



Medicines & Healthcare products
Regulatory Agency



A guide to what is a medicinal product



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A guide to what is a medicinal product

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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 exempt¹, 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 must 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

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 Directive 2001/95/EC)

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

Where medicinal claims are being made, for example for foods or cosmetics, 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 product³.

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, 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 first 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 second 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 ECJ Judgements:

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 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.”* [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 judgement 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 system for registering herbal medicinal products is available. 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 both regulatory schemes 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 a medicinal claim. 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” “dietary maintenance” 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 emphasise 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. Classification of toothpastes as cosmetics, medicinal products or medical devices are dependent on the product's composition, mode of action and presentation.
 - There is new [guidance](#) available on the classification of toothpaste claims, created by the Cosmetics, Toiletry and Perfumery Association (CTPA) in collaboration with the MHRA, which sets a common understanding on the types of claims made for toothpastes and what this means in terms of the regulations that will apply to individual products in light of those claims.

- 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. MHRA has also agreed with the CTPA that consumers with an existing adverse skin condition may wish to know if a cosmetic product is appropriate for them to use. Where this can be substantiated, the following wording can be used.
 - ***“Also suitable for people who may be prone to eczema / psoriasis / dermatitis / rosacea / acne / spots”***
 This wording should be present for advisory purposes and should not be used in a manner which could imply, either explicitly or implicitly, that they can be used for the prevention or treatment of these conditions.

- 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 or fight 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. MHRA does not regard blackheads to be an adverse medical condition. In specific regard to spot, pimple and acne products, the cosmetic function must be made clear and any explicit or implicit claims related to the treatment or prevention of acne, or any other adverse condition, must not be used.
 - A [manual](#) of the Working Group on Cosmetic Products defines what is meant by a blackhead a spot and acne.
 - The manual describes spots as clogged sebum ducts (commonly referred to as “clogged pores”) that form on the skin as a result of the skin's normal functions such as cell renewal, shedding and sebum production, which may be correctly defined as primary comedones. They are transient conditions of the skin and may present as blackheads (open comedones) or whiteheads (closed comedones). Acne is described as a state of the skin that is often characterised by the presence of persistent spots, excessive seborrhea, infection, inflammation and skin damage.

- The manual is clear that products which function to prevent the formation of spots or function to protect the face from spots through a cleansing action may fulfill the cosmetic definition depending on how the product is presented, the claims that are made about the product and the ingredients used in the product.
- Any claims made for such products should be in relation to the cosmetic function of the product; to clean, protect or keep the skin in good condition. MHRA agrees with this position.
- Cosmetic products may also claim **‘also suitable for people who may be prone to acne/spots’** provided that claims do not give the impression, explicitly or implicitly, that they can be used for the prevention or treatment of acne or other adverse skin conditions.

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.

There is published guidance on the Nutrition and Health Claims Regulation which states that, while the Regulation applies to claims made in commercial communications about foods, it is the Department of Health and Social Care’s (DHSC) opinion that it will not apply to claims made in communications within trade (business to business), to doctors or other health professionals, or to their organisations, whether the claims are in the labelling, advertising or other presentation of the food. However, DHSC are due to update their guidance on business to business communications in the near future.

This regulation concerns foods and not medicines, but MHRA is concerned that, on occasions, companies are using these communications to provide the trade or healthcare professionals with evidence of their products being used for a medical purpose. Such communications would bring the products within either or both limbs of the definition of a medicinal product and MHRA will take appropriate action where such communications are seen.

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](#)

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 define what a cosmetic is and prohibit, or place 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 –

https://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products_en

Cosmetic Regulation (EC) No. 1223/2009 -

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

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. Aromatherapy products that do not meet the definition of other industry or product-specific harmonised regulations 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/ukxi/2005/1803/contents/made>

Cosmetic Borderline –

https://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products_en

Cosmetic Regulation (EC) No. 1223/2009 -

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

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 lies 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. 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@food.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:

contactus.dh.gov.uk/

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, the Novel Foods Regulation 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 guidance⁴ 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.

⁴http://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&usq=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 drugs
- Tetrahydrocannabinol (Delta-THC)

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

The Psychoactive Substances Act 2016

The Psychoactive Substances Act makes it an offence to produce, supply or offer to supply any psychoactive substance with the exemption of 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.

The World Anti-Doping Agency's 2015 Prohibited List gives details of substances and methods banned in sports in-and out-of-competition. Further information can be found at:

<https://www.wada-ama.org/en/resources/science-medicine/prohibited-list-documents>

Information regarding World Anti-Doping Agency (WADA) and their key activities can be found at:

<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, especially where there is a clear connection to use in medicine. 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 under other regulations.

Topical anaesthetics (Numbing Gels/Creams)

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

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, nitrous oxide, when used for recreational purposes, is not a matter for the MHRA. 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>

Change in Classification of certain glucosamine containing products

Following a 2016 Court of Appeal Judgement, there has been a change in the MHRA's policy regarding oral glucosamine containing products.

This change of policy applies to oral products containing a daily dose of base glucosamine at, or exceeding, 1178mg/day which will now be regarded to be medicines. Most glucosamine containing products do not refer to this figure but, in practice, this will impact products which are marketed with levels of 1500mg glucosamine sulphate or hydrochloride, as these contain base glucosamine levels of 1178mg and 1246mg respectively.

This position is complicated by the fact that glucosamine sulphate is available in two salt forms; a sodium (NaCl) and potassium (KCl) salt form. In practice, more than 1500mg of either salt form is added to achieve 1500mg of glucosamine sulphate and, therefore, a base glucosamine level of 1178mg. Though the potassium salt is not used in licensed medicines, 1884.60mg of the sodium salt is added to achieve 1500mg/day of glucosamine sulphate, providing 1178mg of base glucosamine.

Work done by the MHRA in response to the Court Judgement included a consumer review, carried out to accurately gauge the manner of use of glucosamine containing products in the UK, as well as an evaluation of the threshold of pharmacological effect of glucosamine. The Court of Appeal Judgment, as well as the MHRA's published decision, are available via the links below.

MHRA Published Decision: <https://www.gov.uk/government/news/change-in-the-classification-of-certain-glucosamine-products>

Court of Appeal Judgment: <http://www.bailii.org/ew/cases/EWCA/Civ/2016/554.html>

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 varies according to the product in question. This section provides summaries of relevant cases⁵.

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:

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

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:

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 terveystieteiden tutkimuskeskus (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:

1. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended, does 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.
2. 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.
3. 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. 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 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 lightening 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.

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.
AREDS and AREDS2	References to these studies, which relate to advanced AMD and its associated vision loss, suggest a claim to treat disease
“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.
“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/Healing”	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.

**Last Amended March 2019
Medicines Borderline Section**

March 2019

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**Last Amended March 2019
Medicines Borderline Section**

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.
- advertising material for a product makes clear medical claims such that the product falls within Limb 1 of the definition of medicinal product and the company responsible has not voluntarily complied with a MHRA request to remove or reword the material within a set timescale.

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

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.

Last Amended October 2018
Medicines Borderline Section

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 EU, medicinal products which are placed on the market, are required to have marketing authorisations in accordance with The Human Medicines Regulations 2012 (S.I. 2012/1916) (the **Regulations**). 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 EU law 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 Directive 2001/83/EC, which is implemented by Regulation 2 of the Regulations. The definition, which is in two 'limbs' is:

"Any substance or combination of substances presented as having properties for treating or preventing disease in human beings (Limb 1).

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 (Limb 2)".

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 function, that is, its effects (when administered) on human physiology.

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

Where unauthorised products are marketed for a medical purpose MHRA will take appropriate action to achieve compliance. Where necessary, MHRA can use the statutory determination process described in Appendix 3 of this Guidance to formally classify a particular product.

Any product that makes a medicinal claim would fall within Limb 1 of the definition. For the avoidance of doubt, this includes any testimonies that are included on websites or any other promotional material. Further guidance in relation to medicinal claims can be found in Appendices 1, 8 and 9 of this guidance.

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 for the purpose of treating the addiction.

A number of new products have been developed and grown in popularity in the years after the Panel gave its advice. Many of these offer an alternative to tobacco products while still delivering nicotine to the consumer. Claims to stop smoking tobacco products in favour of switching to an alternative form of nicotine delivery, would not be considered as medicinal claims, provided there is no suggestion of also helping to treat nicotine addiction.

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.

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).

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, nicotine gum or mouth sprays, are likely to be regarded as medicinal products.

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Last Amended March 2019
Medicines Borderline Section

GUIDANCE ON TOPICAL PRODUCTS FOR:

ANTI-BACTERIAL, ANTISEPTIC, ANTI-MICROBIAL, GENERAL DISINFECTION AND CLEANSING, AND PREOPERATIVE PREPARATION OF SKIN

Introduction

The purpose of this guidance is to provide help and information on the regulatory status of topical products for application to human skin that are sold, supplied or promoted as anti-bacterial/septic/microbial/viral or disinfectants. It also contains a section covering products which contain chlorhexidine.

The Medicines Borderline Section regularly has to scrutinise products being sold with direct or implied claims or information relating to the treatment or prevention of specifically named pathogens and diseases, in particular MRSA, *Escherichia coli* (e.g. *E. coli* 0157), Weil's disease and strains of 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 regulatory action.

The Regulations

In the UK, as in the rest of the EU, medicinal products which are placed on the market, are required to have marketing authorisations in accordance with The Human Medicines Regulations 2012 (S.I. 2012/1916) (the **Regulations**). 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 EU law 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 Directive 2001/83/EC, which is implemented by Regulation 2 of the Regulations. The definition, which is in two 'limbs' is:

"Any substance or combination of substances presented as having properties for treating or preventing disease in human beings (Limb 1).

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 (Limb 2)".

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 function, that is, its effects (when administered) on human physiology.

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

Where unauthorised products are marketed for a medical purpose MHRA will take appropriate action to achieve compliance. Where necessary, MHRA can use the statutory determination process described in Appendix 3 of this Guidance to formally classify a particular product.

Any product that makes a medicinal claim would fall within Limb 1 of the definition. For the avoidance of doubt, this includes any testimonies that are included on websites or any other promotional material. Further guidance in relation to medicinal claims can be found in Appendices 1, 8 and 9 of this guidance.

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

1. Products for use on humans

Products for topical administration to human skin will fall into one of four regulatory groups: medicines, medical devices, biocides or cosmetics. The distinctions between these categories are detailed below. Products used for general disinfection of surfaces and which are neither medicines nor medical devices, cannot fall within the remit of 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*).

2 (a) Medicines

Under the first limb of the definition of a medicinal product (see “Regulations” above), any claim 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 MRSA.

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 the way in which medicines are classified are Cases 227/82 (van Bennekom); 369/88 (Delattre) and 112/89 (Upjohn).

Under the second limb of the definition, a product may be medicinal if it contains an agent that is known to be capable of correcting, restoring, or modifying a physiological function through pharmacological, immunological or metabolic means. There are a large number of licensed topical antimicrobial products that fall within this category.

This classification also applies to products that are intended for pre-operative or surgical use, e.g. swab or medical scrub.

2 (b) Medical Devices

Medical devices also fall under the remit of the MHRA and will bear claims to treat or prevent adverse medical conditions or for clinical/surgical use. The major difference is the mode of action of the product types. A product that is intended to prevent infection by providing a physical barrier against pathogens, or acting in a physical rather than pharmacological, immunological or metabolic manner, may be classed as a medical device instead of a medicine.

Products that contain alcohol as the only active agent and which are used in a clinical setting on human skin are typically regarded to be medical devices rather than medicines, including those for pre-operative and surgical use. This is because the anti-microbial action is achieved by physical effect.

A product specifically intended to disinfect or clean a medical device, will be regulated as a medical device itself, although secondary claims for use as a general disinfectant (e.g. for surfaces) are permitted provided the product also meets the requirements of the regulations covering biocidal products. Additional claims for use on patients or for use as a surgical scrub would not be permitted under the medical device regulations.

Information about medical devices can be found at:

<https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety>

2 (c) Biocides

In the UK, biocidal products are controlled under the EU Biocides Regulation (528/2012) – BPR – which defines 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 lies with the Health and Safety Executive (HSE). The BPR covers a wide range of products, 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. Biocidal products that also have intended purposes that would bring them within the remit of the medical device (and / or medicines) regulations, that is, which have a dual use, would be regulated under, and need to satisfy the provisions of both BPR and MHRA legislation (medical devices or medicines).

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 (www.hse.gov.uk/biocides).

Claims made for biocidal products should not extend beyond a broad spectrum, e.g. kills**% of known bacteria/germs/micro-organisms. There should be no references to the term “disease” or any specific examples. Citing quality test results (e.g. EN 12345-67) is acceptable as long as no definition or explanation is added.

2 (d) Cosmetic products:

The definition of a cosmetic product as cited in Cosmetic Regulations is particularly helpful in that it sets out clearly the scope and uses of the products 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 medicinal products and are not intended for the treatment or prevention of any specific adverse condition in humans. Cosmetic products for topical cleansing may claim to be anti-bacterial, anti-septic or anti-microbial and these should be expressed in general terms only. Note 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 Trading Standards 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.

3. Products containing Chlorhexidine

Pre-operative and surgical use products frequently contain chlorhexidine as the active agent. 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, and medical scrubs 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.

However, chlorhexidine is also available in non-medicinal forms which are extensively and legitimately used for non-medicinal purposes, including in a clinical setting. There are also scenarios where, by virtue of its intended purpose, chlorhexidine products are classified as medical devices (i.e. they are intended specifically to disinfect medical devices). Such products are accordingly subject to the Medical Devices Regulations 2002 rather than the Human Medicines Regulations 2012.

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

Medicinal use:	Topical disinfectant for clinical use (e.g. pre-operatively).
Medical Device:	Disinfectant specifically intended to clean particular medical devices.
Biocide use:	General topical disinfectant (e.g. washing hands).
Cosmetic use:	When used for the primary purpose of preservation of a cosmetic product or when performing a broad spectrum / non-specific anti-microbial function (or purpose) secondary to a main cosmetic function (or purpose).

Similar products in different concentrations are properly classified and authorised differently for particular purposes. Companies or manufacturers who are selling chlorhexidine products or allowing it to be supplied for a medicinal use, where there is no marketing authorisation for that product, are in breach of the Human Medicines Regulations 2012.

MHRA would also like to highlight that there are health risks associated with using chlorhexidine in neonates¹ and 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.

4. Products for dual use on both human skin and general surfaces

Products that are manufactured and presented for dual use, as both a skin and surface cleansers (e.g. anti-bacterial wipes), will need to satisfy all sets of applicable regulations, with the human use element being the overriding consideration, meaning that, depending on purpose, they be regulated as medicines, devices or cosmetics.

In particular, the claims made for a dual use product must be in line with those permitted for a human use only product.

Summary

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 may 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

¹ <https://www.gov.uk/drug-safety-update/chlorhexidine-solutions-reminder-of-the-risk-of-chemical-burns-in-premature-infants>

since all other regulations exclude such products from their provisions (Refer to Art 2.2 of Council Directive 2001/83/EEC).

Products that are deemed to fall within the definition of a medicine due to their presentation, are subject to the provisions of Human Medicines Regulations 2012. Companies who wish to continue marketing such products as non-medicines will be required to amend all forms of product presentation and promotional material, such as 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 re-formulated or appropriately authorised.

Still not sure how your product will be classified?

If you need further advice about the status of your product you can seek an opinion by emailing borderline_medicine@mhra.gov.uk

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Last Amended March 2019
Medicines Borderline Section

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 and the adverse effects of consuming alcohol. 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 EU, medicinal products which are placed on the market, are required to have marketing authorisations in accordance with The Human Medicines Regulations 2012 (S.I. 2012/1916) (the **Regulations**). 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 EU law 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 Directive 2001/83/EC, which is implemented by Regulation 2 of the Regulations. The definition, which is in two 'limbs' is:

“Any substance or combination of substances presented as having properties for treating or preventing disease in human beings (Limb 1).

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 (Limb 2)”.

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 function, that is, its effects (when administered) on human physiology.

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

Where unauthorised products are marketed for a medical purpose MHRA will take appropriate action to achieve compliance. Where necessary, MHRA can use the statutory determination process described in Appendix 3 of this Guidance to formally classify a particular product.

Any product that makes a medicinal claim would fall within Limb 1 of the definition. For the avoidance of doubt, this includes any testimonies that are included on websites or any other promotional material. Further guidance in relation to medicinal claims can be found in Appendices 1, 8 and 9 of this guidance.

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

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 outside of the UK, where they may be sold lawfully under a different regulatory scheme operating within or outside of the EU.

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 typically include headache and nausea and just as numerous products for treating these are sold as licensed medicines, it is the MHRA’s view that it is clear to the averagely well informed consumer a product for treating both or either symptom during a hangover will also be a medicine.

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 and consumer reviews. It is the message conveyed rather than the actual wording that is taken into account and, where this is deemed inappropriate, further action will be taken.

Licensed hangover products

There are a number of approved medicinal products available for the symptoms of a hangover described above. 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 Notice** to the company concerned in accordance with Regulation 165. This will require the immediate removal of the product from sale in the UK and cancellation of all promotional material but affords the opportunity to comply with the regulations without further legal action being taken. It should be noted that there is no legal obligation for the Borderline Section 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 Division 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 Division 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.

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Last Amended March 2019
Medicines Borderline Section

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 EU 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/pediculicidal 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 EU, medicinal products which are placed on the market, are required to have marketing authorisations in accordance with The Human Medicines Regulations 2012 (S.I. 2012/1916) (the **Regulations**). 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 EU law 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 Directive 2001/83/EC, which is implemented by Regulation 2 of the Regulations. The definition, which is in two 'limbs' is:

"Any substance or combination of substances presented as having properties for treating or preventing disease in human beings (Limb 1).

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 (Limb 2)".

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 function, that is, its effects (when administered) on human physiology.

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

Where unauthorised products are marketed for a medical purpose MHRA will take appropriate action to achieve compliance. Where necessary, MHRA can use the statutory determination process described in Appendix 3 of this Guidance to formally classify a particular product.

Any product that makes a medicinal claim would fall within Limb 1 of the definition. For the avoidance of doubt, this includes any testimonies that are included on websites or any other promotional material. Further guidance in relation to medicinal claims can be found in Appendices 1, 8 and 9 of this guidance.

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 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.
E-mail: borderline_medicine@mhra.gov.uk

Devices: Medical Device Regulatory Team.
E-mail: devices.regulatory@mhra.gov.uk

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Last Amended March 2019
Medicines Borderline Section

GUIDANCE ON USING THE INTERNET TO SELL AND PROMOTE PRODUCTS ON THE MEDICINES BORDERLINE

The internet is routinely used to sell and promote products of all kinds, either in addition to more traditional retail outlets or in place of them. It is also used to provide information about products and services that was previously available in leaflets, brochures, catalogues and advertisements. The sale and advertising of medicines must comply with all relevant regulatory requirements.

The Regulations

In the UK, as in the rest of the EU, medicinal products which are placed on the market, are required to have marketing authorisations in accordance with The Human Medicines Regulations 2012 (S.I. 2012/1916) (the **Regulations**). 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 EU law by the licensing authority or the European Commission.

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

Where unauthorised products are marketed for a medical purpose MHRA will take appropriate action to achieve compliance. Where necessary, MHRA can use the statutory determination process described in Appendix 3 of this Guidance to formally classify a particular product.

Any product that makes a medicinal claim would fall within Limb 1 of the definition. For the avoidance of doubt, this includes any testimonies that are included on websites or any other promotional material. Further guidance in relation to medicinal claims can be found in Appendices 1, 8 and 9 of this guidance.

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".

Medicinal claims

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

Only authorised medicinal products are permitted to be sold with claims to treat or prevent adverse medical conditions or their symptoms and guidance on this aspect can be found in MHRA's 'Blue Guide'².

Medicinal claims can be either direct or implied (refer to Appendix 1 of this Guidance). Implied medicinal claims can be made in a number of different ways, but all will lead a consumer to perceive that a product is either intended to be used, or can be used, for a medicinal purpose. As a consequence, the regulations take into account all such information placed in the public domain, including information published on a website. If you are using the internet to sell products that are not medicines, you should ensure that your entire website or social media content is free of all direct and implied medicinal claims. These may include the following:

- Direct claims for a product's use.
- Information about historic or traditional medicinal use.
- Information about medicinal uses of a product's ingredient(s), even if they do not directly relate to the product in question.
- Lists of adverse medical conditions which take a consumer to a page displaying a product or group of products when selected.
- Publication of third party articles, reports, clinical data, medical research or newspapers articles.
- Use of graphics to display or imply an adverse medical condition, such as pictures of swollen joints, people displaying signs of stress, pictures of skin damage, etc. or before and after pictures depicting recovery from an adverse medical condition.
- Use of medical graphics such as a green cross, NHS or pharmacy sign.
- Information pages about adverse medical conditions for which a product being sold might be associated.
- Use of videos to convey medicinal use information.
- Use of Blogs which make reference to medicinal use.
- Use of customer testimonials or reviews that make reference to medicinal use. (See below).

Testimonials

The use of customer testimonials which also make medicinal claims has been taken into account when classifying products for many years and pre-dates internet sales.

Customers now routinely post their own reviews and many sites actively encourage these, primarily so that they can be read by other customers before making a purchase.

While the use of testimonials may be acceptable under certain regulatory frameworks, testimonials which make a medical claim or imply a medical purpose, form part of a product's presentational material. They should not be used as a means to make medicinal claims that would not be permitted elsewhere. Two hypothetical examples are:

Product 1 (food supplement) for maintaining healthy joints, muscles and bones.

Customer review "*I have been using this product for less than a month and am now pain free*".

Product 2 (Cosmetic) for skin moisturising.

Customer review "*This product is wonderful. I have suffered from psoriasis for years and now it has gone*".

The publication of these reviews is likely to bring the products within the definition of a medicine if they remain in the public domain. The MHRA appreciates that third party input is potentially challenging for companies to control but, nonetheless, recommends that measures are instigated to ensure that such testimonies are regularly and effectively policed. Where there are reviews

² <https://www.gov.uk/government/publications/blue-guide-advertising-and-promoting-medicines>

which make medicinal, or implied medicinal claims, these should be removed from public view as soon as possible.

If it is not going to be possible to quickly remove or discourage such reviews, you may need to consider withdrawal of the customer review facility. Use of a product rating system – such as 1 – 5 stars would not be considered as a breach of the Regulations and would be acceptable.

Sale of authorised medicinal products

Authorised medicinal products may only be sold from either registered on-line pharmacies, or, if they are “General Sales List (GSL) products (non-pharmacy), by companies displaying the Common EU Logo <https://www.gov.uk/guidance/register-for-the-eu-common-logo> .

Authorised medicinal products may only be promoted for their licenced indications (refer to MHRA Blue Guide, above) and uses described in their licence particulars.

Provision of generic information which is not regarded to be a medicinal claim

The searching of generic information about ingredients should be a voluntary action and not encouraged by a company to sell specific products.

You may however, be able to offer consumers details of, or a link to, a separate and un-associated website that provides information about a range of ingredients and their uses, provided that there are no references to any specific products. Only one reference/link to the information site should be provided and should be positioned on a page that does not display any of the products being sold from your website, and it should not imply any association with products being sold on your website or have a purchase facility on the same page. The following wording (or similar) could be used “Information on [*e.g. Herbs/Vitamins*] and their uses can be found here”.

You should bear in mind that the information provided on a separate website may be referred to by MHRA as part of its evidence in the determination process, in particular if it includes or implies details of medicinal uses for a product being sold by you.

The MHRA would expect the generic information provided to be about ingredients and not diseases/adverse medical conditions.

Information which is intended solely for Health Care Professionals

The use of ‘pop-ups’ or pages targeted at health care professional is not encouraged. If companies wish to use them, they must ensure that:

- The pages cannot be viewed by ordinary members of the public.
- None of the information contained within Health Care Professionals Only sites or pages make, or infer, a medical purpose for the products in question.

Use of social media sites

The Borderline Section does not envisage the need for separate rules for use of social media sites. If you are advertising and selling products through one of these platforms, you need to comply with the same requirements as for websites described above.

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Last Amended March 2019
Medicines Borderline Section

GUIDANCE TO DISTINGUISH PRODUCTS FROM LICENSED MEDICINES

Introduction

The purpose of this document is to provide guidance to ensure that products are presented in a manner which ensures the purpose and classification of products are clear to consumers and retailers.

MHRA recognises that an overlap between cosmetics, food supplements, biocides and medicines can, on occasion, exist. This guidance is therefore applicable to the retail sale of non-medicines such as food supplements, cosmetics and biocides, but particular emphasis is given to the sale of food supplements.

The Regulations

In the UK, as in the rest of the EU, medicinal products which are placed on the market are required to have marketing authorisations (formerly product licences) in accordance with Council Directive 2001/83/EEC (the **Directive**). The Directive is implemented in the UK by the Human Medicines Regulations 2012 (S.I. 2012/1916) (the **Regulations**). Amongst other things these provide that, unless exempt, no medicinal product shall be placed on the market unless an appropriate authorisation has been granted by the licensing authority or the European Commission.

It is an offence to sell, supply or advertise an unauthorised medicinal product.

A "medicinal product" is defined in Article 1 of the Directive, which is reflected in Regulation 2 of the Regulations. The definition has two limbs, as follows:

"Any substance or combination of substances presented as having properties for treating or preventing disease in human beings" (the First 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 Limb).

If a product falls under either of these limbs it may be classed as a medicinal product and in broad terms, when classifying a product, MHRA looks at:

- the way it is presented (claims, advertising etc); and
- its actual or perceived function, that is, its effects (when administered) on human physiology.

Products should be presented/ marketed in accordance with the guidance set out below, so that they do not give consumers the impression that they are in fact medicinal products. If they are presented/ marketed as medicinal products, then they may fall under the first Limb of the definition of a medicinal product. For the avoidance of doubt, this includes any testimonies that are included on websites or any other promotional materials.

Where products are potentially capable of restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, then they may in fact be medicinal products under the Second Limb. It is important to note that even where products could potentially fall within the scope of another regulatory framework (such as that relating to food supplements), where they also meet the definition of a medicinal product under medicines legislation, then the latter will apply (see Article 2(2) of the Directive).

Examples of claims which may bring product within the First Limb of the Definition³

- Direct claims to treat or prevent an adverse medical condition or its symptoms.
- Direct claims to correct or restore deficient nutrient levels in humans or to treat or prevent associated adverse conditions.
- References to adverse medical conditions.
- Duplication and publication of generic information (including media reports) relating to adverse medical conditions.
- References to medical or professional recommendations.
- Publication of testimonials which refer to treatment or prevention of adverse medical conditions.
- References to possible medicinal uses of individual product ingredients.
- Comparison to licensed medicines.
- Use of product names which refer to or imply adverse medical conditions.
- References to medical and / or clinical research and testing.
- Graphics that imply medicinal uses.
- Promotion to doctors, pharmacies, health authorities implying use as alternatives to licensed medicinal products.
- References to potential harm or ill-health by not using a product.

Guidance Note 8 also summarises the regulatory requirements for foods, cosmetics, biocides, and aromatherapy products in the context of borderline products. MHRA would recommend that you are fully conversant with the relevant regulatory framework for your product.

Measures to avoid the marketing of non-medicines as medicinal products

In order to fall outside the First Limb of the definition of a medicinal product the overall impression given to the consumer must be that the product they are purchasing is not a for a medical purpose and this can be achieved by a number of relatively simple measures.

Packaging

The packaging and labelling of any product should have an appearance which is distinct from a typical licensed medicinal product, particularly prescription only medicines which have plain packaging with limited use of colour. Products can be made more distinct by the use of bright colours and suitable graphics that are not associated with medicinal products.

The description "Food Supplement" should be clearly shown on the labelling etc.

In the vast majority of scenarios, the use of an approved nutrition or health claim⁴ on food supplements would not be regarded to be a medicinal claim and MHRA would regard the use of approved health claims to be a factor that can be used to distinguish the regulatory status of products.

Conversely, when considering the overall presentation of a product, the absence of an approved health claim (where one is available) on a product where other aspects of the packaging seem closer to medicinal in appearance, may be a factor which could be questioned by MHRA when advising on status of a borderline product.

³See also Appendix 1 of Guidance Note 8

⁴ A nutrition or health claim must now be authorised before use in the EU. The European Commission has established a register which records those claims that are authorised and also those that are not authorised
http://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=register.home

Wording

MHRA is of the view that non-medicines including food supplements should not refer to consumers as “patients” and/or make reference to nutritional deficiencies. Use of wording such as “or as directed by your healthcare professional” on the product packaging or any advertising material, can also imply the product is to be used for a medical purpose and is discouraged.

Accompanying leaflets or product inserts must never be described as “Patient Information Leaflets” and the terms “indications” and “contraindications” should not be used as these are associated with medicinal products.

Graphics

These should portray either a neutral or positive message. Pictures of healthy looking people can help to enforce a positive impression. Negative images such as depictions of people looking unwell, or showing apparent areas of pain or inflammation may create an impression that products are medicinal and should not be used. Images displaying “medical crosses” or any other symbols commonly associated with pharmacies and medical treatment also should not be used.

Sale in store or on websites

The positioning of the product in store or on websites can influence classification. MHRA would expect non-medicines to be separated from licensed medicinal products and sit in a category that does not refer to adverse medical conditions. Companies should ensure that this is the case for their stores and websites and look to advise third party retailers as appropriate for example by reference to this Appendix and/or Guidance Note 8.

Product Name

The product name should not imply that it is to be used for a medical purpose. If reference is made, either in the product name or in the ingredient listing to a pharmacopeia monograph e.g. contains ascorbic acid BP. the overall packaging should be clear that the intended purpose is not medicinal. This is because a pharmacopeia is associated with medicines and products containing such references could be mistakenly regarded to be medicines.

Sale in pharmacies

Given the clear role, and perception, of pharmacies in the sale and supply of medicinal products, including on prescription, it is particularly important that the purpose of non-medicines sold on pharmacy premises and websites should be both clear and distinct from the medicinal products that they sell or dispense. The EU directive which sets out the definition of a food supplement makes it clear that they are intended to supplement the normal diet⁵ and should be marketed accordingly. Where food supplements or other non-medicines are intended for, and by extension, advertised or promoted for supply by pharmacies only these should not be promoted, including by inference, as alternatives to licensed or unlicensed medicinal products⁶. This also applies to advice given by sales representatives in relation to cost effectiveness. Such promotion could result in products being classified as medicinal products.

Where the intention is to treat an underlying medical condition, MHRA’s view is that licensed medicinal products which meet patient need, should always be the first-choice supply if available¹¹.

⁵ EU Directive 2002/46/EC; Recitals 2 and 3 and Article 2

⁶ Guidance Note 14

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products_specials.pdf

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Last Amended March 2019
Medicines Borderline Section

GUIDANCE ON CANNABIDIOL (CBD) PRODUCTS

Introduction

In 2016 MHRA published an opinion that products containing CBD, when used for a *medical purpose*, should be regulated as medicinal products⁷.

The MHRA's opinion was issued with the intention of seeking voluntary compliance by companies supplying CBD for *medical purposes*.

This guidance has been published in response to a significant number of requests for regulatory advice regarding the sale of CBD products for *non-medical purposes* and is intended to supplement MHRA's published opinion.

The Regulations

In the UK, as in the rest of the EU, medicinal products which are placed on the market, are required to have marketing authorisations in accordance with The Human Medicines Regulations 2012 (S.I. 2012/1916) (the **Regulations**). 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 EU law 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 Directive 2001/83/EC, which is implemented by Regulation 2 of the Regulations. The definition, which is in two 'limbs' is:

"Any substance or combination of substances presented as having properties for treating or preventing disease in human beings (Limb 1).

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 (Limb 2)".

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 function, that is, its effects (when administered) on human physiology.

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

Where unauthorised products are marketed for a medical purpose MHRA will take appropriate action to achieve compliance. Where necessary, MHRA can use the statutory determination process described in Appendix 3 of this Guidance to formally classify a particular product.

Any product that makes a medicinal claim would fall within Limb 1 of the definition. For the avoidance of doubt, this includes any testimonies that are included on websites or any other promotional material. Further guidance in relation to medicinal claims can be found in Appendices 1, 8 and 9 of this guidance.

It is a matter of fact that there have been a number of clinical trials which demonstrate that CBD has a therapeutic effect, particularly in the treatment of severe epilepsy. MHRA's clinical assessors have reviewed relevant scientific and clinical evidence to support the mode of action of CBD in the treatment of a range of medical conditions. It should also be noted that the European Medicines

⁷ <https://www.gov.uk/government/news/mhra-statement-on-products-containing-cannabidiol-cbd>

Agency has given CBD products an orphan designation on four occasions, for three different clinical conditions; graft versus host disease, perinatal asphyxia and Dravet syndrome.

Approval was granted on 19/09/2019 under the centralised procedure for Epidyolex, an oral solution containing CBD for use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients from 2 years of age. Clinical studies for Epidyolex indicate a posology starting at 5mg/kg/bw per day titrated by 5mg/kg/bw each week to a maximum of 25mg/kg/bw.

Currently Epidyolex is classified as a Class B, Schedule 2 Drug. However, the Advisory Council on the Misuse of Drugs (ACMD) Technical Committee recently considered the issue of the scheduling for Epidyolex and on 29 January 2020 recommended to the Minister of State for Crime, Policing and the Fire Service, that it would be most appropriate for Epidyolex to be placed in Schedule 5 under the Misuse of Drugs Regulations 2001. The limited quantity of Δ^9 -THC in Epidyolex is stated to have guided the ACMD scheduling recommendation.

CBD products for non-medical purposes

With the emerging evidence of clinical efficacy outlined above MHRA could, in future, regard certain CBD products, which may currently be marketed under other regulatory frameworks, to fall within the second limb of the definition of a medicinal product.

Given this, MHRA can give no assurance that any particular product, including products under development, will not subsequently be classified as a medicinal product. Classification as a medicinal product overrides other regulatory frameworks and it is important that a company considering the marketing of CBD products as a non-medicine should be aware that the regulatory status of their product may change.

Compliance with other regulatory frameworks

MHRA will never advise that a product is 'legal'. This is because our remit is limited to the regulation of medicines and medical devices and any advice given in relation to CBD products will be in respect of classification as a medicinal product. Products which are not deemed to be medicines will be subject to other regulatory frameworks and it is the responsibility of those who manufacture and/or market a product to ensure that it complies with the relevant legislation. MHRA encourage companies to seek advice from the relevant authorities.

Local Authority Trading Standards or Environmental Health Departments can advise on relevant aspects of food law (including food supplements). This may include, but would not be limited to, registration as a food business operator, compliance with food hygiene regulations and products which might be regarded to be novel foods.

On 13/02/2020, the Food Standards Agency issued a press release⁸ and guidance to Local Authority Enforcers regarding their policy on the regulation of foods containing CBD. This was accompanied by a policy announcement highlighting the following key points:

- When consumed as food, CBD extracts, isolates, distillates and other new forms of CBD are novel foods.
- Hemp products, such as cold-pressed oils, are not novel because there is evidence to show a history of consumption before May 1997. This is not the case for CBD extracts.
- None of the CBD products on the market at the moment have completed the novel foods authorisation process.

⁸ <https://www.food.gov.uk/news-alerts/news/food-standards-agency-sets-deadline-for-the-cbd-industry-and-provides-safety-advice-to-consumers>

- FSA are moving to regulate the CBD industry by giving businesses until March 2021 to submit valid novel foods authorisation applications. After 31 March next year, only products which have submitted a valid application will be allowed to remain on the market.
- FSA are also advising consumers to think carefully before taking CBD products as they do not know as much as they would like about these products.
- For healthy adults FSA are recommending they consume no more than 70mg a day, which is about 28 drops of 5% CBD, unless a doctor agrees. This follows advice from the UK Committee on Toxicity.
- FSA are recommending that vulnerable groups, including those who are pregnant, breastfeeding, or taking any medications do not consume CBD.

Products containing CBD that are intended to be placed in contact with the external parts of the human body with a view exclusively or mainly to fulfil a cosmetic function as per article 2 of the Cosmetic Products Regulation (EC) 1223/2009⁹ must meet the regulatory requirements set out by this Regulation. Regulation (EC)1223/2009 ensures the safety of cosmetic products, their cosmetics ingredients (irrespective of their source) and protect consumers from misleading claims.

MHRA is occasionally asked whether claims can be made for CBD in respect of the endocannabinoid system. The endocannabinoid system is a neuromodulator system that has a role in central nervous system development and in regulating a variety of physiological and cognitive processes.

Claims which imply that CBD can modify, stimulate or enhance the endocannabinoid system (or similar) may in context, be regarded to be medicinal claims. Where claims are not regarded to be medicinal claims, companies are advised to be mindful of health claims legislation which applies to foods (Regulation (EC) 1924/2006¹⁰) and/or check with Trading Standards or Environmental Health to see whether they can be used without prior approval.

Companies should be mindful that if products contain detectable levels of other cannabinoids such as THC, including at very low levels, these may be regarded to be controlled substances. The Home Office has issued a factsheet, called 'Cannabis, CBD and other cannabinoids' which sets out the Exempted Product Definition and how these products should be regulated. This can be accessed at the following website:

<https://www.gov.uk/guidance/controlled-drugs-licences-fees-and-returns>

CBD products for medical purposes

In the absence of any licensed CBD medicinal products, MHRA would advise individuals with underlying medical conditions who are using CBD to discuss this with their doctor who may prescribe medicinal products to appropriately manage the symptoms. Companies wishing to supply CBD products for a medical purpose should consider the following:

(i) Supply of an unlicensed medicine (a 'Special')

A medicine is generally required to have a marketing authorisation (product licence) before being placed on the market. However, unlicensed medicinal products containing CBD could be made available to individuals on prescription, but this supply is subject to certain conditions. An unlicensed medicine can only be supplied to meet the special needs of an individual patient. Responsibility for deciding whether an individual patient has "special needs" (interpreted as clinical needs) which a licensed product cannot meet should be a matter for the prescriber responsible for

⁹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009R1223-20160812&from=EN>

¹⁰ <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A02006R1924-20121129>

the patient's care. An unlicensed medicine may not be advertised; a manufacturer, importer or wholesaler may provide factual responses related to the supply of products, but these cannot include medicinal claims. See MHRA Guidance Note 14 for further information regarding the sale and supply of unlicensed medicines.

<https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials>

(ii) Obtaining a licence to supply a licensed medicine

For general information on licensing applications, please refer to:

www.gov.uk/medicines-medical-devices-blood/marketing-authorisations-variations-licensing;
<https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk>.

Our Regulatory Information Service can also advise on how to submit new licence applications on Tel: 020 3080 7400 or via email at RIS.NA@mhra.gov.uk

Where CBD is being considered for a clinical trial in humans (an MHRA responsibility) the material will need to be manufactured or imported by the holder of the appropriate manufacturer's authorisation for an investigational medicinal product, [known as an MIA(IMP)] and have a clinical trial authorisation (CTA). These links may be helpful:

www.gov.uk/government/collections/clinical-trials-for-medicines
www.gov.uk/guidance/medicines-get-scientific-advice-from-mhra

Summary

This guidance sets out MHRA's current position in respect of the classification of CBD products. It also briefly covers the supply of CBD products as medicines. Companies need to be mindful of MHRA's remit and ensure that they have obtained advice from all relevant regulators prior to placing products on the market.

Still not sure how your product will be classified?

MHRA cannot provide bespoke advice to companies seeking detailed advice about the sale and marketing of products and companies, however, if you need further advice about the status of your product which is not covered in this document you can seek an opinion by emailing borderline_medicine@mhra.gov.uk .

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Medicines Borderline Section

Faecal Microbiota Transplantation (FMT)

MHRA's position

When classifying a product, the Agency looks at the way the product is presented (especially any claims) and at its function, that is, its effects (when administered) on human physiology. This is in line with the definition of a medicinal product that is set out in Article 1 of Directive 2001/83/EC as *amended* and Regulation 2 of S.I 2012/1916 (The Human Medicines Regulations) and defines a “medicinal product” as:

“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”.

The MHRA is aware of the recent guidance issued by the National Institute for Health and Care Excellence (NICE) in March 2014, regarding the use of FMT to treat for recurrent *Clostridium difficile* infection. This guidance also considered the efficacy outcomes, based on published literature and concluded that the current evidence of the efficacy and safety of FMT for *C. difficile* infection is adequate to support the use of this procedure. NICE suggest that the process for introducing the resulting suspension into the recipient's gut is carried out via a nasogastric tube, nasoduodenal tube, rectal enema or via the biopsy channel of a colonoscopy.

Given this, and based both on the purpose (limb one of the definition) of FMT and the efficacy outcomes (limb two of the definition) which are detailed in NICE's report, the MHRA is of the view that FMT falls within the definition of a medicinal product.

If the FMT product is subject to a level processing which would be regarded to be ‘industrially produced’, either by virtue of the batch sizes, the extent of processing and/or whether potential use includes supply between legal entities, these are factors relevant to how it is regulated as medicine.

The Medicines Directive 2001/83 applies to medicinal products for human use intended to be placed on the market in Member States and either *prepared industrially* or manufactured by a method involving an *industrial process* (Article 2.1). Products that are not so produced are not subject to the requirements of the Medicines Directive.

Prepared in a pharmacy

The Medicines Directive 2001/83 shall not apply to medicinal products prepared in a pharmacy in accordance with a medical prescription for an individual patient (commonly known as the magistral formula), or to any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question (commonly known as the officinal formula), or to medicinal products intended for research and development trials, but without prejudice to the provisions of Directive 2001/20/EC regarding clinical trials on medicinal products for human use (further to Article 3).

Special Need

Further to Article 5(1) of the Medicines Directive 2001/83, to fulfil special needs, the provisions of this Directive can be excluded where medicinal products are supplied in response to a *bona fide*

unsolicited order, formulated in accordance with the specifications of an authorised health-care professional and for use by an individual patient under his direct personal responsibility.

Further advice on the sale and manufacture of unlicensed medicinal products ('Specials') can be found in MHRA's Guidance Note 14.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products_specials.pdf

Where none of the above exemptions apply, a Marketing Authorisation or equivalent is required for medicines in order for them to be lawfully placed on the market in the UK.

The following information can be found on the website www.gov.uk:

- (a) How to obtain a marketing authorisation - <https://www.gov.uk/apply-for-a-licence-to-market-a-medicine-in-the-uk>
- (b) Clinical trials for medicines: apply for authorisation in the UK - <https://www.gov.uk/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk>
- (c) How to obtain a manufacturer's licence for investigational medicinal products - <https://www.gov.uk/apply-for-manufacturer-or-wholesaler-of-medicines-licences>

If you have any regulatory queries regarding licensing please contact our service desk on 020 3080 7400, or alternatively you can e-mail your enquiry to ris.na@mhra.gov.uk.

For enquires relating to good manufacturing practices please email gmpinspectorate@mhra.gov.uk

Further advice

Establishments seeking to, or are currently performing, FMT should contact the MHRA Medicines Borderline Section for further advice or clarification. Where appropriate please fill in our advice request form.

borderline_medicine@mhra.gov.uk

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