product i.e. cleansing, moisturising, perfumery, keeping the skin in good condition. Article 20(1) of Regulation (EC) 1223/2009 on cosmetic products refers to product claims and states *“In the labelling, making available on the market and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have.”*

As a guide the following are examples of claims which MHRA could regard to be adverse medical conditions:

- toothpastes which are intended to be used to relieve the pain of sensitive teeth will fall to be either medicinal products or medical devices depending on their mode of action. However,

toothpastes which are designed to be used without exacerbating sensitivity remain as cosmetics

- to protect /prevent eczema, dermatitis and psoriasis. These are all adverse medical conditions which can be exhibited by dry, inflamed, scaly and itchy skin and products will fall to be either medicinal products or medical devices depending on their mode of action.
- references to specifically named pathogens e.g. MRSA is an implied medicinal claim to prevent or treat infections that are caused by the MRSA micro-organism
- nappy rash is a form of dermatitis. Claims to protect against nappy rash would not be regarded to be acceptable if in the context they amount to claims to prevent nappy rash
- shampoos may be cosmetics or medicines, depending on the constituents and the claims being made. Those mainly intended for hygiene, or are for anti-dandruff, are likely to be cosmetic products. However, if the claims are for the alleviation or treatment of itchy scalp, or dermatitis, then the product would fall to be a medicinal product as it suggests that an underlying medical condition exists
- products to treat/prevent spots and acne are medicines as these are all adverse medical conditions. However, depending on the product's presentation, claims that the product is intended to be used solely to conceal spots/acne will generally mean some products will be regarded to be cosmetic products. A cosmetic product should be primarily used for its cosmetic purpose as listed in the definition of a cosmetic product and advertised to consumers accordingly.

Food claims

The Food Information to Consumers Regulation (FIC) (Regulation (EC) 1169/2011), contains provisions for both the labelling and advertising of food. In particular, any claim that a food has the property of preventing, treating or curing human disease is not permitted. This covers any implication that a foodstuff is capable of protecting against, or relieving the symptoms of, disease, infection or other adverse conditions. The MHRA must therefore be mindful of the primary purpose of the product when investigating whether medicinal claims which are made for food products (including food supplements) should be subject to the Regulations.

In addition any nutrition or health claims made on food must now be authorised before use in the EU. The Nutrition and Health Claims Regulation (Regulation (EC) 1924/2006), sets out the requirements for authorisation of claims for foods and the European Commission has established a register of permitted, rejected and pending nutrition and health claims.

11. Products judged to be non-medicinal

The MHRA can only decide if a product is or is not a medicinal product and cannot classify products that fall under other product legislation. Compliance with other product regulations should be checked with the appropriate authority.

It should be noted that a "non-medicinal" decision does not constitute an authority to place a product on the market, nor does it mean that a product has been approved or endorsed by the MHRA. The MHRA can only give approval for medicinal products and non-medicinal products must never be promoted with claims or suggestions that they are MHRA "approved".

The Agency reserves the right to change its view in the event of any information or evidence which has a bearing on the status of the product, including the way in which it is packaged, promoted or presented, or if there is a change in scientific knowledge or the law. The Agency can give no assurance that any particular product, including products under development, will not subsequently be classified as a medicinal product.

12. Borderline Interface with other regulatory frameworks

Medical Devices

Medical devices are subject to the controls of Directives 93/42/EEC, 98/79/EC and 90/385/EEC, implemented in the UK by the Medical Devices Regulations 2002 (SI 2002/618) as amended.

Products that incorporate, or are used to administer, a drug may be regulated as either medical devices or as medicinal products, depending on the principal intended function of the product and the method by which this action is achieved.

In order to decide whether a product is considered to be a medical device or a medicinal product, the following points are taken into consideration:

- the intended purpose of the product taking into account the way the product is presented;
- the method by which the principal intended action is achieved.

The principle mode of action for a medical device is typically fulfilled by physical means (including mechanical action, physical barrier, replacement of, or support to, organs or body functions).

Medical devices may contain medicinal substances, including herbal and plant extracts and substances derived from human blood or blood plasma, which act on the body in a manner ancillary to the device. However, when such substances act in a manner that is more than ancillary, the product is likely to be regulated as a medicinal product.

Product is already CE marked

Where a product has been correctly CE marked as a medical device it may be sold freely throughout the EU market without further regulation restriction. However, the classification of a product as a medical device in another country does not preclude a national competent authority from classifying the same product as a medicinal product.

The MHRA's power to determine the classification of a product has been confirmed by the ECJ judgment in Laboratoires Lyocentre, October 2013 (C-109/12). The judgment says:

"In addition, the fact that a product is classified as a medical device in accordance with Directive 93/42 in one Member State does not prevent it being classified, in another Member State, as a medicinal product in accordance with Directive 2001/83 if it displays the characteristics of such a product (see, by analogy, Case C-150/00 Commission v Austria [2004] ECR I-3887, paragraph 60, and HLH Warenvertriebs and Orthica, paragraph 56)."

"In the light of all the foregoing considerations, the answer to the first question is that the classification of a product in one Member State as a medical device bearing a CE marking, in accordance with Directive 93/42, does not preclude the competent authorities of another Member State from classifying the same product, on the basis of its pharmacological, immunological or metabolic action, as a medicinal product within the meaning of Article 1(2)(b) of Directive 2001/83."

Further guidance on the borderlines between medical devices and medicinal products can be found using the link below which gives examples of products regulatory status under Section 5 headed 'Drug-device demarcations'.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/284493/Borderlines_between_medical_devices_and_medicinal_products.pdf

Manual on borderline and classification in the Community regulatory framework for medical devices –

http://ec.europa.eu/health/medical-devices/files/wg_minutes_member_lists/borderline_manual_ol_en.pdf.

Cosmetics

The EU Cosmetic Products Regulation ((EC) No. 1223/2009 harmonises the requirements for cosmetics in the European Community to achieve free trade whilst ensuring that the products are safe and consumers are not misled. The EU Cosmetic Products Regulation is directly applicable in all Member States and is given effect in the UK through the Cosmetic Products Enforcement Regulations 2013 SI 1478.

Article 12(1)(a) of the Cosmetics Regulation (EC) 1223/2009 as amended defines 'Cosmetic Product' as:

"any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;"

Article 2.2 states that "...a substance or mixture intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product."

Recital (7) to the Regulation provides an illustrative list of products which are considered to be cosmetic products for example, face masks, anti-wrinkle products.

The Cosmetic Regulations defines what a cosmetic is and prohibits, or places restrictions on, certain ingredients within a product. The definition envisages that a cosmetic product may have a secondary preventative (but not curative), purpose. When deciding whether or not a product on the borderline between cosmetics and medicines is a medicinal product, the MHRA will apply the tests set out in Directive 2001/83/EC. If a product falls within the definition of a cosmetic and within the definition of a medicinal product it will be classified as a medicinal product (Delattre 1991, C-369/88). The regulatory status of products in other Member States will also be taken into account.

Further guidance regarding cosmetic products can be found using the links:

Cosmetic Borderline -

http://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products/docs/manual_borderlines_ol_en.pdf

Cosmetic Regulation (EC) No. 1223/2009 -

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF

Trading Standards Cosmetic advice sheet -

http://www.tradingstandards.gov.uk/cgi-bin/glos/bus1item.cgi?file=*badv072-1111.txt

There may be other legislation which may be relevant and you should seek advice from your local Trading Standards Officer.

Aromatherapy

Aromatherapy is defined as '…systematic use of essential oils and absolutes in holistic treatments to improve physical and emotional well-being. Aromatherapy treatments may include, for example; massage, inhalation, waterborne methods, topical applications and compress.

Aromatherapy products are marketed to support the practice of aromatherapy. In the UK there is no industry or product specific harmonised regulations that define an aromatherapy product. Depending on the product's composition, presentation and intended use they may meet the definition of other consumer products and therefore must meet the safety regulations for those categories of products, including medicines, medical devices, cosmetics, foods, food additives or flavourings. For aromatherapy products that do not meet the definition of an industry or product-specific harmonised regulation will be regulated by the General Product Safety Regulation 2005.

Aromatherapy products are a heterogeneous collection of consumer products typically composed of, or containing one or more, essential oils or related aroma-chemicals.

Aromatherapy products, whether essential oils derived from a single named botanical source, a mixture of essential oils, or consumer products that contain them, primarily intended to maintain or support emotional and physical wellbeing or a healthy lifestyle, would not normally be considered to be medicinal products. As essential oils have no accepted nutritional benefit they would not normally be considered to be foods, other than flavourings. Consequently aromatherapy products containing essential oils, depending on their composition, presentation and intended use would normally be regulated as general products or cosmetics (please see section on Cosmetics for further information).

Further guidance regarding aromatherapy can be found using the links:

Standard for providing aromatherapy to clients -
https://tools.skillsforhealth.org.uk/competence/show/html/id/2801/

General Product Safety Regulation 2005 - http://www.legislation.gov.uk/uksi/2005/1803/contents/made

Cosmetic Borderline -
http://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products/docs/manual_borderlines_ol_en.pdf

Cosmetic Regulation (EC) No. 1223/2009 -
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF

Trading Standards Cosmetic advice sheet -
http://www.tradingstandards.gov.uk/cgi-bin/glos/bus1item.cgi?file=*badv072-1111.txt

Biocides

In the UK biocidal products are controlled under the EU Biocides Regulation (528/2012) – BPR – which define a biocidal product as:

"*any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action: or*

any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless,

preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

A treated article that has a primary biocidal function shall be considered a biocidal product."

The responsibility for the administration and some enforcement of the BPR lie with the Health and Safety Executive (HSE). The BPR covers a wide range of products, 22 product types covering disinfectants, pest control, preservatives and specialty biocides. For disinfectants, this can include both products used on surfaces or equipment, and products used on human skin. However, the BPR specifically excludes uses that are within the scope of the medicines/medical devices legislation – essentially products or the uses of products only fall to be regulated under the BPR if they are not regulated under medicines. However a product with dual uses, a medicinal use and a general disinfectant use for example, would be regulated under both BPR and the medicines legislation. Further information regarding topical skin disinfection products can be found in appendix 5 and 6.

All biocidal products regulated under the BPR will eventually need to be authorised under the regulations, though there is an on-going transitional period and you should contact the HSE for further advice. As from the 1 September 2015, a biocidal product consisting of, containing, or generating a relevant substance, cannot be made available on the UK market if the active substance supplier or product supplier is not included in the Article 95 list for the product type(s) to which the product belongs. Further information regarding biocides can be obtained using the link www.hse.gov.uk/biocides.

General Product Safety Directive

The General Product Safety Directive (GPSD) 2001/95/EC which was implemented into UK law under The General Product Safety Regulations 2005 is administered and enforced by Trading Standards Authorities and Environmental Health Officers. This Directive applies in the absence of specific European regulations on safety of certain product categories and complements the provisions of sector legislation, which do not cover certain matters, for instance in relation to producers' obligations and authorities' powers and tasks. Further information can be found on the European Commission's website using the link

http://ec.europa.eu/consumers/consumers_safety/product_safety_legislation/general_product_safety_directive/index_en.htm

Food including food supplements

Regulation (EC) 178/2002, (Article 2) defines a food, or foodstuff as:

"…any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans……'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment."

The same Regulation (at Article 2 (d)) also states that a product which is regarded to be a medicinal product cannot be a food:

"Food shall not include…medicinal products within the meaning of Council Directive 65/65/EEC [now Directive 2001/83/EC.]"

The (Directive 2002/46/EC) defines food supplements as:

"…foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form…"

The Directive includes a list of permitted vitamins and minerals and their sources and specifies additional labelling requirements for food supplements.

A product which the average consumer would regard as something to be eaten, drunk or chewed as part of a diet, because of its taste, flavour, or nutritional value etc., is unlikely to be classified by the MHRA as a medicinal product unless it contains one or more ingredients generally regarded as medicinal and indicative of a medicinal purpose. If the MHRA determines that such a product is not a medicine, it is likely to be regulated under food law. However, a product which satisfies equally well the conditions for classification as a food and the conditions for classification as a medicinal product will generally be classified as a medicinal product taking into account all of the product's characteristics.

While claims to treat, prevent or cure disease cannot be used with 'food', an MHRA determination that a product is not a medicine should not be considered as an approval that the product may legally be supplied under food law as there may be restrictions on the claims that can be made (see section on Food Claims). The food must also be safe to eat in compliance with Article 14 of Regulation 178/2002. In addition foods or food ingredients which do not have a history of significant consumption within the EU prior to 15 May 1997 may be regarded to be novel foods and are subject to Regulation (EC) 258/97. All novel foods require a safety assessment and authorisation before they can be marketed in the EU and advice on this aspect should be sought from the Food Standards Agency either in writing (address provided in Appendix 2) or by e-mailing using the following addresses: novelfoods@foodstandards.gsi.gov.uk

Advice on food supplements should be sought from the Department of Health either in writing (address provided in Appendix 2) or by using the web contact form at this location:
http://www.dh.gov.uk/en/ContactUs/DH_066319

Manufacturers and persons intending to place a food product on the market should seek confirmation from the Environmental Health Department / Trading Standards Service of their Local Authority that the product complies with all relevant food law including the Nutrition and Health Claims Regulations and the requirements of the Food Supplements Directive. They should also inform the local authority of any significant changes to their food business or register as a food business with the Local Authority if they have not previously done so.

Food Supplements – Application of Mutual Recognition

The European Commission has issued specific guidance[4] for food supplements in relation to the applicability of Regulation (EC) 764/2008, which concerns mutual recognition in the EU. This guidance is helpful in relation to borderline products, noting that there may be instances where a product is regarded to be a food supplement in one Member States and a medicinal product in another. In such a scenario Regulation (EC) 764/2008 does not apply.

[4] http://www.google.co.uk/url?url=http://ec.europa.eu/DocsRoom/documents/5808/attachments/1/translations/en/renditions/native&rct=j&frm=1&q=&esrc=s&sa=U&ved=0CBQQFjAAahUKEwjLhNjxoe7GAhWCuxQKHdYNAJA&usg=AFQjCNEzEghaunL_QEhaW74fejUYEx_yNA

Misuse of Drugs Act 1971 and amendments

The Misuse of Drugs Act 1971 controls drugs that are dangerous or otherwise harmful. One of the purposes of the Misuse of Drugs Act 1971 is to regulate controlled drugs which have no current medicinal uses.

The Home Office publishes a list of controlled drugs, which refers only to the most commonly encountered drugs and is not an exhaustive list.

Examples of drugs controlled under the Misuse of Drugs Act and amending orders include:

- Anabolic steroids classified as Class C drugs
- Synthetic cannabinoid receptor agonists (synthetic cannabinoids) classified as Class B drug

Further information can be found on the website www.gov.uk.

The Psychoactive Substances Act 2016

In April 2016 the Psychoactive substances Act, which received Royal Ascent in February 2016 and will enter into force . This Act will make it an offence to produce, supply or offer to supply any psychoactive substance with the exemption a small number of legitimate substances (e.g. certain foods, nicotine, alcohol, and medicinal products.)

https://www.gov.uk/government/collections/psychoactive-substances-bill-2015

UK Anti-Doping

UK Anti-Doping is responsible for ensuring sports bodies in the UK are compliant with the World Anti-Doping Code through implementation and management of the UK's National Anti-Doping Policy.

On 1 January 2015, the World Anti-Doping Agency's 2015 Prohibited List came into effect. This list details of substances and methods banned in sports in-and out-of-competition. Further information can be found using the link http://list.wada-ama.org/prohibited-all-times/prohibited-substances/

Information regarding World Anti-Doping Agency (WADA) and their key activities can be found using the link https://www.wada-ama.org/en.

13. Miscellaneous

Sports supplements

Products to provide nutritional support to athletes and persons who exercise ("sports supplements") are regarded by the MHRA to fall outside the definition of a medicinal product. However, sports products which contain substances that significantly modify physiological functions by pharmacological, metabolic or immunological means can fall within the definition of a medicinal product. In making such a determination the MHRA will need to be mindful of case law, in particular Markus D (C-358/13) and G. (C-181/14) and it should be noted that a number of active substances which significantly modify physiological function and are added to sports supplements are controlled elsewhere (refer to Section 13).

Topical anesthetics (Numbing Gels/Creams)

Topical anesthetics which are administered to reduce sensibility to pain e.g. lidocaine, prilocaine, epinephrine prior to carrying out a procedure, including a non-medicinal procedures are regarding

to be medicinal products. Examples of non medicinal procedures include tattoos, and cosmetic procedures such as semi-permanent makeup.

Weight loss products

Many supplement products which make claims to reduce weight are not medicinal products. However where the use is for a medical purpose, such as to treat clinical obesity, products can fall within the definition of a medicinal product if: (a) they make medicinal claims; (b) if they modify physiological functions by acting pharmacologically, immunologically or metabolically.

It is also possible that some ingested products with claims to be medical treatments and which act by a physical action, such as by preventing fat being absorbed by the body or as bulking agents could be classified as medical devices.

Nitrous oxide

Nitrous oxide, also known as 'laughing gas' is a substance with a number of legitimate uses in medicine and catering. It is a medical gas (a medicinal product) and, when mixed with oxygen, it is used to treat analgesia and as an anaesthetic. Use as a medicinal product typically involves large cylinders containing the gases which are administered to the patient using a face mask in a variety of settings such as hospitals, dental surgeries and by ambulance crews. Nitrous oxide is also an approved food additive (E942) when used as a propellant for whipped cream. Unless the products used are clearly medicinal the MHRA nitrous oxide, when used for recreational purposes is not a matter for the MHRA and the Home Office has issued guidance to enforcement bodies to restrict supply for recreational purposes which can currently be found at the following link. (Also refer to information about the Psychoactive Substances Act in Section 13, above.

https://www.gov.uk/government/publications/guidance-on-restricting-the-supply-of-nitrous-oxide-for-recreational-use

What to do if you are still unsure of the status of your product

Classification is carried out on a product by product basis. If you have looked at all the literature in this Guidance Note and on the website and you are still unsure, complete the advice request form which is available on the website at

https://www.gov.uk/decide-if-your-product-is-a-medicine-or-a-medical-device

under the sub-heading 'Getting advice about your product'. When seeking advice from the Agency it is expected that enquirers have read and taken into account the guidance contained in this document and also have some knowledge of the use and function of the ingredients contained in their product.

Marketing authorisations

Guidance on marketing authorisations is provided in the "Notice to Applicants" (Volume II of the Rules Governing Medicinal Products in the European Community) and can be obtained using the link http://ec.europa.eu/health/documents/eudralex/index_en.htm.

14. A summary of case law that is relevant to decisions concerning borderline products

The applicability of case law to borderline decisions various according to the product in question. This section provides summaries of relevant cases[5].

BIOS Naturprodukte GmbH v Saarland (C-27/08)

Date of Judgment of the Court – 30 April 2009

This judgment refers to the interpretation of the definition of a medicinal product and the classification of a food supplement marketed in Germany containing Indian incense extract.

"The Judgment ruled that Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, must be interpreted as meaning that a product which includes in its composition a substance which has a physiological effect when used in a particular dosage is not a medicinal product by function where, having regard to its content in active substances and under normal conditions of use, it constitutes a risk to health without, however, being capable of restoring, correcting or modifying physiological functions in human beings."

Commission of the European Communities v Kingdom of Spain (C-88/07)

Date of Judgment of the Court – 5 March 2009

This judgment refers to the free movement of goods, products which are based on medicinal herbs that are classified as medicinal products and products marketed as food supplements or dietary products in other Member States.

The Judgment stated:

The Court (First Chamber) hereby:

1 declares that, by withdrawing from the market products based on medicinal herbs lawfully produced and/or marketed in another Member State, under an administrative practice consisting in withdrawing from the market any product based on medicinal herbs not included either in the annex to the Ministerial Order on the creation of a special register of medicinal herb-based preparations (Orden Ministerial por la que se establece el registro especial para preparados a base de especies vegetales) of 3 October 1973, as amended, or in the annex to the Order SCO/190/2004 of the Ministry of Health and Consumer Affairs, establishing the list of plants sale of which to the public is prohibited or restricted because of their toxicity (Orden SCO/190/2004 por la que se establece la lista de plantas cuya venta al público queda prohibida o restringida por razón de su toxicidad) of 28 January 2004, other than a preparation the constituents of which are exclusively one or more medicinal herbs or whole parts of such herbs, or crushed or powdered parts of such herbs, on the ground that that product is deemed to be a medicinal product marketed without the requisite marketing authorisation, and

–by not communicating that measure to the Commission of the European Communities,

the Kingdom of Spain has failed to fulfil its obligations under Articles 28 EC and 30 EC and Articles 1 and 4 of Decision No 3052/95/EC of the European Parliament and of the Council of 13 December 1995 establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community.

Hecht-Pharma GmbH v Staatliches Gewerbeaufsichtsamt Lüneburg (C-140/07)

Date of Judgment of the Court – 15 January 2009

This judgment refers to the concept of 'medicinal product by function' and concerns the classification of a product called 'Red Rice' as a food additive or a medicinal product for the purposes of its marketing in German territory.

The Court (First Chamber) hereby rules:

---

[5] European Court of Justice case summaries have been taken from the website http://curia.europa.eu/jcms/jcms/j_6/.

1. Article 2(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, must be interpreted as meaning that Directive 2001/83, as amended by Directive 2004/27, does not apply to a product in respect of which it has not been scientifically established that it is a medicinal product by function, without its being possible to exclude that possibility.
2. Article 1(2)(b) of Directive 2001/83, as amended by Directive 2004/27, must be interpreted as meaning that the characteristics of the manner in which a product is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail are still relevant to determining whether that product falls within the definition of a medicinal product by function.
3. Article 1(2)(b) of Directive 2001/83, as amended by Directive 2004/27, must be interpreted as meaning that, apart from the case of substances or combinations of substances intended for the purpose of making a medical diagnosis, a product cannot be regarded as a medicinal product within the meaning of that provision where, having regard to its composition – including its content in active substances – and if used as intended, it is incapable of appreciably restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action.

Commission of the European Communities v Federal Republic of Germany (C-319/05)

Date of Judgment of the Court –15 November 2007

This judgment refers to garlic capsules marked as a food supplement in a number of Member States.

The Court (First Chamber) hereby:

1. Declares that, by classifying as a medicinal product a garlic preparation in capsule form not satisfying the definition of a medicinal product within the meaning of Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, the Federal Republic of Germany has failed to fulfil its obligations under Article 28 EC and Article 30 EC;
2. A garlic product in capsule form, whose effect on physiological functions is no more than the effects which a foodstuff consumed in a reasonable quantity may have on those functions, does not have a significant effect on the metabolism and cannot, therefore, be classified as a product capable of restoring, correcting or modifying physiological functions within the meaning of the second subparagraph of Article 1(2) of Directive 2001/83. Because the mentioned risks and contra-indications related to taking garlic preparations are limited and, more importantly, are no different from those linked to taking garlic as a foodstuff, and because the criterion of the method of using of the product concerned cannot be decisive, given that capsule form is not unique to medicinal products, such a preparation cannot be classified as a medicinal product by function within the meaning of the second subparagraph of Article 1(2) of Directive 2001/83

HLH Warenvertriebs GmbH (C-211/03) and Orthica BV (C-299/03 and C-316/03 to C-318/03) v Bundesrepublik Deutschland.

Date of Judgment of the Court – 9 June 2005

All of the cases in this judgment refer to products marketed in the Netherlands as food supplements.

The Court (First Chamber) hereby rules:

1. The classification of a product as a medicinal product or as a foodstuff must take account of all the characteristics of the product, established both in the initial stage of the product and where it is mixed, in accordance with the method by which it is used, with water or with yoghurt.

2. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety constitutes an additional set of rules in relation to Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, the application of which is precluded to the extent to which a Community rule, such as that directive, contains specific provisions for certain categories of foodstuffs.
3. Only the provisions of Community law specific to medicinal products apply to a product which satisfies equally well the conditions for classification as a foodstuff and the conditions for classification as a medicinal product.
4. The pharmacological properties of a product are the factor on the basis of which the authorities of the Member States must ascertain, in the light of the potential capacities of the product, whether it may, for the purposes of the second subparagraph of Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings. The risk that the use of a product may entail for health is an autonomous factor that must also be taken into consideration by the competent national authorities in the context of the classification of the product as a medicinal product.
5. A product which constitutes a medicinal product within the meaning of Directive 2001/83 may be imported into another Member State only upon acquisition of a marketing authorisation issued in accordance with the provisions of that directive, even where it is lawfully marketed as a foodstuff in another Member State.
6. The concept of 'upper safe levels' in Article 5(1)(a) of Directive 2002/46 is of no importance for the purposes of drawing a distinction between medicinal products and foodstuffs.
7. In the context of an evaluation by a Member State of the risks that foodstuffs or food supplements may constitute for human health, the criterion of the existence of a nutritional need in the population of the Member State may be taken into consideration. However, the absence of such a need does not in itself suffice to justify, either under Article 30 EC or under Article 12 of Directive 2002/46, a complete ban on marketing foodstuffs or food supplements lawfully manufactured or placed on the market in another Member State.
8. The fact that the discretion enjoyed by the national authorities as regards the establishment of an absence of nutritional need is subject to only limited review by the courts is compatible with Community law, on condition that the national procedure for judicial review of the decisions in that regard taken by those authorities enables the court or tribunal seized of an application for annulment of such a decision effectively to apply the relevant principles and rules of Community law when reviewing its legality.
9. Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients is to be interpreted as meaning that a food or a food ingredient has not been used for human consumption to a significant degree within the Community if, when all the circumstances of the case are taken into account, it is established that that food or that food ingredient has not been consumed in a significant quantity by humans in any of the Member States before the reference date. 15 May 1997 is the reference date for the purpose of determining the extent of human consumption of that food or food ingredient.
10. A national court cannot refer questions on the classification of products to the European Food Safety Authority. An opinion delivered by that Authority, possibly in a matter forming the subject-matter of a dispute pending before a national court, may constitute evidence that that court should take into consideration in the context of that dispute.

Upjohn Company and Upjohn NV v Farzoo Inc. and J. Kortmann (C-112/89)

Date of Judgment of the Court – 16 April 1991

This Judgment refers to the marketing of minoxidil as a cosmetic product.

The Court (Fifth Chamber) hereby rules:

(1) A product which is not 'for treating or preventing disease in human beings or animals' is a medicinal product if it may be administered 'with a view to ... restoring, correcting or modifying physiological functions', and it is for the national courts to determine on a case-by-case basis the classification of each product having regard to its pharmacological properties as they may be ascertained in the current state of scientific knowledge, to the way in which it is used, to the extent to which it is sold and to consumers' familiarity with it;

(2) Any product satisfying either of the sets of criteria laid down in Article 1(2) of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products is a medicinal product and must, if it is a proprietary medicinal product, be subject to the corresponding legal rules, to the exclusion of those governing cosmetic products.

In Criminal proceedings against Markus D. (C-358/13) and G. (C-181/14)

Date of Judgment of the Court – 10 July 2014

This Judgment refers to the interpretation of the concept of a medicinal product based on the capacity to modify physiological functions regarding herb and cannabinoid-based products. The requests have been made in criminal proceedings instigated against Mr D.and Mr G., respectively, in which they have been charged with selling herb mixtures containing, inter alia, synthetic cannabinoids, which, at the material time, did not fall under the German law on narcotic drugs (Betäubungsmittelgesetz) (‘the BtMG’).

The judgment stated that Article 1(2)(b) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, must be interpreted as not covering substances, such as those at issue in the main proceedings, which produce effects that merely modify physiological functions but which are not such as to have any beneficial effects, either immediately or in the long term, on human health, are consumed solely to induce a state of intoxication and are, as such, harmful to human health.

Laboratoires Lyocentre v Lääkealan turvallisuus- ja kehittämiskeskus and Sosiaali- ja terveysalan lupa- ja valvontavirasto (C-109/12)

Date of Judgment of the Court – 3 October 2013

This judgment refers to the rights of a competent national authority to classify as a medicinal product a product marketed in another Member State as a medical device bearing a CE marking. The product in question is a vaginal capsule containing live lactobacilli intended to restore balance to bacterial flora in the vagina, called Gynocaps.

The Judgment concluded:

In the light of the foregoing considerations, I am of the opinion that the Court should answer the questions referred by the Korkein hallinto-oikeus to the following effect:

– Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended, oes not preclude a Member State from classifying a product, on the basis of its pharmacological, immunological or metabolic effects, as a medicinal product in accordance with Article 1(2)(b) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended, even where another Member State considers that product to be a medical device within the meaning of Directive 93/42.

– Article 18 of Directive 93/42 applies to a product to which a CE marking was affixed despite the fact that the product is not covered by that directive. By contrast, Article 8 of the same directive can apply only by virtue of Article 18. In addition, the relevant procedures in Directive 2001/83 must

be satisfied in order to put on the market a product that is properly classified as a medicinal product rather than as a medical device.

– Where there are two similar products containing the same substance and having the same modes of action European Union law does not preclude a Member State from classifying one as a medicinal product and the other as a medical device. By contrast, a single Member State cannot, in the case of two identical products, classify one as a medicinal product and the other as a medical device.

Chemische Fabrik Kreussler & Co. GmbH v Sunstar Deutschland GmbH (C-308/11)

Date of Judgment of the Court – 6 September 2012

This judgment refers to the definition of the term 'pharmacological action' within the definition of a medicinal product. The product is a mouthwash solution called 'PAROEX 0.12%' which contains chlorhexidine, an antiseptic, which accounts for 0.12% of the product contents. The following is stated on the packaging, namely 'Mouthrinse for oral care – Helps reduce dental plaque accumulation – Protects gums and maintains oral health'. The information leaflet provided with the product states that users should rinse their mouth with 10 ml of undiluted solution for 30 seconds twice daily.

The Court (Fifth Chamber) hereby rules:

1. Article1 (2)(b) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, must be interpreted as meaning that, for the purpose of defining the term 'pharmacological action' within the meaning of that provision, account may be taken of the definition of that term in the Guidance Document on the demarcation between the Cosmetic Products Directive 76/768 and the Medicinal Products Directive 2001/83 as agreed between the Commission services and the competent authorities of the Member States.
2. Article 1(2)(b) of Directive 2001/83 must be interpreted as meaning that, for a substance to be regarded as exerting a 'pharmacological action' within the meaning of that provision, it is not necessary for there to be an interaction between the molecules of which it consists and a cellular constituent of the user's body, as an interaction between that substance and any cellular constituent present within the user's body may be sufficient.

Criminal proceedings against Jean-Marie Delattre (C-369/88)

Date of Judgment of the Court – 21 March 1991

This judgment refers to the concepts of illness or disease and medicinal products and the marketing of various products in France.

The Court (Fifth Chamber) hereby rules:

(1) Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products gives no definition of disease.

(2) (a) A product presented as being intended to facilitate certain physiological functions falls within the scope of the Community definition of medicinal product in the second subparagraph of Article 1(2) of Council Directive 65/65/EEC. In order to decide whether that product is to be categorized as a medicinal product or as a foodstuff, it is necessary to have regard to its pharmacological properties. The fact that such a product is classified as a foodstuff in one Member State does not preclude its being treated as a medicinal product in the State concerned if it possesses the relevant characteristics. The specific features of the legislation concerning natural mineral waters have no relevance to the definition of medicinal product within the meaning of Directive 65/65/EEC;

(b) There is no provision obliging Member States to consult the consultative committees specialized in medicinal products attached to the Community institutions before taking the

steps dictated in internal law by the definitions of medicinal product given in Directive 65/65/EEC;

(c) It is for the national authorities to determine, subject to judicial review, whether or not, having regard to its composition, the risks which its prolonged consumption may entail or its side-effects and, more generally, all of its characteristics, a product presented as counteracting certain conditions or sensations, such as hunger, heaviness in the legs, tiredness or itching constitutes a medicinal product;

(d) A product may be regarded as being presented as a medicinal product if its form and the manner in which it is packaged render it sufficiently similar to a medicinal product and, in particular, if on its packing and in the information provided with it reference is made to research by pharmaceutical laboratories, to methods or substances developed by medical practitioners or even to testimonials from medical practitioners commending the qualities of the product. A statement that the product is not medicinal is persuasive evidence which the national court may take into consideration but is not in itself conclusive.

(3) Under Community law as it now stands, the determination of the rules governing the distribution of pharmaceutical products remains a matter for the Member States, provided that the provisions of the Treaty, and in particular those relating to the free movement of goods, are respected.

A monopoly of the right to distribute medicinal or other products, granted to dispensing pharmacists, may constitute a barrier to importation.

If a Member State chooses to restrict to pharmacists the right to distribute products of that kind, such a barrier is, in principle and in the absence of any evidence to the contrary, justified in so far as it concerns medicinal products within the meaning of Council Directive 65/65/EEC.

Where other products are concerned, however they may be classified in national law, it is for the national court to determine whether a monopoly of the right to market such products granted to pharmacists is necessary for the protection of public health or of consumers and whether those two aims cannot be achieved by measures less restrictive of intra-Community trade.

(4) Council Directive 74/329/EEC and Articles 30 and 36 of the EEC Treaty must be interpreted as meaning that a measure whereby a Member State makes a product such as guar gum subject to marketing authorization and to the sales monopoly of pharmacists when it is used as part of a method intended to facilitate weight loss, however that product may be classified in any other sphere of national law, does not fall within the scope of that directive, but may constitute a barrier to importation. When the product in issue is not a medicinal product within the meaning of Directive 65/65/EEC, such a measure is not permissible under Community law unless it is necessary in order to protect public health or consumers and is proportionate to those aims.

Criminal proceedings against Leendert van Bennekom (C-227/82)

Date of Judgment of the Court – 30 November 1983

This judgment refers to a wholesale dealer in health foods, vitamins and minerals products who was charged, *inter alia,* with the purpose of supply in Amsterdam, a large quantity of packed and unregulated proprietary medicinal products or medicinal products.

The Court (Fifth Chamber) hereby rules:

1. Substances, such as the vitamin preparations at issue, which are not "indicated or recommended" expressly as being suitable for curing, treating or preventing an infection, may none the less constitute substances "presented for treating or preventing disease in human beings or animals" within the meaning of the Community definition of "medicinal product" contained in Directive 65/65.

2. A product which falls neither under the first nor the second part of the Community definition of "medicinal product" cannot be considered a medicinal product within the meaning of Directive 65/65.
3. The classification of a vitamin as a medicinal product within the meaning of the second part of the definition in Directive 65/65 must be carried out case by case, having regard to the pharmacological properties of each of them, to the extent to which they have been established in the present state of scientific knowledge.
4. Where certain vitamin or multi-vitamin preparations may
   (a) be regarded as medicinal products within the meaning of Directive 65/65, but are not covered by the legislation on medicinal products of one or more Member States, or

   (b) are not covered by the Community definition of medicinal products, the law of a Member State may prohibit the sale, or the holding in stock for the purpose of supply, of such preparations imported from another Member State, in particular when they are presented in pharmaceutical form or when they are highly concentrated. However, such rules are justified only if authorizations for marketing are granted when they are compatible with the requirements of health protection.

Opinion of the Lords of Appeal for Judgment [2001] UKHL 32

Date – 28 June 2001

Optident Limited and Another v Secretary of State for Trade and Industry and Another

This case concerned a product which had been CE marked as a medical device but which was intended to be used as a cosmetic, a question in relation to which the manufacturers marketing claims for the product was of central importance.

The product in question, Opalescence, is intended to be used for bleaching natural teeth. Due to the amendment of the Cosmetic Directive by Directive 92/86 to limit the hydrogen peroxide permitted to 0.1% for oral hygiene products, which came into force on 30 June 1993, the product was withdrawn from sale in the United Kingdom as a cosmetic product. Following the introduction of the Medical Devices Directive the product was CE marked as a medical device.

This appeal case was brought under the Medical Device Regulations to legally determine the classification of a product that was indicated for use to whiten teeth. The case came to court as a result of the (then) Medical Devices Agency's view that the product was not a medical device as its primary intended purpose was 'cosmetic', i.e. to whiten the teeth for cosmetic purposes, whereas the manufacturer was claiming a medical purpose.

While the product 'fitted' the definition of a cosmetic under the Cosmetic Directive and also that of a medical device under the Medical Device Directive, under the regulations, a product cannot be both, as the directives are mutually exclusive. Article 1 of the Medical Devices Directive 93/42/EEC defines that a medical device is intended to "used for human beings for the purpose of: — diagnosis, prevention, monitoring, treatment or alleviation of disease,.." This definition clearly establishes a link between prevention or treatment and disease.

The House of Lords Judgment on the matter indicated that the product should be considered to come within the remit of the Cosmetics Directive, as the primary purpose of the product was to whiten teeth, a cosmetic procedure, not a medical one.

This decision confirmed that where a product has been incorrectly classified by the manufacturer and in fact falls within the scope of a directive other than the Medical Devices Directive the appropriate course is for the Competent Authority to take action under the directive under which the product would properly be regulated.

Furthermore, this ruling means that MHRA are able to make a determination regarding the classification of a product where they do not agree to the manufacturers' determination of a product as a medical device, even where this determination has been accepted in another Member State.

The Commission has confirmed that tooth whitening products placed on the market for the principal purpose of lightning discoloured teeth, whether or not they contain peroxide and

regardless of concentration, cannot be considered as medical devices since they do not meet the definition of a ‘medical device’ contained in Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Further details of this judgment is available on the website www.parliament.uk using the link http://www.publications.parliament.uk/pa/ld200102/ldjudgmt/jd010628/optid-1.htm

Further information regarding ‘tooth whitening’ can be found in the Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices which is available on the European Commission’s website http://ec.europa.eu/health/medical-devices/files/wg_minutes_member_lists/borderline_manual_ol_en.pdf

APPENDIX 1

WORDS AND PHRASES

The words and phrases listed below have all contributed to a determination by the MHRA that the product they were associated with was a medicinal product. But it is not the case that use of any of these words or phrases to promote or describe a product will **necessarily** lead to the MHRA determining that the product is a medicine. **The intended and implied meaning of such words and phrases has to be considered in context**.

The list is not exhaustive. All the words and phrases used in relation to a product will be considered by the MHRA in the determination process.

WORDS & PHRASES	WHAT THESE MAY SUGGEST OR IMPLY ABOUT A PRODUCT
"Alleviates"	In context, may suggest a claim to treat disease by reducing, ameliorating or correcting disease or an adverse condition.
"At the first sign of a spot..."	Implied claim to treat 'spots', an adverse condition.
"Avoids"	In context, may be a claim to prevent specific disease(s).
"Boosts"	In context, claim may tend to suggest that the product may be administered with a view to modifying physiological function and having a significant effect.
"Burns fat"	A claim that the product may be administered with a view to having a significant effect on the metabolism and modifying physiological function.
"Calm/calms/calming"	In context, may be a claim to sedate.
"Can benefit those who suffer from..."	A claim to treat or prevent disease in specific patient groups or in those at particular risk of specific diseases or adverse conditions.
"Clears"	In context, may be a claim to effectively treat or correct disease or an adverse condition.
"Clinical Trials Evidence"	Implied claim to (medicinal) efficacy in relation to disease or an adverse condition.

“Clinically proven”	An implied claim that the product has met the appropriate efficacy test in relation to disease or an adverse condition.
“Combats”	In context, a claim to work directly to treat, prevent or cure disease or an adverse condition.
“Controls”	In context, a claim to treat disease or adverse condition and prevent further problems.
“Counteracts”	In context, a claim to treat or cure disease or symptoms of disease.
“Cure/cures”	A claim to treat disease.
“Eliminates”	In context, a claim to treat or cure disease or adverse condition.
“Fights”	In context, a claim to work directly to treat or cure disease or an adverse condition.
“Heals”	A claim to treat or cure disease or an adverse condition, and to restore health.
“Helps body adjust after crossing time zones”	A claim that the product, when administered, has a significant (sedating) effect on the metabolism by modifying the body clock and sleep cycle. (Especially in relation to the adverse condition known as Jet Lag.)
“Help maintain a normal mood balance”	In context, an implied claim that the product may be administered with a view to altering mood, that is, it has a sedating or anti-depressant activity.
“Help maintain normal water balance”	In context, an implied claim that the product may be administered with a view to preventing or correcting water retention, that is, it is a diuretic medicine.
“Help/help with...”	In context, may be a claim to treat, provide relief from, and cure symptoms of disease or an adverse condition.
“Increases metabolic rate”	A claim that the product may be administered with a view to a significant effect on the metabolism.

“Is said to help with...”	In context, may be an implied claim to efficacy in relation to disease or adverse condition.
“Medical research...”	An implied claim to efficacy as a medicine.
“Prevents/preventing”	In context, a claim to stop development of, and prevent disease or an adverse condition.
“Protects against...”	In context, a claim to prevent a specific disease or an adverse condition.
“Relieves/relief condition”	In context, a claim to alleviate the symptoms of a disease or adverse condition.
“Remedies....”	A claim that the product may be administered to treat, correct or cure disease or an adverse condition.
“Removes”	In context, may be a claim to treat (cure or clear) disease or an adverse condition.
“Repairs”	In context, a claim to treat (heal, cure, restore) damaged body tissues or correct dysfunctional systems of the body or mind.
“Restores”	In context, a claim to restore physiological function.
“Stimulates the nervous system”	In context, this claim tends to suggest the product may be administered with a view to modifying physiological function and have a significant effect on the metabolism.
“Stops”	A claim to prevent, or arrest the development of disease or an adverse condition.
“Stops craving for ....”	A claim to treat an addiction (a disease) by modifying physiological function.
“Strengthens the immune system”	In context, claim tends to suggest the product may be administered with a view to modifying physiological function and having a significant effect on the metabolism.

“Strips off sun- damaged pre-cancerous cells”	A claim to treat, prevent or correct disease or an adverse condition.
“Traditionally used for....”	In context, a claim to treat or prevent disease or an adverse condition.
“Treats/clears infestations”	In relation to humans, a claim to stop, treat or remove parasitic infestations such as head/body/public lice. An infestation of lice is an adverse condition.
“Treats/Treatment/Treating”	In context, these are claims to treat or prevent disease or an adverse condition.

APPENDIX 2

USEFUL ADDRESSES

The Advertising Standards Authority Ltd (ASA)

Mid City Place

71 High Holborn

London

WC1V 6QT

Tel: 020 7492 2222

Fax: 020 7242 3696

E-mail: enquiries@cap.org.uk

Aromatherapy Trade Council (ATC)

PO Box 219

Market Rasen

LN8 9BR

Tel: 01673 844672

E-mail: info@a-t-c.org.uk

Association of British Healthcare Industries (ABHI) (Trade Association medical technology)

250 Waterloo Road
London
SE1 8RD

Tel: 020 7960 4360
Fax: 020 7960 4361

Email: enquiries@abhi.org.uk

Association of British Pharmaceutical Industry (ABPI)

12 Whitehall

London

SW1A 2DY

Tel: 020 7930 3477

Fax: 020 7747 1411

British Herbal Medicine Association (BHMA)

PO Box 583

Exeter

EX1 9GX

Tel: 0845 680 1134

Fax: 0845 680 1136

E-mail: secretary@bhma.info

Chinese Medicine Association of Suppliers

8th Floor

87-90 Albert Embankment

London

SE1 7UD

Tel: 020 7587 6700

Fax: 020 7587 6720

Clearcast Ltd

3rd Floor

4 Roger Street

London

WC1N 2JX

Tel: 020 7339 4700

Email: help@clearcast.co.uk

Committee of Advertising Practice (CAP)

Mid City Place

71 High Holborn

London

WC1V 6QT

Tel: 020 7492 2200

Fax: 020 7242 3404

E-mail: advice@cap.org.uk

Cosmetics, Toiletry & Perfumery Association Limited (CTPA)

Josaron House

5/7 John Princes Street

London

W1G OJN

Tel: 020 7491 8891

Fax: 020 7493 8061

Council for Responsible Nutrition UK

100 Pall Mall

St James

London

SW1Y 5NQ

Tel: 020 7664 8970

E-mail: secretariat@crnuk.org / web www.crnuk.org

Department for Business, Innovation and Skills

1 Victoria Street

London

SW1H OET

Tel: 020 7215 5000

Email: enquiries@bis.gsi.gov.uk

Department of Health

(Customer Service Centre)

Richmond House

79 Whitehall

London

SW1A 2NS

Tel: 020 7210 4850

Fax: 020 7210 5952

European Specialist Sports Nutrition Alliance (ESSNA)

222 Southbank House

Black Prince Road

London

SE1 7SJ

Tel: 020 7463 0690

Food Standards Agency

Aviation House

125 Kingsway

London

WC2B 6NH

Tel: 020 7276 8000

Fax: 020 7276 8833

Health and Safety Executive (Biocides Helpdesk)

Chemicals Regulation Directorate

5S.1Redgrave Court

Merton Road

Bootle
Merseyside
L20 7HS

Email: biocidesenquiries@hse.gsi.gov.uk

Health Food Manufacturers' Association (HFMA)
1 Wolsey Road
East Molesey
Surrey
KT8 9EL

Tel: 020 8481 7100
Fax: 020 8481 7101

Medicines and Healthcare products Regulatory Agency
(Devices Sector)
Floor 4-O
151 Buckingham Palace Road
London
SW1W 9SZ

Tel: 020 8030 7386

The Organisation for Professionals in Regulatory Affairs (TOPRA)
Bellerive House
3 Muirfield Crescent
London
E14 9SZ

Tel: 020 7510 2560
Fax: 020 7537 2003
E-mail: info@topra.org

Proprietary Association of Great Britain (PAGB)

Vernon House

Scilian Avenue

London

WC1A 2QS

Tel: 020 7242 8331

Fax: 020 7405 7719

E-mail: info@pagb.co.uk

Radio Advertising Clearance Centre

6th Floor

55 New Oxford Street

London

WC1A 1BS

Tel: 020 7010 0608

E-mail: adclear@racc.co.uk

Website: racc.co.uk

APPENDIX 3

THE STATUTORY DETERMINATION PROCEDURE

Introduction

The purpose of this appendix is to provide information regarding the statutory determination process under Part 9 of the Human Medicines Regulations 2012, as amended (The Regulations).

Background

The MHRA frequently finds that the initial referral or complaint contains insufficient information to determine whether the product is a medicinal product. If this is the case, the MHRA will consider available information that may have a bearing on the issue. Generally, this will include asking the manufacturer, importer or, distributor, depending on which of them has placed the product on the UK market, for full details of the product's composition, presentation and purpose. Account will be taken of material being used to promote the product, including material on the internet.

Following a thorough assessment of the status of a product, which may include review of an earlier provisional determination, the MHRA may give notice that it has determined that a product is a medicinal product, and cannot be marketed without a marketing authorisation or other registration. If compliance is not obtained voluntarily, the MHRA will make a determination in accordance with the procedure set out in Part 9, Regulations 159-164 of The Regulations 2012, as amended.

Determination procedure in cases where the statutory procedure is not appropriate

Generally, determination of the status of a product will follow the statutory determination procedure set out in Regulation 159 of The Regulations and described in the following sections. However, the MHRA is empowered by Regulation 165 to determine that a product is a relevant medicinal product without following the statutory determination procedure in certain circumstances. Examples of circumstances where such an approach may be necessary include, but are not limited to where :

- there is an identifiable risk to public health and /or patient safety;
- the product is a copy of, or is identical in all material respects to, another relevant medicinal product that has already been the subject of review panel advice, or an existing licensed or registered medicine.

In such cases, a Notice will be issued without delay and requiring compliance with the Regulations. The MHRA may publish details of the Notice where it thinks it appropriate.

The Statutory Procedure

Provisional determinations

In all other cases where the MHRA is of the opinion that a product without a marketing authorisation, a traditional herbal registration or a certificate of registration as a homoeopathic medicinal product **and** not otherwise exempt is a relevant medicinal product, the MHRA will give notice of its provisional determination, together with the reasons for it. The notice will say that, if the company disagrees with the provisional determination, it may make oral or written representations about it to the Review Panel ("the Panel").

Final determinations if no request for review is made

If no notice of intention to seek an oral hearing or submit representations is received in time, or if the company asks to make representations but does not then do so, the MHRA (acting as the Licensing Authority) will consider the product again, and make and issue a final determination, together with the reasons for it. If the product is classified as a relevant medicinal product, the company will be reminded of the legal provisions for the marketing of such products and what it needs to do to comply with these provisions. It will be asked to notify the MHRA of its compliance with the final determination within a timescale set out in the final determination notice. The MHRA has power to issue a notice under Regulation 163 of the Regulations, formally requiring the company to stop marketing the product, or not to place it on the market, unless or until a marketing authorisation, a traditional herbal registration or a certificate of registration as homoeopathic medicinal product has been granted in respect of the product. Breach of such a notice can be a criminal offence under the Regulations.

Challenge to a provisional determination notice

The Independent Review Panel

The Panel is responsible for giving advice to the Licensing Authority on whether the product is a medicinal product within the meaning of Article 1 of Directive 2001/83/EC. The Panel considers the written and/or oral representations from the company and any representations made by the Licensing Authority. It will take account of the relevant legislative provisions and previous advice and consider the evidence before it. It may take further evidence from the MHRA and the company concerned, and hear expert witnesses. It will advise the Licensing Authority whether in its opinion the product is, or is not, a medicinal product, and give its reasons.

The Panel operates independently of the MHRA. The Chairman is legally qualified and is supported by members appointed by the Licensing Authority for their expertise and standing in relevant disciplines or areas of business. Members are required to follow a code of practice, which amongst other things requires declarations of interest at meetings and withdrawal from discussion of cases where an interest might influence a member's contribution to the discussion. Members' interests will be published annually.

The Panel's Secretariat will suggest Members for Panel meetings to the Chairman on the basis of relevant expertise and availability. The Secretariat will arrange meetings, copy and circulate papers, and provide support to the Panel. Papers and proceedings will be treated as confidential to protect commercially sensitive information in accordance with relevant legislation and Government guidance. The Secretariat will also provide detailed guidance in terms of timescales for the submission of representations etc.

The Panel's advice to the Licensing Authority, which may be arrived at by majority vote, will be issued in writing, under both the oral and written representation procedures. The MHRA's consideration and communication of that advice to the company, is dealt with below.

Written Representations Procedure

The Review Panel will consider the company's written representations and a written submission by the MHRA. Exceptionally, the Panel may wish to adjourn to seek additional expert advice. Once it has completed its deliberations, it will aim to advise the Licensing Authority as quickly as possible. The Licensing Authority, having considered the Panel's advice, will aim to issue its final determination, again giving reasons and enclosing a copy of the Panel's advice. If, exceptionally, the Licensing Authority does ***not*** accept the Panel's advice, it will at the same time give its reasons for doing so to the company.

Oral Hearings Procedure

The hearing will be in private. To facilitate the review process, companies will be expected to send in copies of any written representations or documentary evidence they want the panel to consider in advance of the hearing. If it is necessary to submit new evidence before the hearing, the Panel Secretariat should be notified as early as possible. The MHRA will also provide a written report for the Panel to consider.

At the hearing the company or the MHRA may, at the discretion of the Chairman, field expert and other witnesses to give evidence on its behalf. The MHRA will have an opportunity to respond to the company's statement and witnesses' evidence. The Panel will, as they think fit, question witnesses as well as the company and MHRA representatives, and may adjourn to a later date in order to seek additional information or advice.

If a company gives notice that it no longer wishes to be heard or fails to attend without good reason, the Panel will consider the matter on the basis of the information before it, including any written representations from the company.

Once the Panel has completed its deliberations, it will issue its advice to the Licensing Authority. The Licensing Authority, having considered the advice, will aim to issue its final determination again giving reasons and enclosing a copy of the panel's advice,. If, the Licensing Authority does ***not*** accept the Panel's advice, it will at the same time give its reasons for doing so to the company.

There will be instances where the final determination will have wider application. In these cases, before coming to its final determination, the Licensing Authority may consult interested bodies and accept further representations on the issues, including those identified by the Panel. When appropriate, the Licensing Authority may refer cases back to the Panel to reconsider in the light of any new evidence.

Final determinations following review

Notice under Regulation 161 or 162 of the Regulations

The Notice will set out the Licensing Authority's reasons for its determination. Should the determination confirm that the product is a medicine, it will include a reminder of the legal provisions for marketing relevant medicinal products, and what the company needs to do to comply. The company will be asked to notify the MHRA of its intention to comply, giving details, usually within three weeks from the date of the determination notice. The MHRA also has power to issue a notice under the Regulations, as amended, formally requiring the company to stop marketing the product, or not to place it on the market, unless or until a marketing authorisation, a traditional herbal registration or a certificate of registration as homoeopathic medicinal product has

been granted in respect of the product. Breach of such a notice is a criminal offence under the Regulations if the product *is* a relevant medicinal product.

Publication of final determinations

It will be normal practice to publish material details of all final determinations. The company concerned will have an opportunity to comment on what the MHRA proposes to publish. Details of final determinations can be found on the gov.uk website using the link https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/404785/Final-determinations-Vol4_1_.pdf.

March 2016

GUIDANCE NOTE ON SMOKING CESSATION PRODUCTS AND ALTERNATIVES TO TOBACCO PRODUCTS

Introduction

Products that are sold and promoted with material aimed at assisting with the cessation or reduction in use of tobacco products, and/or as nicotine replacement therapy (NRT), are classified as medicinal products and will require prior authorisation before being sold, supplied or advertised in the UK. This is because they are deemed to fall within the first limb of the definition of a medicinal product (medicinal by presentation) as products intended to treat an addiction.

The Regulations

In the UK, as in the rest of the EC, medicinal products which are placed on the market, are required to have marketing authorisations (formerly product licenses) in accordance with The Human Medicines Regulations 2012 (S.I. 2012/1916),). Amongst other things these provide that, unless exempt, no medicinal product shall be placed on the market unless an appropriate authorisation has been granted in accordance with Community provisions by the licensing authority or the European Commission.

It is an offence to sell or supply or to advertise a medicinal product which does not have authorisation.

A "medicinal product" is defined in Article 1 of Council Directive 2001/83/EEC and included as Regulation 2 of the 2012 Human Medicines Regulations. The definition is:

> *"Any substance or combination of substances presented as having properties for treating or preventing disease in human beings.*
>
> *Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis*".

If a product satisfies either of the above criteria, it may be classed as a medicinal product. In broad terms, when classifying a product, the Agency looks at the way it is presented and its actual or perceived function, that is, its effects (when administered) on human physiology.

The term “disease” is defined in Regulation 8 of the Human Medicines Regulations 2012 as: “includes any injury, ailment or adverse condition, whether of body or mind”.

Addictions

All forms of addiction are regarded as adverse conditions (diseases).

An addiction is the uncontrollable desire or compulsion to self-administer a substance, or to perform an activity (e.g. Obsessive Compulsive Disorder “OCD”) and which cannot be controlled by self-will alone.

The UK Government is committed to significantly reducing the number of people who use tobacco products through a system of education, counselling and support programs and the provision of easily available and approved medicinal products and medical devices. These take the form of inhalers, chewing gums, mouth sprays, transdermal patches, lozenges and orally administered drugs. Only authorised products may be sold for this purpose.

The status of nicotine

Nicotine is not regarded as a medicinal substance. Its only use in medicine is for the treatment of nicotine addiction. Subsequently, nicotine does not fall within the second limb of the definition of a medicinal product (medicinal by function).

The regulatory history of smoking/nicotine cessation products in the UK

The MHRA (and formerly the MCA) has regarded products to treat or reduce an uncontrollable desire to use nicotine products as medicines for many years, and its advice to companies on this subject has been consistent throughout. The agency’s view has been challenged on two occasions by companies that were marketing such products without the appropriate authorisation. The first in 2002 called “Quit Now” and the second called “Smoke No More in 2003”. Under the statutory review process now contained in the provisions of The Human Medicines Regulations 2012 (S.I. 2012/1916), (formerly *The Medicines For Human Use (Marketing Authorisations) Regulations 1994 (S.I.1994/3144)*) both companies made representations to an Independent Review Panel.

The Panel, after considering all of the evidence (which included several expert witness submissions) and examined the definition of a medicinal product, concurred with the agency that products presented for the cessation of smoking are regarded as being for the treatment of nicotine addiction.

This confirmed that it is not lawful to sell, supply or advertise an unlicensed product that claims – or implies that it can assist in the cessation of using nicotine products and smoking.

The fact that the status of products presented for the cessation of nicotine use as medicines is already established, means that they are not, in effect, deemed to be borderline and cannot be subject to fresh determination procedures.

Upon discovery of the sale, supply or promotion of an unlicensed hangover related product in the UK, the agency's Medicines Borderline Section may issue an **Urgent Warning Notice** to the company concerned. It should be noted that there is no legal obligation to do so, and in circumstances where it is considered that the inappropriate marketing may be a deliberate act (e.g. where a warning has already been given), the matter may instead be referred to the agency's Enforcement Unit for consideration of proceedings in the criminal courts.

Product presentation

For the purposes of determining product status, the MHRA takes into account everything and anything that may come to the general public's attention. This includes, labelling, leaflets, packaging, use of graphics, advertisements, customer testimonials, internet promotions, editorials and broadcasts. It is the message conveyed rather than the actual wording that is taken into account and, where this is deemed inappropriate, regulatory action will be taken.

Alternatives to tobacco products

Products that are sold as alternatives to the use of tobacco products and which do not fall within the definition of a medicinal product will not be regulated by the MHRA.

Guidance on the regulation of these products may be obtained from Trading Standards Service. Some products such as electronic cigarettes will now fall within the scope of the Tobacco Products Directive (2014/40/EU) once this has been adopted into UK law.

Products may be sold as an alternative to tobacco as a temporary measure such as during periods or in places where smoking is not permitted, or as a longer term regime, perhaps on grounds of comparable costs.

Products that do not make any cessation claims but, in the opinion of the MHRA, may be viewed by consumers as an obvious alternative to an authorised medicinal product such as transdermal patches or mouth sprays, are likely to be regarded as medicinal products.

This Guidance should not be taken as a complete or definitive statement of the law. It is not intended as a substitute for legal or other professional advice. The MHRA accepts no liability for any loss or damage caused, arising directly, or indirectly, in connection with reliance on the contents of this Guidance.

February 2016

APPENDIX 5

GUIDANCE NOTE ON THE USE OF TOPICAL CHLORHEXIDINE FOR SKIN PREPARATION AS PART OF A MEDICAL PROCEDURE

Introduction

The MHRA's Medicines Borderline Section receives many enquiries and complaints about products which are presented as skin disinfection products, in particular those containing chlorhexidine. The purpose of this appendix is to provide help and information on the legal position and status of products which are intended to be used for application to human skin as part of a medical procedure. The appendix focusses on products containing chlorhexidine but could similarly apply to skin disinfection products containing other active ingredients.

The Regulations

In the UK, as in the rest of the EC, medicinal products which are placed on the market, are required to have marketing authorisations (formerly product licenses) in accordance with The Human Medicines Regulations 2012 (S.I. 2012/1916). Amongst other things these provide that, unless exempt, no medicinal product shall be placed on the market unless an appropriate authorisation has been granted in accordance with Community provisions by the licensing authority or the European Commission.

<u>It is an offence to sell or supply or to advertise a medicinal product which does not have authorisation.</u>

A "medicinal product" is defined in Article 1 of Council Directive 2001/83/EEC and included as Regulation 2 of the 2012 Human Medicines Regulations. The definition is:

> *"Any substance or combination of substances presented as having properties for treating or preventing disease in human beings.*
>
> *Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis".*

If a product satisfies either of the above criteria, it may be classed as a medicinal product. In broad terms, when classifying a product, the Agency looks at the way it is presented and its actual or perceived function, that is, its effects (when administered) on human physiology.

The term "disease" is defined in Regulation 8 of the Human Medicines Regulations 2012 as: "includes any injury, ailment or adverse condition, whether of body or mind".

MHRA's position

Topical chlorhexidine antiseptic products that are intended by the manufacturer to be used for a medical purpose, such as the preparation of the skin prior to surgery, will be classified as a medicinal product.

The manufacture and supply of a medicinal product containing chlorhexidine should be in accordance with Human Medicines Regulations 2012,. The product should have a marketing authorisation which may include restrictions on how it may be used Chlorhexidine is also available in a non-medicinal form which is extensively and legitimately used for non-medicinal purposes, including in a clinical setting. These versions of the product are not subject to regulation under the Human Medicines Regulations 2012, as amended.

The MHRA's view is that chlorhexidine is classified differently for different presentations. These are:

- Medicinal Use: Topical disinfectant for clinical use (e.g. pre-operatively)
- Medical Device: Disinfectant for medical equipment
- Biocide: General use as a disinfectant (e.g. washing hands)

Similar products in different concentrations are properly classified and authorised differently for particular purposes. Companies or manufacturers who are selling chlorhexidine, or allowing it to be supplied for a medicinal use, where there is no marketing authorisation for that product, are in breach of UK medicines regulatory requirements. MHRA would like to highlight that there are health risks associated with using chlorhexidine. Using the appropriately authorised product for its specific intended use, in accordance with manufacturer's instructions for use, is the best way of minimising harm.

February 2016

APPENDIX 6

GUIDANCE ON TOPICAL PRODUCTS FOR ANTI-BACTERIAL, ANTISEPTIC, ANTI-MICROBIAL, GENERAL DISINFECTION AND CLEANSING OF SKIN

Introduction

The purpose of this guidance is to provide help and information on the legal position and status of topical products for application to human skin that are sold, supplied or promoted as anti – bacterial/septic/microbial/viral or disinfectants.

MHRA's Borderline Section has been consulted about a number of products making claims to treat or prevent specific pathogens and diseases, in particular MRSA and Flu (including Avian and Swine Flu). In some cases products have been placed directly onto the market without seeking appropriate advice and have subsequently been subject to investigation and possible enforcement action.

The Regulations

In the UK, as in the rest of the EC, medicinal products which are placed on the market, are required to have marketing authorisations (formerly product licenses) in accordance with The Human Medicines Regulations 2012 (S.I. 2012/1916). Amongst other things these provide that, unless exempt, no medicinal product shall be placed on the market unless an appropriate authorisation has been granted in accordance with Community provisions by the licensing authority or the European Commission.

<u>It is an offence to sell or supply or to advertise a medicinal product which does not have authorisation.</u>

A "medicinal product" is defined in Article 1 of Council Directive 2001/83/EEC and included as Regulation 2 of the 2012 Human Medicines Regulations. The definition is:

> *"Any substance or combination of substances presented as having properties for treating or preventing disease in human beings.*
>
> *Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis".*

If a product satisfies either of the above criteria, it may be classed as a medicinal product. In broad terms, when classifying a product, the Agency looks at the way it is presented and its actual or perceived function, that is, its effects (when administered) on human physiology.

The term “disease” is defined in Regulation 8 of the Human Medicines Regulations 2012 as: “includes any injury, ailment or adverse condition, whether of body or mind”.

Legal status of products

Products used for general disinfection of surfaces and not for administration to humans cannot fall within the remit of the regulations administered by the MHRA. Instead these should fall within the regulatory responsibilities of either Trading Standards or the Health and Safety Executive (HSE). (*See relevant sections below*)

Products for topical administration to humans for the purpose of preventing or killing pathogenic agent will generally fall into one of four regulatory groups: medicines, biocides, cosmetics or medical devices. The distinction between these categories is as follows:

Medicines :

Under the first limb, any direct claim or implication that a product can be used to treat, or prevent a virus or an infection associated with specifically named pathogens, will be deemed as medicinal. This particularly applies to micro organisms that are frequently brought to the attention of the general public by the media, such as MRSA, E.coli and Salmonella, Swine Flu, Avian Flu etc.

Example: “Kills/effective against MRSA” is an implied medicinal claim to prevent or treat infections that are caused by the MRSA micro organism.

Under the second limb, a product will be deemed as medicinal if it contains an agent that is known to be capable of affecting physiological functions through pharmacological, immunological or metabolic means. There are a number of licensed topical medicines available that fall within this category. This limb also applies to products that are presented in a manner that would lead a consumer to expect such a physiological effect to occur, even if there is no substantiation for the claims being made or implied.

The MHRA considers both direct claims and those made by implication. It also takes account of all published product related information (e.g. websites, advertising, editorials etc.) This approach is derived from ECJ case law. Of particular relevance to way in which medicines are classified are Cases 227/82 (van Bennekom); 369/88 (Delattre) and 112/89 (Upjohn).

Biocides: In the UK biocidal products are controlled under the EU Biocides Regulation (528/2012) – BPR – which define a biocidal product as:

“*any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action: or*

any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless,

preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

A treated article that has a primary biocidal function shall be considered a biocidal product."

The responsibility for the administration and some enforcement of the BPR lie with the Health and Safety Executive (HSE). The BPR covers a wide range of products, 22 product types covering disinfectants, pest control, preservatives and specialty biocides. For disinfectants, this can include both products used on surfaces or equipment, and products used on human skin. However, the BPR specifically excludes uses that are within the scope of the medicines/medical devices legislation – essentially products or the uses of products only fall to be regulated under the BPR if they are not regulated under medicines. However a product with dual uses, a medicinal use and a general disinfectant use for example, would be regulated under both BPR and the medicines legislation.

All biocidal products regulated under the BPR will eventually need to be authorised under the regulations, though there is an on-going transitional period and you should contact the HSE for further advice. As from the 1 September 2015, a biocidal product consisting of, containing, or generating a relevant substance, cannot be made available on the UK market if the active substance supplier or product supplier is not included in the Article 95 list for the product type(s) to which the product belongs. Further information regarding biocides can be obtained using the link www.hse.gov.uk/biocides.

Medical Devices: As with medicines, medical devices fall under the remit of the MHRA and both bear claims to treat or prevent adverse medical conditions. The major difference is the mode of action of the product types. A product that is intended to prevent infection solely by providing a physical barrier against pathogens, may be classed as a medical device instead of a medicine. A product specifically intended to disinfect or clean a medical device, may be regulated as a medical device itself, provided that it is not intended for use as a general disinfectant (e.g. for surfaces) or for use on patients or by healthcare professionals.'

Cosmetic products: The definition of a cosmetic product as cited in Cosmetic Regulations is particularly helpful in that it sets out clearly the scope of products that it covers.

Article 12(1)(a) of the Cosmetics Regulation (EC) 1223/2009 as amended defines 'Cosmetic Product' as:

"any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;"

Cosmetic products are not licensed products and are not for the treatment or prevention of any specific adverse condition in humans. Cosmetic products for topical cleansing may claim to be anti-bacterial, anti-sceptic or anti-microbial and these should be expressed in general terms. It is not acceptable to make claims to be anti-fungal or anti-viral as these are normally perceived as being related to a range of specific adverse conditions such as athlete's foot and herpes.

Cosmetics regulations are administered locally by the Trading Standards Service who can also give advice on permitted ingredients and labelling requirements. Your local office can be traced via the internet, your local Council or one of the directory enquiry services.

Summary and Conclusion:

All products for topical administration to humans are subject to at least one piece of UK legislation. Products that specify or name individual pathogens imply that their use is for either the prevention or treatment of related diseases. Therefore they will be subject to regulatory control by MHRA, either as medicines or Medical Devices. Although it is possible for products to fit within the definitions of both medicines and another product type, the medicinal status takes precedence since all other regulations exclude such products from their provisions.

Products that are deemed as falling within the definition of a medicine, are subject to the provisions of The Medicines For Human Use (Marketing Authorisations) Regulations 2012 (S.I.2012/1916) and must either, not be placed upon, or removed from the market until such time as a marketing authorisation (formerly known as product licence) is granted for them. Placing unauthorised products on the market is a criminal offence and MHRA will take appropriate enforcement action in such cases.

Companies that wish to continue marketing products will be required to amend all forms of product presentation and promotional material, by removing all references to named pathogens, or as advised by the Medicines Borderline Section. Products that contain ingredients considered to be for medicinal purposes, must either be either re-formulated or appropriately authorised.

February 2016

APPENDIX 7

GUIDANCE NOTE ON HANGOVER PREVENTIVES AND CURES

Introduction

The purpose of this note is to provide help and information on the legal position and status of products that are sold, supplied or promoted for the purpose of preventing or treating hangovers. It is mainly aimed at companies and individuals, who may be considering the idea of placing such a product on the UK market, or who have already done so without first seeking appropriate advice.

The Regulations

In the UK, as in the rest of the EC, medicinal products which are placed on the market, are required to have marketing authorisations (formerly product licenses) in accordance with The Human Medicines Regulations 2012 (S.I. 2012/1916). Amongst other things these provide that, unless exempt, no medicinal product shall be placed on the market unless an appropriate authorisation has been granted in accordance with Community provisions by the licensing authority or the European Commission.

<u>It is an offence to sell or supply or to advertise a medicinal product which does not have authorisation.</u>

A "medicinal product" is defined in Article 1 of Council Directive 2001/83/EEC and included as Regulation 2 of the Human Medicines Regulations. The definition is:

"*Any substance or combination of substances presented as having properties for treating or preventing disease in human beings.*

Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis".

If a product satisfies either of the above criteria, it may be classed as a medicinal product. In broad terms, when classifying a product, the Agency looks at the way it is presented and its actual or perceived function, that is, its effects (when administered) on human physiology.

The term "disease" is defined in Regulation 8 of the Human Medicines Regulations 2012 as: "includes any injury, ailment or adverse condition, whether of body or mind".

Background

In the UK, unlicensed products are considered and determined by the MHRA's Medicines Borderline Section (Borderline Section). Many products are sold under labels such as "food supplements" or "cosmetics". However, in some cases these descriptions are inappropriately applied and it is the statutory role of the Borderline Section to determine whether or not they should instead be classified as medicines.

Every year, particularly in the run up to Christmas, MHRA's Borderline Section is required to advise on and investigate a number of unlicensed products that are presented for either the prevention or cure of hangovers.

Many of the products examined emanate from the United States, where they are mostly sold legally under the Dietary Supplement Health and Education Act (DHSEA). This permits the sale of products of natural origin in the USA, without the requirement to have them licensed as medicines, subject to certain rules regarding the claims that may be made for them. This also means that such products are not evaluated by the US Food and Drugs Administration (FDA).

The free availability of hangover products in the USA may possibly be one reason that many people assume a similar position is adopted in the United Kingdom. However, this is not the case. The UK does not have any equivalent legislation and unlike the USA, it is tied into the medicines and food regulations that operate throughout the European Union.

EU regulations are applied throughout its member states to control the authorisation and marketing of licensed and registered medicines. Unlicensed medicinal products however, are regulated under national rules and the legislation which operates in each member state often varies for a number of reasons, which reflect the different cultures, attitudes and histories that exist. Each interpretation is also subject to published Guidance by the European Commission, often in the light of judgments by the European Court of Justice (case law).

The Status of Hangover products in the UK

The MHRA (and formerly the MCA) has regarded products to treat or prevent hangovers as medicines for many years and its advice to companies on this subject has been consistent throughout. The agency's view was challenged by a company marketing a product called "Hangover Helper" in 2001. Under the statutory review process now contained in the provisions of The Human Medicines Regulations 2012 (S.I. 2012/1916), (*formerly The Medicines For Human Use (Marketing Authorisations) Regulations 1994 (S.I.1994/3144)*), it made representations to the Independent

Review Panel for Borderline Products.

The Panel, after considering all of the evidence and examining the definition of a medicinal product, concurred with the agency. It also gave advice to the effect that the term "hangover" is well recognised as describing the symptoms associated with over indulgence with alcohol. These symptoms may include nausea, headache, dizziness and lethargy.

This confirmed that it is not lawful to sell, supply or advertise an unlicensed product that claims – or implies that it can treat or prevent a hangover or any of its symptoms. (e.g. In the context of alcohol consumption, the term “The morning after” would normally be associated with hangovers). Restrictions also extend to claims to de-toxify the liver or protect against toxic effects of alcohol consumption.

Product presentation

For the purposes of determining product status, the Borderline Section takes into account everything and anything that may come to the general public’s attention. This includes, labelling, leaflets, packaging, use of graphics, advertisements, internet promotions, editorials and broadcasts. It is the message conveyed rather that the actual wording that is taken into account and, where this is deemed inappropriate, further action will be taken.

Legal hangover products

There are a number of approved medicinal products available for the symptoms of a hangover. The majority are available over the counter in general sales outlets such as supermarkets, as well as from pharmacies.

Action that MHRA’s Borderline Section will take upon discovery of an unlicensed hangover product on UK market

The fact that the status of products presented for the prevention or treatment of hangovers as medicines is already established, means that they are not, in effect, deemed to be borderline and cannot be subject to fresh determination procedures. Therefore, there is no onus on the Borderline Section to deal with them.

Upon discovery of the sale, supply or promotion of an unlicensed hangover related product in the UK, the agency’s Medicines Borderline Section may issue an **Urgent Warning Notice** to the company concerned. It should be noted that there is no legal obligation to do so, and in circumstances where it is considered that the inappropriate marketing may be a deliberate act (e.g. where a warning has already been given), the matter may instead be referred to the agency’s Enforcement Unit for consideration of proceedings in the criminal courts.

It should also be noted that information from a third party may be sent direct to the Enforcement Unit, or be discovered by investigators in the course of their business. In these circumstances, it is likely that proceedings will be considered without a referral to the Borderline Section.

Further information about the work of the MHRA and the Borderline Section can be found on the website https://www.gov.uk/decide-if-your-product-is-a-medicine-or-a-medical-device

This Guidance should not be taken as a complete or definitive statement of the law. It is not intended as a substitute for legal or other professional advice. The MHRA accepts no liability for any loss or damage caused, arising directly, or indirectly, in connection with reliance on the contents of this Guidance.

February 2016

GUIDANCE NOTE ON HEAD LICE PRODUCTS

Introduction

All products that are presented as treatments for headlice infestation are controlled by MHRA, which is the UK body responsible for the administration and enforcement of medicines and medical devices regulations.

In coming to a view about any headlice product's status, and which regulations it falls under, the Agency takes into account UK and EC legislation, relevant court decisions, and its own guidance.

All headlice products fall into one of three categories: -

- Medicines - used to kill headlice and nits by insecticidal/pediculocidal action.

- Medical Devices and Accessories - used in conjunction with a headlice comb or to treat infestation by means of a physical or chemical action only.

- Biocides - repellents used solely to repel headlice and avoid the need for treatment.

The regulations

In the UK, as in the rest of the EC, medicinal products which are placed on the market, are required to have marketing authorisations (formerly product licenses) in accordance with The Human Medicines Regulations 2012 (S.I. 2012/1916). Amongst other things these provide that, unless exempt, no medicinal product shall be placed on the market unless an appropriate authorisation has been granted in accordance with Community provisions by the licensing authority or the European Commission.

It is an offence to sell or supply or to advertise a medicinal product which does not have authorisation.

A "medicinal product" is defined in Article 1 of Council Directive 2001/83/EEC and included as Regulation 2 of the 2012 Human Medicines Regulations. The definition is:

"*Any substance or combination of substances presented as having properties for treating or preventing disease in human beings.*

Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis".

If a product satisfies either of the above criteria, it may be classed as a medicinal product. In broad terms, when classifying a product, the Agency looks at the way it is presented and its actual or perceived function, that is, its effects (when administered) on human physiology.

The term "disease" is defined in Regulation 8 of the Human Medicines Regulations 2012 as: "includes any injury, ailment or adverse condition, whether of body or mind".

Medical Devices and Accessories

A "**medical device"** is defined in Article 1 of Council Directive 93/42/EEC and in UK law under The Medical Device Regulations 2002 (Statutory Instrument Number 618). The definition is as follows:

"'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;"

In determining whether or not a product may be considered to be a medical device, the Agency looks at the claims made for the product, its intended purpose and the mode of action on the human body.

Fine-toothed combs for the removal of head lice and nits are regarded as medical devices and must meet the requirements of the Medical Device Directive 93/42/EEC and associated UK legislation, including bearing the CE mark.

Any product that is specifically intended for the treatment of head lice infestation by facilitating the use of a fine tooth/head lice and presented for this purpose only, may be regarded as an accessory to a medical device. If so it will be subject to the requirements of the Medical Device Directive 93/42/EEC.

Other products which may act physically (e.g. electro-action, suffocation) are also likely to be regulated as medical devices and must comply with the same regulatory requirements.

While the inclusion of a suitable comb is optional, the product particulars must include clear instructions for the combined use of head lice or fine tooth comb with the product if applicable.

Biocides - Products used to repel headlice

Repellents are regarded and regulated differently to the other categories, since their purpose is to protect an external human surface and thereby **avoid** the presence of headlice from occurring. As such, any product recommended solely for use prior to infestation as a repellent, will fall under the Biocidal Product Directive

Products cannot be regulated as a Biocide if they fall within the definition of a medicinal product (see Paragraph 2 above). In order to fall **outside** of the definition, repellent products must observe the following conditions:

- They should be should be clearly presented for use in circumstances when headlice and nits are not present and to be used to avoid infestation.

- They must neither claim nor imply that they may have a secondary use as a treatment for headlice.

- They should not refer to nits/eggs as these can only occur as a result of an infestation.

- They must be clearly named or labelled as repellents, in a way that avoids confusion with products sold under medicines or medical devices regulations.

If necessary, advice should be sought from MHRA before marketing.

For further information contact:

Medicines: Simon Parker. Medicines Borderline Section, MHRA, c/o 151 Buckingham Palace Road. London SW1W 9SZ

E-mail: simon.parker@mhra.gsi.gov.uk

Devices: Mrs Clare Headley. MHRA, European Regulatory Affairs, 151 Buckingham Palace Road. London SW1W 9SZ

Tel: 020 3080 7386

E-mail: clare.headley@mhra.gsi.gov.uk

February 2016

GUIDANCE NOTE ON THE MEDICINES BORDERLINE SECTION AND THE INTERNET

The Regulations

In the UK, as in the rest of the EC, medicinal products which are placed on the market, are required to have marketing authorisations (formerly product licenses) in accordance with The Human Medicines Regulations 2012 (S.I. 2012/1916). Amongst other things these provide that, unless exempt, no medicinal product shall be placed on the market unless an appropriate authorisation has been granted in accordance with Community provisions by the licensing authority or the European Commission.

It is an offence to sell or supply or to advertise a medicinal product which does not have authorisation.

A "medicinal product" is defined in Article 1 of Council Directive 2001/83/EEC and included as Regulation 2 of the 2012 Human Medicines Regulations. The definition is:

> *"Any substance or combination of substances presented as having properties for treating or preventing disease in human beings.*
>
> *Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis".*

If a product satisfies either of the above criteria, it may be classed as a medicinal product. In broad terms, when classifying a product, the Agency looks at the way it is presented and its actual or perceived function, that is, its effects (when administered) on human physiology.

The term "disease" is defined in Regulation 8 of the Human Medicines Regulations as: "includes any injury, ailment or adverse condition, whether of body or mind".

Internet

A constant question to the Medicines Borderline Section is "how can I give my customers information without making medicinal claims"?

Information linked to an unlicensed product which makes direct or implied claims may well cause the Section to say that a product falls within the definition of a medicinal product.

A particular problem is information on the internet. It should be noted that material on the internet is not excluded from the definition of an 'advertisement' contained in Regulation 7 of the Human Medicines Regulations 2012, as amended.

Where a product is sold on or has links to a website which presents that product as a medicine, the website will be used by the Section as evidence in the determination process. Similarly, where a customer is directed from a website selling a product, to another website for more information about the substances contained in a product and their uses, that may also be used by the Section as evidence in the determination process.

Companies would be able to refer consumers to a website with a non-product specific list of ingredients and their uses, provided that there were no references to any actual products. To demonstrate that the information was not being used by the website selling the products to make medicinal claims, the information must be contained on a separate site. To further separate the products and the information there must be no purchase facility on the entry page of the company's site.

All products should be featured on subsequent pages to the entry page. In addition, the only reference to the information site/pages should be on the entry page where the following wording (or similar) could be used "Information on food supplements and their uses can be found by clicking here". The MHRA would expect the information to be indexed on ingredients and not diseases/adverse medical conditions.

The Medicines Borderline Section envisages the relationship between sites as follows: