Medicines & Healthcare products
Regulatory Agency

MHRA Guidance Note 8

A guide to what is a medicinal product

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MHRA

10 South Colonnade

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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 Human Medicines Regulations 2012 [SI 2012/1916] ("the Regulations"). 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 Leads in the MHRA's Borderlines Section. If a Lead does decide that a product is a medicinal product, then unless an exemption applies, it will be subject to the Regulations.

A person or company marketing a product has a responsibility to do so in accordance with the law. The Regulations provide that, unless exempt, 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 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' may not be immediately obvious.

This Guidance explains how, and on what basis, the MHRA decides whether products are medicines or otherwise and clarifies the MHRA's position on traditional herbal medicinal products.

2. MHRA policy and practice

The MHRA is required to classify products on a case-by-case basis. If a final determination is issued by the Borderlines Section it will provide brief details of the determination for the product at the time it was investigated and, where relevant, refer to the product ingredients. Final determinations are available on the borderline products page on the MHRA website:

https://www.gov.uk/guidance/borderline-products-how-to-tell-if-your-product-is-a-medicine

Further information regarding the statutory determination procedure can found in Appendix 4.

Where medicinal claims are 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 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.

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 UK and European Court of Justice (ECJ) Court precedents.

When considering the 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 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.

4. What is a medicinal product?

Definition

Regulation 2 of The Human Medicines 2012 defines a "medicinal product" as:

> *"Any substance or combination of substances presented as having properties for*

treating or preventing disease in human beings; ['limb one'/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" ['limb two'/functional limb]

Medicinal products may well fall under both limbs of the definition but falling under either limb is sufficient to classify a product as a medicinal product.

Meaning of Disease

Regulation 8 of the Regulations defines "disease" as including "… *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 including colds, headaches, cuts and bruises, smoking addiction, obesity, arthritis, depression, stress and all childhood disorders and serious diseases.
- references to conditions of the mind such as depression, addictions, attention deficit hyperactivity disorder (ADHD).
- 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 activities which are designed to promote the prescription, supply, sale or use of medicines by the general public.

Regulation 279 of the Regulations states:

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

(a) a UKMA(GB) or UKMA(UK)

(aa) an authorisation by the licensing authority on a temporary basis under regulation 174

(b) a COR(GB) or COR(UK) or

(c) a THR(GB) or THR(UK).

In Northern Ireland there may be an additional requirement for an Article 126a authorisation granted under Part 8 of the Regulations.

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

- references to medical conditions
- comparison with licensed medicines
- references to effects upon 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 '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 10.

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

What factors does MHRA take into account when determining a product under limb one?

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. 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, linked publications, or in social media. 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 MHRA take into account when determining a product under limb two?

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 today in determining whether a product falls within the second limb of the definition are primarily based on the following ECJ Judgements:

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

"…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):

"… 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):

"... 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 will consider a number of factors including the following:

- 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, 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 ECJ 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. The Judgment states:

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

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

8. Is my product a herbal medicinal product?

There are many herbs with known medicinal uses and at the same time uses as either foods or cosmetics. When considering the status of a herb that does have various uses the Agency will make a 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.

Medicinal products containing herbal preparation(s) are subject to the provisions of Part 7 of the Regulations. Herbal medicinal products must either be granted a Marketing Authorisation (Regulation 49) or a Traditional Herbal Registration (Regulation 125) before they can be marketed in the UK.

Marketing Authorisations and Traditional Herbal Registrations cover finished herbal medicinal products, and the herbal preparation(s) included, and their manufacturer(s), quality control and batch release site(s).

Marketing Authorisation

Applications for a Marketing Authorisation for a herbal medicinal product need to be supported by a dossier providing quality, safety and efficacy data. Further information and guidance can be obtained from the MHRA website:

https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk

Traditional Herbal Registration Scheme

The Traditional Herbal Registration (THR) Scheme requires a herbal medicinal product to meet specific and appropriate standards of safety and quality and for the product to be accompanied by the necessary information for the product to be used safely.

The requirement to demonstrate efficacy of the product is replaced by a requirement to demonstrate traditional use. In order to obtain a Traditional Herbal Registration under the scheme, it is necessary to prepare and submit a registration dossier.

Registrations under the scheme are restricted to herbal medicinal products which are intended for the relief of minor conditions/symptoms that do not require the supervision of a medical practitioner. Herbal medicinal products indicated for the relief or treatment of serious conditions would require a Marketing Authorisation.

Further information and guidance can be obtained from the MHRA website:

https://www.gov.uk/guidance/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 Regulation 8 of the Regulations.

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 MHRA website:

https://www.gov.uk/guidance/register-a-homeopathic-medicine-or-remedy

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. When used in relation to a disease, illness or specific adverse condition, products marketed with claims including words and phrases such as these will be considered as presented for the treatment or prevention of disease and may be classified as medicines accordingly.

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

Claims to "maintain" or "help to maintain", "dietary maintenance", or "support" health or a healthy lifestyle, can be approved under food law, and MHRA 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, and keeping the skin in good condition. Article 20(1) of UK Retained 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 medicinal claims:

- While toothpastes which are designed to be used without exacerbating sensitivity are cosmetics, 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. Classification of toothpastes as cosmetics, medicinal products or medical devices is dependent on the product's composition, mode of action and presentation. Guidance on the classification of toothpaste claims is available from 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:

https://www.ctpa.org.uk/news/new-ctpa-guide-on-common-understanding-of-borderline-toothpaste-claims-4093

- Eczema, dermatitis and psoriasis are adverse medical conditions which can be exhibited by dry, inflamed, scaly and itchy skin, and products intended to protect from or prevent these conditions are either medicinal products or medical devices depending on their mode of action. However, MHRA has 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 wording "***Also suitable for people who may be prone to eczema / psoriasis / dermatitis /rosacea / acne / spots***" can be used. This wording should be present for advisory purposes only and should not be used in a manner which could imply, either explicitly or implicitly, that a product 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 and claims to protect against it are unacceptable if, in context, they amount to claims to prevent the condition.

- Shampoos may be cosmetics or medicines, depending on the constituents and the claims being made. Those mainly intended for hygiene, or that are 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 adverse medical conditions. However, depending on a product's presentation, claims that it is intended to be used solely to conceal spots or acne may mean that it can be regarded to be a cosmetic product. The cosmetic function must be made clear and any explicit or implicit claims related to the treatment or prevention of spots or acne, or any other adverse condition, must not be used.

  The EC *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 (clogged pores) that form on the skin as a result of the skin's normal functions such as cell renewal, shedding and sebum production. They are transient conditions of the skin and may present as blackheads or whiteheads. MHRA does not regard blackheads to be an adverse medical condition. Acne is adverse medical condition that is 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 to protect the face from spots through a cleansing action may fulfil 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. However, any claims to treat or prevent spots by pharmacological, immunological or metabolic means by having anti-inflammatory, anti-infective, or sebum production controlling effects will be considered medicinal claims.

Claims made for cosmetic products should be in relation to cleaning, protecting, or keeping the skin in good condition. Cosmetic products may claim to be **'also suitable for people who may be prone to acne/spots'** provided that the impression is not given, explicitly or implicitly, that they can be used for the prevention or treatment of acne or other adverse skin conditions.

https://ec.europa.eu/docsroom/documents/29002

Food claims

The UK Food Information Regulations 2014 came into force on the 14 July 2014 and enables local authorities to enforce assimilated Regulation (EU) 1169/2011 on food information to consumers (FIC Regulations). It 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 be authorised before use in the UK. The Great Britain nutrition and health claims (NHC) register sets out all authorised and rejected nutrition and health claims. Only authorised claims in the Great Britain NHC register may be used in Great Britain. The annex to the Great Britain NHC register lists health claims authorised on the basis of proprietary (privately owned) data:

https://www.gov.uk/government/publications/great-britain-nutrition-and-health-claims-nhc-register

These Regulations apply to claims made in commercial communications about foods, and it is the Department of Health and Social Care's (DHSC) opinion that they 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.

MHRA is aware that on occasions companies may use these communications to provide the trade or healthcare professionals with evidence of their products being used for a medical purpose. Such communications will 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 which fall under other regulatory areas. Compliance with regulations covering products which are not medicines 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 intended purpose of the product taking into account the way the product is presented, and the method by which the principal intended action is achieved, must be taken into consideration.

The principal 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://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948871/Borderlines_between_medical_devices_and_medicinal_products.pdf

https://health.ec.europa.eu/system/files/2020-08/md_borderline_manual_05_2019_en_0.pdf

Cosmetics

All cosmetic products placed on the market in Great Britain (England, Wales and Scotland) must comply with Schedule 34 of the Product Safety and Metrology Statutory Instrument consolidated legal text UK Retained Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (the UK Cosmetics Regulation). Products placed on the market in Northern Ireland must comply with Regulation EC 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (hereafter 'the EU Cosmetic Products Regulation' or EU CPR).

Article 2(1)(a) of the UK Retained 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 a product on the borderline between cosmetics and medicines is a medicinal product, the MHRA will apply the tests set out in The Human Medicines Regulations 2012.

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 medicinal products. As essential oils have no accepted nutritional benefit, they would not normally be considered 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-details/html/2801/

General Product Safety Regulation 2005:

https://www.legislation.gov.uk/uksi/2005/1803/contents/made

Cosmetic Borderline:

https://single-market-economy.ec.europa.eu/sectors/cosmetics/cosmetic-products-specific-topics/borderline-products_en

UK Retained Regulation (EC) 1223/2009 on cosmetic products:

https://www.legislation.gov.uk/eur/2009/1223/introduction

Biocides

In the UK biocidal products are controlled under the GB Biocidal Products Regulation (GB 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 GB BPR lies with the Health and Safety Executive (HSE). The GB BPR covers a wide range of 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 GB 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 GB 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 GB BPR and the medicines legislation. Further information regarding topical skin disinfection products can be found in Appendix 6.

Further information regarding biocides can be obtained from the HSE website:

https://www.hse.gov.uk/biocides/index.htm

General Product Safety Regulations

The General Product Safety Regulations 2005 (GPSR) are administered and enforced by Trading Standards Authorities and Environmental Health Officers. The GPSR requires all products to be safe in their normal or reasonably foreseeable usage. Enforcement authorities have powers to take appropriate action when this obligation is not met. From 13 December 2024 Regulation (EU) 2023/988 on general product safety applies in Northern Ireland.

Food including food supplements

Assimilated 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 Directives 65/65/EEC and 92/73/EEC.

The Food Supplements (England) Regulations 2003 defines a food supplement as any food the purpose of which is to supplement the normal diet and which:

a) is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination; and

b) is sold in dose form

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 or UK prior to 15 May 1997 may be regarded to be novel foods and subject to Regulation (EU) 2015/2283. 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 novelfoods@food.gov.uk

Advice on food supplements should be sought from the Department of Health (address provided in Appendix 2) in the first instance: dhsc.publicenquiries@dhsc.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 Regulations. 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.

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:

https://www.gov.uk/government/organisations/home-office

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).

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/world-anti-doping-code-and-international-standards/prohibited-list

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

14. 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 under the sub-heading 'Getting advice about your product' at:

https://www.gov.uk/guidance/borderline-products-how-to-tell-if-your-product-is-a-medicine

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.

APPENDIX 1

WORDS AND PHRASES

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

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

WORDS & PHRASES	WHAT THESE MAY SUGGEST OR IMPLY ABOUT A PRODUCT
"Alleviates"	In context, may suggest a claim to treat disease by reducing, ameliorating or correcting disease or an adverse condition.
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"	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 a disease or an adverse condition.

“Protects against...”	In context, a claim to prevent a specific disease or an adverse condition.
“Relieves/relief”	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 precancerous 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.

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APPENDIX 2
USEFUL ADDRESSES

The Advertising Standards Authority Ltd (ASA)
Castle House
37-45 Paul Street
London
EC2A 4LS

Tel: 020 7492 2222
Fax: 020 7242 3696
E-mail: enquiries@cap.org.uk

Aromatherapy Trade Council (ATC)
PO Box 219
Market Rasen
LN8 9BR

Tel: 01673 844672
E-mail: info@a-t-c.org.uk

Association of British HealthTech Industries (ABHI)
Suite 2, 4th Floor,
1 Duchess St
London
W1W 6AN

Email: enquiries@abhi.org.uk

Association of British Pharmaceutical Industry (ABPI)
2nd Floor Goldings House
Hay's Galleria
2 Hay's Lane
London
SE1 2HB

British Herbal Medicine Association (BHMA)
PO Box 583
Exeter
EX1 9GX

Tel: 0845 680 1134
E-mail: secretary@bhma.info

Cannabis Trade Association
41 Wincolmlee,
Hull
Yorkshire
HU2 8AG

Clearcast Ltd
3rd Floor
4 Roger Street
London
WC1N 2JX

Tel: 020 7339 4700
Email: help@clearcast.co.uk

Committee of Advertising Practice (CAP)
Castle House
37-45 Paul Street
London
EC2A 4LS

Tel: 020 7492 2200
Fax: 020 7242 3404
E-mail: advice@cap.org.uk

Cosmetics, Toiletry & Perfumery Association Limited (CTPA)
Sackville House

49 Whitehall
LONDON SW1A 2BX

Tel: 020 7491 8891
Fax: 020 7493 8061

Council for Responsible Nutrition UK
1110 Elliott Court
Coventry Business Park
Herald Avenue
Coventry
CV5 6UB

Tel: 020 7078 3997
E-mail: crnsecretariat@crnuk.org

Department for Business and Trade
Old Admiralty Building

Admiralty Place
London
SW1A 2DY

Tel: 020 4551 0011
Email: enquiries@beis.gov.uk

Department of Health and Social Care
39 Victoria Street
London
SW1H 0EU

Tel: 020 7210 4850

Department for Science, Innovation and Technology
100 Parliament Street
London
SW1A 2BQ

Email: correspondence@dsit.gov.uk

European Specialist Sports Nutrition Alliance (ESSNA)
10 Polperro Mews
London
SE11 4TY

Food Standards Agency
Floors 6 and 7
Clive House
70 Petty France
London
SW1H 9EX

Tel: 0330 332 7149
Fax: 020 7276 8833

Health and Safety Executive
Redgrave Court
Merton Road
Bootle
Merseyside
L20 7HS

Email: biocidesenquiries@hse.gov.uk

Health Food Manufacturers' Association (HFMA)

1 Wolsey Road

East Molesey

Surrey

KT8 9EL

Tel: 020 8481 7100

Email: hfma@hfma.co.uk

The Organisation for Professionals in Regulatory Affairs (TOPRA)

6th Floor
3 Harbour Exchange
London

E14 9GE

Tel: 020 7510 2560

Email: info@topra.org

Proprietary Association of Great Britain (PAGB)

New Penderel House

283-288 High Holborn

London

WC1 7HP

Tel: 020 7242 8331

E-mail: info@pagb.co.uk

Radiocentre

15 Alfred Place
London

WC1E 7EB

Tel: 020 7010 0608

Email: clearance@radiocentre.org

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MHRA Borderlines Section

APPENDIX 3

A SUMMARY OF CASE LAW 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 cases.

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

Date of Judgment of the Court – 30 April 2009

This judgment referred 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 Court ruled that a product which includes a substance which has a physiological effect is not a medicinal product by function where it constitutes a risk to health without being capable of restoring, correcting or modifying physiological functions.

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

Date of Judgment of the Court – 5 March 2009

This judgment referred 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 Court ruled that an administrative practice adopted by the Spanish Medicines Agency of withdrawing herbal products lawfully produced and sold in another Member State from the Spanish market on the grounds that they contained herbs that were not included on a national register was unlawful. The Spanish agency had adopted the administrative practice of classifying any product based on medicinal herbs which was not listed on the register as medicinal by function. The Court stated that regulatory authorities could not rely on a register of herbal substances in order to classify products as medicines. They must scientifically establish that a product can have an effect on physiological functions on a case-by-case basis before classifying it as a medicinal product.

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

Date of Judgment of the Court – 15 January 2009

The judgment referred to the concept of ‘medicinal product by function’ and concerned whether a product called ‘Red Rice’ should be classified as a food additive or a medicinal product in Germany. The German authorities had decided that the product, composed of fermented red rice, was a medicinal product because it contained significant levels of monacolin k, a substance which could be found in a number of prescription medicines. They argued that it was a medicinal product because the manufacturer had failed to prove the absence of pharmacological action.

The Court ruled that Directive 2001/83/EC did not apply where it had not been scientifically established that a product was medicinal by function, even if the possibility could not be ruled out. The active substances contained in a product must be taken into account in determining whether it is a medicinal product by function, and this should include consideration of the dosage. Apart from substances or combinations of substances intended for the purpose of making a medical diagnosis, a product could not be regarded to be a medicinal product if it was incapable of appreciably restoring, correcting or modifying physiological function 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

The Court ruled that a garlic extract powder capsule could not be classified as a medicinal product by function as its physiological effects were no more than the effects of a foodstuff containing garlic consumed in a reasonable quantity. The German authorities had classified the product as medicinal without taking into consideration the extent of its therapeutic effects. The Court decided that the product would not have a significant effect on the metabolism and so could not be classified as capable of restoring, correcting or modifying physiological functions. The classification of medicinal products must be restricted to those which have the function of treating or preventing disease, or whose pharmacological properties have been scientifically observed and which are genuinely designed to make a medical diagnosis or restore, correct or modify physiological functions.

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

The Court ruling established that regulatory authorities must proceed on a case-by case basis, taking into account all of the characteristics of the product. In order for it to be classified as a medicine, at least one therapeutic affect must be present, and account must be taken of:

1. The product's composition
2. The product's pharmacological properties, to the extent that they can be established in the present state of scientific knowledge.
3. The manner in which it is used.
4. The extent of its distribution.
5. Its familiarity to consumers.
6. 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 decide whether it may 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 risks associated with the use of the product may be taken into account in determining whether or not a product is a medicinal product, but these are not

decisive and at least one demonstrable ‘therapeutic effect’ must also be present.

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

Date of Judgment of the Court – 16 April 1991

This judgement concerned the marketing of Minoxidil as a cosmetic in the Netherlands by the company Farzoo. The product was identical in its purpose and use to the Upjohn ‘Regaine’ product licensed as a medicine. The Court agreed that natural male baldness (alopecia androgenetica) was not a disease; the question was therefore whether a product which was not intended to cure or prevent any disease could still be classified as a medicinal product on the basis that it was administered with a view to restoring, correcting or modifying physiological function.

The Court considered that the presentational limb was designed to catch not only products having a genuine therapeutic or medical effect but also those which are not sufficiently effective, or which do not have the effect which their presentation might lead to expect. The functional limb was intended to include all products which are intended to restore, correct or modify physiological functions. A substance which had properties for treating or preventing disease in humans within the meaning of the first part of the definition, but which was not presented as such, would fall within the scope of the second part. The Court noted that products which alter physiological functions in the absence of disease, such as contraceptive substances, also fall within the scope of the definition.

The Court ruled that a product which is not intended for treating or preventing disease in humans will nonetheless be a medicinal product if it is administered 'with a view to ... restoring, correcting or modifying physiological functions'. 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, the way in which it is used, the extent to which it is sold, and to consumers' familiarity with it. If a product is a medicinal product, it must 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

The Markus D & G case was significant in that it concluded that products which produce effects that merely modify physiological function, but which do not have any benefit, are not medicines. Specifically, the case referred to substances such as synthetic cannabinoids which are consumed solely to induce a state of intoxication.

The judgment stated that the term 'medicinal product' does not include products which have the effect of modifying physiological functions but have no immediate or long-term beneficial effects on human health, and that a product must have a beneficial effect on human health in order for a product to qualify as a medicinal product. The term ‘medicinal product’ must be interpreted as not covering substances such as synthetic cannabinoids which merely modify

physiological functions with no beneficial effects on human health, either immediately or in the long term, but which are consumed solely to induce a state of intoxication and as such are harmful to human health.

In the absence of any therapeutic benefit substances and mixtures such as synthetic cannabinoids should be excluded from the legal definition of a 'medicinal product'.

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

Date of Judgment of the Court – 3 October 2013

The judgment referred to the right 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 was a vaginal capsule containing live lactobacilli intended to restore balance to bacterial flora in the vagina, called Gynocaps. The Judgment concluded that Member States are not precluded from classifying a product on the basis of its pharmacological, immunological or metabolic effects as a medicinal product, even where another Member State considers that product to be a medical device.

Where there are two similar products containing the same substance and having the same modes of action Member States are not precluded from classifying one as a medicinal product and the other as a medical device. However, 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

The judgment referred to the definition of the term ‘pharmacological action’ within the definition of a medicinal product. The product was a mouthwash solution called ‘PAROEX 0.12%’ which contained 0.12% chlorhexidine.

The Court ruled that for a substance to be regarded as exerting a ‘pharmacological action’ within the meaning of Directive 2001/83, 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

The defendant was charged with unlawfully practising the profession of pharmacist on the ground that he had sold certain products which under the applicable French legislation were regarded as medicinal products. The products were imported from Belgium where they were considered food supplements and cosmetics. The Court was asked for a judgement on several

questions including whether there was a Community definition of the terms 'disease' and 'illness' which prevented a product from being classified as food in one Member State and as a medicine in another, and whether a Member State was allowed to limit the import and marketing of products extracted from a commonly consumed plant simply because the external form of the products was typical of a medicinal product.

The judgment concerned the concepts of illness or disease and medicinal products and the marketing of various products in France. The Court ruled that a product presented as being intended to facilitate certain physiological functions falls within the scope of the Community definition of medicinal product. 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 a product is classified as a foodstuff in one Member State does not preclude its being treated as a medicinal product in another state if it possesses the relevant characteristics. It is for the national authorities to determine whether, taking into account 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 constitutes a medicinal product.

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.

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 with possession, for the purpose of supply in Amsterdam, a large quantity of packed and unregulated proprietary medicinal products or medicinal products including vitamin and multi-vitamin tablets, pills and capsules. The dealer denied they were medicinal products.

The Court ruled that:

1. Substances which are not "indicated or recommended" as being suitable for curing, treating or preventing an infection, may none the less constitute substances "presented for treating or preventing disease inhuman beings or animals" within the meaning of the Community definition of a "medicinal product".

2. A product which falls neither under the first nor the second part of the Community

definition of a "medicinal product" cannot be considered a medicinal product within the meaning of the definition.

3. The classification of a vitamin as a medicinal product within the meaning of the functional part of the definition in the Directive must be carried out case-by-case, having regard to the pharmacological properties of each product, 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 be regarded as medicinal products within the meaning of the Directive, but are not covered by the legislation on medicinal products of one or more Member States, or, 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, was 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.

The 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, the ruling meant that MHRA was able to make a determination regarding the classification of a product where they do not agree to the manufacturers' determination that it is a medical device, even where this determination had been accepted in another Member State.

The Commission confirmed that tooth whitening products placed on the market for the principal purpose of lightning discoloured teeth, whether or not they contain peroxide and regardless of concentration, could not be considered as medical devices since they did 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.

Amended September 2025

MHRA Borderlines Section

APPENDIX 4

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.

Background

The MHRA frequently finds that an 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.

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 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 Regulation 2 of The Human Medicines Regulations 2012. 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 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 among 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

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 relevant page on the MHRA website:

https://www.gov.uk/guidance/borderline-products-how-to-tell-if-your-product-is-a-medicine

APPENDIX 5

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, medicinal products which are placed on the market are required to have marketing authorisations in accordance with The Human Medicines Regulations 2012. Among other things these regulations provide that, unless exempt, no medicinal product shall be placed on the market unless an appropriate authorisation has been granted by the licensing authority.

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 Regulation 2 of The Human Medicines Regulations 2012. The definition is in two 'limbs:

"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: “….any injury, ailment or adverse condition, whether of body or mind”.

Addictions

All forms of addiction are regarded as adverse medical conditions (diseases). An addiction is the uncontrollable desire or compulsion to self-administer a substance or to perform an activity (for example obsessive compulsive disorder “OCD”) 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 (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 having 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.

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.

Amended September 2025

MHRA Borderlines Section

APPENDIX 6

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 MHRA 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 some cases, products have been placed directly onto the market without seeking appropriate advice and have subsequently been subject to regulatory action.

MHRA is of the view that while generic antibacterial claims are acceptable for products intended for human hygiene purposes, targeted claims which highlight a specific pathogen or genus of pathogens are medicinal claims.

The Regulations

In the UK, 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). Among 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.

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 Regulation 2 of The Human Medicines Regulations 2012. The definition is in two ‘limbs’:

“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: “…..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 4 of this Guidance to formally classify a particular product.

Any product that makes a medicinal claim will 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, 9 and 10 of this guidance.

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 which are neither medicines nor medical devices do not fall within the remit of the MHRA. They will 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 a specifically named or genus of 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.

For 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 was derived from ECJ case law, and cases 227/82 (van Bennekom); 369/88 (Delattre) and 112/89 (Upjohn) are of particular relevance to the way in which medicines are classified.

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/government/publications/report-a-non-compliant-medical-device-enforcement-process

2 (c) Biocides

Biocidal products are controlled under The GB Biocidal Products Regulation (GB BPR) and the EU Biocidal Products Regulation (EU BPR) in Northern Ireland. The definition of a biocidal product is:

"*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 GB 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 (https://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 20(1) of UK Retained Regulation (EC) 1223/2009 defines a '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. It should be noted that it is not acceptable to make anti-fungal or anti-viral claims as these are normally perceived as being related to a range of specific adverse conditions such as athlete's foot or herpes.

Cosmetics regulations are administered locally by Trading Standards Offices 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 neonates. 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, and they therefore 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 since all other regulations exclude such products from their provisions.

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 MHRA Borderlines 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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Amended September 2025

MHRA Borderlines Section

APPENDIX 7

GUIDANCE NOTE ON HANGOVER PREVENTIVES AND CURES

Introduction

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

The Regulations

In the UK 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). Among 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.

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 Regulation 2 of the Human Medicines Regulations 2012 and consists of two 'limbs':

"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 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: "…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 4 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, 9 and 10 of this guidance.

Background

Every year, particularly in the run up to Christmas, MHRA's Borderlines 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 different regulatory schemes 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 that 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 detoxify the liver or protect against toxic effects of alcohol consumption.

Product presentation

For the purposes of determining product status, the Borderlines Section takes into account everything 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 Borderlines 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 Borderlines 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 Borderlines Section to issue such a Notice, 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 Section 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 Section 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 Borderlines Section.

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.

Amended September 2025

MHRA Borderlines Section

Appendix 8

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 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). Among 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.

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 Regulation 2 of The Human Medicines Regulations 2012. The definition consists of two ‘limbs’:

“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 4 of this Guidance to formally classify a particular product.

Any product that makes a medicinal claim will 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, 9 and 10 of this guidance.

Medical Devices and Accessories

A “medical device” is defined in regulation 2 of the Medical Device Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002). The definition is as follows:

“*Medical device” means an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which—*

(a) is intended by the manufacturer to be used for human beings for the purpose of-

i. diagnosis, prevention, monitoring, treatment or alleviation of disease,

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

iii. investigation, replacement or modification of the anatomy or of a physiological process, or

iv. control of conception; and

(b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is 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 UK MDR including bearing the UKCA 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 UK MDR. 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 GB Biocidal Products Regulation (GB BPR).

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 the MHRA Borderlines Section:
borderline_medicines@mhra.gov.uk

Amended September 2025

MHRA Borderlines Section

APPENDIX 9

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 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). Among 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.

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 Regulation 2 of The Human Medicines Regulations. The definition consists of two ‘limbs’:

“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 Human Medicines Regulations 2012 as: “….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 4 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, 9 and 10 of this guidance.

Medicinal claims

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':

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

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 newspaper articles.
- Use of graphics to display or imply an adverse medical condition, such as images of swollen joints, people displaying signs of stress, images of skin damage, etc. or before and after images 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 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 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 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

From 1 January 2021 Great Britain (England, Wales and Scotland) based online sellers are no longer required to display the EU common logo (in the UK known as the Distance selling Logo) and for Great Britain the MHRA is considering an alternative to the use of the Distance Selling Logo in the future. Further information may be found on the MHRA website:

https://www.gov.uk/guidance/register-for-the-distance-selling-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 unassociated 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, particularly if it includes or implies details of medicinal uses for a product being sold by your company.

The MHRA would expect the generic information provided to be about ingredients and not diseases or 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.

Amended September 2025

MHRA Borderlines Section

APPENDIX 10

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 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). Among 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.

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

A "medicinal product" is defined in Regulation 2 of The Human Medicines Regulations 2012. The definition consists of two ‘limbs’:

“*Any substance or combination of substances presented as having properties for treating or preventing disease in human beings”* (limb one).

“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 two).

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 and 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 or marketed as medicinal products, then they may fall under the limb one

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 limb two. 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 medicines regulations will apply.

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

- 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.

The regulatory requirements for foods, cosmetics, biocides, and aromatherapy products in the context of borderline products have been summarised earlier in this document, and 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 packaging and labelling.

In the vast majority of scenarios, the use of an approved nutrition or health claim 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.

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 such images should not be used. Images displaying “medical crosses” or any other symbols commonly associated with pharmacies and medical treatment should also 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 advise third party retailers as appropriate for example by reference to this Appendix and/or the full document.

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. Food supplements are intended to supplement the normal diet and should be marketed accordingly. Where food supplements or other non-medicines are promoted for supply by pharmacies only it should not be inferred that these are intended as alternatives to licensed or unlicensed medicinal products. 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.

Amended September 2025

MHRA Borderlines Section

APPENDIX 11

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 products. This 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 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). Among 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.

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 Regulation 2 of the Regulations. The definition consists of two 'limbs':

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

2. *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 two).*

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: "…..*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 may use the statutory determination process described in Appendix 4 of this Guidance.

Any product that makes a medicinal claim would fall within limb one 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, 9 and 10 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 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 in September 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.

The Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2020 (Statutory Instrument (SI) 2020 No. 559) places Epidyolex in Schedule 5 of those Regulations, with the effect that it is excepted from the prohibition on importation, exportation and possession under the Misuse of Drugs Act 1971.

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.

In February 2020 the Food Standards Agency issued a press release 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.

- FSA were moving to regulate the CBD industry by giving businesses until March 2021 to submit valid novel foods authorisation applications, after which only products which had submitted a valid application would be allowed to remain on the market.

- FSA advised consumers to think carefully before taking CBD products as they do not know as much as they would like about these products.

- FSA recommended that vulnerable groups, including those who are pregnant, breastfeeding, or taking any medications do not consume CBD.

In October 2023 FSA issued updated precautionary advice on CBD, recommending healthy adults should limit their consumption of CBD from food to 10mg per day, which is about 4-5 drops of 5% CBD oil. This change in advice was based on new evidence from the industry and updated advice from the Advisory Committee on Novel Foods and Processes (ACNFP) & Committee on Toxicity (COT)

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) 1924/2006) 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/government/collections/drugs-licensing

CBD products for medical purposes

In the absence of any authorised 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 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:

https://www.gov.uk/government/collections/medicines-licensing-and-applications

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:

https://www.gov.uk/government/collections/clinical-trials-for-medicines

https://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 the MHRA Borderlines Section: borderline_medicine@mhra.gov.uk

Amended September 2025

MHRA Borderlines Section

APPENDIX 12

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 Regulation 2 of The Human Medicines Regulations 2012 (S.I 2012/1916) which defines a "medicinal product" as:

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

2. *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 two).*

MHRA is aware of the 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 Human Medicines Regulations 2012 apply to medicinal products for human use intended to be placed on the market in the UK and either *prepared industrially* or manufactured by a method involving an *industrial process*. Products that are not so produced are not subject to the requirements of the Regulations.

Prepared in a pharmacy

The Regulations do 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). Similarly the Regulations do not apply to medicinal products intended for research and development trials, but without prejudice to the provisions in the Regulations regarding clinical trials on medicinal products for human use.

Special Need

Unless exempt, a medicinal product must be the subject of a marketing authorisation or product licence before being placed on the market. Regulation 167 of the Human Medicines Regulations 2012 provides an exemption from the need for a marketing authorisation for a medicinal product which is supplied:

- in response to an unsolicited order;
- manufactured and assembled in accordance with the specification of a person who is a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber;
- for use by a patient for whose treatment that person is directly responsible in order to fulfil the special needs of that patient; and meets the conditions specified in regulation 167(2)-(8).

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/publications/supply-unlicensed-medicinal-products-specials

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:

- How to obtain a marketing authorisation –

  https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk

- Clinical trials for medicines: apply for authorisation in the UK -

  https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk

- How to obtain a manufacturer's licence for investigational medicinal products https://www.gov.uk/guidance/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 Borderline Section for further advice or clarification: borderline_medicine@mhra.gov.uk

Where appropriate please fill in our advice request form: https://info.mhra.gov.uk/forms/borderline_advice.aspx

Amended September 2025

MHRA Borderlines Section

APPENDIX 13

GUIDANCE ON MENOPAUSE CLAIMS

Introduction

There has been considerable media attention recently surrounding products marketed for the relief of menopause symptoms and MHRA has received many enquiries on the issue. While the menopause is not an adverse medical condition and claims to support women undergoing the menopause are not medicinal claims, claims for the relief of menopause symptoms, either direct or implied, are medicinal claims and not permitted in the marketing of products which are not authorised medicines.

The Regulations

In the UK 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). Among 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.

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 Regulation 2 of the Human Medicines Regulations 2012 and consists of two ‘limbs’:

“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 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: “…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 4 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, 9 and 10 of this guidance.

Menopause claims

There has been a rapid growth in the number of products marketed to provide support during the perimenopause and menopause recently and MHRA has received a number of complaints about the claims being made for these products. As stated above, claims for the relief of menopause symptoms, either direct or implied, are medicinal claims and these will include claims for hot flushes, night sweats, headaches, and anxiety. We would also consider claims that a product may effect or regulate hormones to be indicative of pharmacological action, as are claims to affect psychological function and testosterone levels.

Phytoestrogen claims in this context are likely to be considered indicative of pharmacological activity, since phytoestrogens mimic estrogen, a steroid hormone responsible for the regulation of the female reproductive system.

It should also be noted that while approved nutrition or health claims used on food supplement products are not generally regarded to be medicinal claims, we would view health claims presented in such a way as to imply a medicinal function to be unacceptable. It should also be noted that the existence of a particular health claim will not necessarily exclude a product marketed with such a claim from being classified as a medicinal product.

Any product which appears to be intended by virtue of its presentation to give the average consumer the impression that it may treat menopause symptoms, even if this is not explicitly stated, will be considered an unauthorised medicine.

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

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

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MHRA Borderlines Section

APPENDIX 14

GUIDANCE ON PLATELET RICH PLASMA (PRP)

Background

Platelet Rich Plasma **(**PRP) therapy is a complex area and PRP products will be regulated in different ways depending on the characteristics of the product and the exact purpose for which they are being supplied or administered to the patient or client. Some PRP products may be classified as (biological) medicinal products, including advanced therapy medicinal products (ATMPs), and these PRP products would be regulated under human medicines legislation. In some cases, unlicensed medicinal products, including PRP, may qualify for manufacturing and supply under the MHRA "specials" scheme.

MHRA's position

In line with the definition of a medicinal product, when classifying a product, the MHRA looks at the way the product is presented (especially any claims) and at its function, that is, its effects (when administered) on human physiology diagnosis.

The MHRA is aware of the guidance issued by the National Institute for Health and Care Excellence (NICE) in January 2019 regarding PRP injections for knee osteoarthritis which involves taking plasma from a small amount of the person's own blood and injecting it into the knee, and autologous blood injection for tendinopathy published in January 2013 which involves supplying the tendon with growth factors that start the healing process.

The guidelines (see Annex) also require that patients are aware of the safety and efficacy evidence and there is a process in place to review patient outcomes. Whilst autologous blood injection is not PRP, both papers recognise the evidence on efficacy is limited in quality or remains inadequate:

https://www.nice.org.uk/guidance/ipg637

https://www.nice.org.uk/guidance/ipg438

Blood products

MHRA has given consideration as to whether PRP should be regulated as a blood component under the Blood Safety and Quality Regulations 2005 (BSQR). MHRA is of the view that the BSQR have relevance in respect of standards of quality and safety for the collection of blood, irrespective of intended use or equivalent standards, but PRP is not administered intravenously and is being administered for the treatment of adverse medical conditions linked with other parts of the body. This is counter to the purpose of the BSQR which is to regulate blood and blood components used for transfusion purposes [see Annex].

The MHRA is of the view that when PRP is being used for medical purposes PRP falls within the definition of a medicinal product, or where a more complex manufacturing process is undertaken (such as pooling for allogeneic use, addition of other substances), the MHRA regards PRP to be a blood product. In such circumstances the sourcing of the starting material will be subject to all relevant aspects of the BSQR, while the manufacture, storage and distribution will be subject to Human Medicines legislation.

Medicinal products

It is the MHRA's position that, if PRP is used with medicinal claims or to be used for a medicinal purpose described in the NICE guidelines referred to above, it will meet the definition of a medicinal product set out in Regulation 2 of the Human Medicines Regulations 2012 (HMRs). Accordingly, PRP will be subject to the provisions of the HMRs [see Annex].

MHRA notes that EU Human Medicines Legislation, which UK medicines legislation transposes, envisages instances where the regulatory status is not clear and, in such instances, that status as a medicine, should take precedence[1].

PRP products used in these circumstances will be subject to authorisation and licensing to market and manufacture respectively unless an exemption exists. Exemptions from the need for a Marketing Authorisation and manufacturer's licence exist under the HMRs in certain circumstances for doctors and dentists. There is also an exemption from the need for a Marketing Authorisation under the UK specials regime which allows a doctor, dentist, nurse, independent prescriber, pharmacist independent prescriber or supplementary prescriber to sell and supply an unlicensed medicine. Both of these are in the HMRs (Regulation 3 and 167 respectively).

Under Regulation 3(5) of the HMR, a doctor may manufacture or assemble a medicinal product without a Marketing Authorisation or manufacturer's licence provided the medicinal product is supplied to a patient during the treatment of that patient or to a patient of another doctor who is a member of the same medical practice. In addition, the medicinal product cannot be manufactured or, as the case may be, assembled on a large scale, or by an industrial process.

'Supplementary prescriber' is defined in Regulation 8 of the HMRs (see Annex). Whilst supplementary prescribers may fulfil the special needs of a patient that they are directly responsible for by requesting a special medicinal product to their specification under Regulation 167 of the HMRs, the special medicinal product, which in this case will be a blood

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[1] 1 Article 2(2) of Directive 2001/83

In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.

product (i.e. PRP), must be manufactured by the holder of a manufacturer's specials licence. Blood, or blood components, used by a licensed manufacturer as a starting material or raw material in the manufacture of a medicinal product must meet the standards of quality and safety set out in the BSQR, or equivalent standards.

MHRA agrees that supplementary prescribers can administer PRP, and the clinic or hospital in which they work could use their own doctor to manufacture and administer the PRP under regulation 3(5) of HMR. Alternatively, the clinic could apply for and obtain a manufacturer's special licence or go to an existing holder of such a licence. The supplementary prescribers' can then provide their specification and have the special medicinal product supplied.

Regulatory changes for medicines under the Windsor Framework from 1 January 2025 require all medicines placed on the UK market to be labelled as 'UK Only', (indicating they are not for sale in the Republic of Ireland or other EU countries); which will have either a UK-wide licence, or a Northern Ireland-specific licence unless the exemptions apply under Regulation 3 and 167 respectively.

PRP Medical Devices

There are products on the market intended for use in the production or preparation of PRP; where the final resulting product (PRP) is intended for medical purposes, these preparation kits are regulated as medical devices and subject to the UK Medical Device Regulations 2002. Such kits must be marketed in line with the legal manufacturer's intended purpose and uses, which in turn must be supported with appropriate evidence in their technical documentation. Depending on the components included with the preparation kits (e.g. inclusion of anti-coagulant solutions), they may be subject to conformity assessment and require UKCA / CE certification from an Approved / Notified Body. The output PRP itself is not a medical device, as it does not meet the definition provided in the Medical Devices Regulations 2002 [see Annex]. Claims regarding the efficacy of the end PRP output from the kit should not therefore be made.

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 the direct personal responsibility of that health-care professional.

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 which requires all medicines placed on the UK market to be labelled as 'UK Only'.

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

(d) Importing Investigational Medicinal Products (IMP) from countries on a list to Great Britain:

https://www.gov.uk/government/publications/importing-investigational-medicinal-products-into-great-britain-from-approved-countries/importing-investigational-medicinal-products-imp-from-countries-on-a-list-to-great-britain

(e) Supply unlicensed medicinal products (specials):

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

(f) Manufacture of unlicensed ATMPs in the UK:

https://www.gov.uk/guidance/advanced-therapy-medicinal-products-regulation-and-licensing

(g) Information about ensuring blood and blood component safety:

https://www.gov.uk/government/collections/blood-regulation-and-safety

If you have any regulatory queries regarding Marketing Authorisation please contact our Regulatory information service (RIS) on Tel: 020 3080 7400, or alternatively you can e-mail your enquiry to ris.na@mhra.gov.uk

If you have any regulatory queries regarding licence requirements for manufacture or wholesale dealing, please contact the MHRA Customer Services Team on Tel: 020 3080 6000 or alternatively you can email MHRACustomerServices@mhra.gov.uk

For enquires relating to good manufacturing practices please email:

gmpinspectorate@mhra.gov.uk

For enquires relating to good manufacturing practices please email:

gdp.inspectorate@mhra.gov.uk

Further Advice

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

https://info.mhra.gov.uk/forms/borderline_advice.aspx or email borderline_medicine@mhra.gov.uk

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.

Annex

Blood Safety and Quality Regulations

1 Citation, commencement and interpretation

(1) These Regulations may be cited as the Blood Safety and Quality Regulations 2005.

(2) Except for regulation 25(1), which shall come into force on 8th November 2005, these Regulations shall come into force on 8th February 2005.

3) In these Regulations—

“autologous transfusion” means a transfusion in which the donor and the recipient are the same person and in which pre-deposited blood or blood components are used;

[“biomedical research institution” means any body which carries out biomedical research;]

“**blood**” means whole human blood collected from a donor and processed either for transfusion or for further manufacturing;

“**blood component**” means a therapeutic constituent of human blood (red cells, white cells, platelets and plasma) that can be prepared by various methods;

“blood component release” means a process which enables a blood component to be released from a quarantine status by the use of systems and procedures to ensure that the finished product meets its release specification;

[“blood establishment” means any person who carries out any of the activities specified in regulation 3(2) which require an authorisation by virtue of that regulation;]

“**blood product**” means any therapeutic product derived from human blood or plasma;

2 Designation of the competent authority for Northern Ireland and scope of the Regulations

[(1) The Secretary of State is designated the competent authority in relation to Northern Ireland for the purposes of the Directive.]

(2) Subject to the following paragraphs, the requirements of these Regulations apply to the collection and testing of blood and blood components, whatever their intended purpose, and to their processing, storage, and distribution when they are intended to be used for transfusion.

Human Medicines Regulations (HMR)

Regulation 2 Medicinal products

2.—(1) In these Regulations "medicinal product" means—

(a) any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or

(b) any substance or combination of substances that may be used by or administered to human beings with a view to—

(i) restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or
(ii) making a medical diagnosis.

(2) These Regulations do not apply to—

(a) whole human blood; or

(b) any human blood component, other than plasma prepared by a method involving an industrial process.

Regulation 37(9) Manufacturing and assembly:

(9) The licence holder must ensure that blood, or blood components, imported into the United Kingdom and used as a starting material or raw material in the manufacture of a medicinal product meet—

(a) the standards of quality and safety specified in [the Blood Quality and Safety Regulations 2005]; or

(b) equivalent standards.

Regulation 167 Supply to fulfil special patient needs

(1) The prohibitions in regulation 46 (requirement for authorisation) do not apply in relation to a medicinal product (a "special medicinal product") if—

(a) the medicinal product is supplied in response to an unsolicited order;

(b) the medicinal product is manufactured and assembled in accordance with the specification of a person who is a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber;

(c) the medicinal product is for use by a patient for whose treatment that person is directly responsible in order to fulfil the special needs of that patient; and

(d) the following conditions are met.

(2) Condition A is that the medicinal product is supplied—

(a) to a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber; or

(b) for use under the supervision of a pharmacist in a registered pharmacy, a hospital or a health centre.

(3) Condition B is that no advertisement relating to the medicinal product is published by any person.

(4) Condition C is that—

(a) the manufacture and assembly of the medicinal product are carried out under such supervision; and

(b) such precautions are taken,

as are adequate to ensure that the medicinal product meets the specification of the doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber who requires it.

(5) Condition D is that written records of the manufacture or assembly of the medicinal product in accordance with condition C are maintained and are available to the licensing authority or to the enforcement authority on request.

(6) Condition E is that if the medicinal product is manufactured or assembled in the United Kingdom [imported into Northern Ireland from a country other than an EEA State or Great Britain, or imported into Great Britain from a country other than an approved country for import or Northern Ireland]—

(a) it is manufactured, assembled or imported by the holder of a manufacturer's licence that relates specifically to the manufacture, assembly or importation of special medicinal products; or

(b) it is manufactured, assembled or imported as an Investigational Medicinal Product by the holder of a manufacturing authorisation granted by the licensing authority for the purposes of regulation 36 of the Clinical Trials Regulations.

(7) Condition F is that if the product is [imported into Northern Ireland from an EEA State or imported into Great Britain from a country other than an approved country for import]—

[(a) it is manufactured or assembled in that State or country (as appropriate) by a person who is the holder of an authorisation in relation to its manufacture or assembly in accordance with—

(i) in the case of a product for sale or supply in Northern Ireland, the provisions of the 2001 Directive as implemented in that State, and

(ii) in the case of a product for sale or supply in Great Britain, in accordance with the provisions applicable in that country; or]

[(b) it is manufactured or assembled as an Investigational Medicinal Product in that State or country (as appropriate) by the holder of an authorisation in relation to its manufacture or assembly in accordance with—

(i) in the case of a product for sale or supply in Northern Ireland, Article 13 of the Clinical Trials Directive as implemented in that State, and

(ii) in the case of a product for sale or supply in Great Britain, regulations 13 and 43 of the Clinical Trials Regulations,]

[and it is imported by the holder of a wholesale dealer's licence in relation to the product in question].

(8) Condition G is that if the product is distributed by way of wholesale dealing by a person (“P”), who has not, as the case may be, manufactured, assembled or imported the product in accordance with paragraph (6)(a) or (7)(a), P must be the holder of a wholesale dealer's licence in relation to the product in question.

(9) In this regulation “publish” has the meaning given in regulation 277(1) (interpretation: Part 14 advertising).

General interpretation

Regulation 8

In these Regulations “supplementary prescriber” means a person who is noted in the relevant register as qualified to order drugs, medicines and appliances as a supplementary prescriber (or, in the case of a registered nurse or registered midwife, as a nurse independent/supplementary prescriber) and is—

(a) a pharmacist;

(b) a registered midwife;

(c) a registered nurse;

(d) a chiropodist, podiatrist, physiotherapist, paramedic or radiographer;

(e) a registered optometrist; or

(f) a registered dietitian;

Medical Device Regulations

Regulation 3

3. These Regulations shall not apply to—

(a) medicinal products governed by Directive 2001/83 [the Human Medicines Regulations 2012] (including medicinal products derived from human blood or human plasma) governed by Title X of Directive 2001/83);

(b) human blood, human blood products, plasma or blood cells of human origin;

(c) devices that incorporate, at the time of placing on the market, human blood, blood products, plasma or blood cells of human origin, except for [—

(i) stable derivatives devices,

(ii) active implantable medical devices and accessories to such devices, and

(iii) *in vitro* diagnostic medical devices and accessories to such devices];

(d) transplants or tissues or cells of human origin or products incorporating or derived from tissues or cells of human origin [except for . . ., in vitro diagnostic medical devices and accessories to such devices] [save where medicinal products are incorporated as ancillary to the device accessories to such devices];

(e) transplants or tissues or cells of animal origin, unless—

(i) a device is manufactured utilising animal tissue which is rendered non-viable or nonviable products derived from animal tissue, or

(ii) a product is ... an *in vitro* diagnostic medical device, or an accessory to such a

device;]

(f) cosmetic products governed by Council Directive 76/768/EEC, as amended [Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30th November 2009 on cosmetic products;] or

NICE

Clinicians wishing to give PRP injections for knee osteoarthritis should:

• Inform the clinical governance leads in their NHS trusts.

• Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these. Provide them with clear information to support shared decision making. In addition, the use of NICE's Information for the public | Platelet-rich plasma injections for knee osteoarthritis | Guidance | NICE is recommended.

• Audit and review clinical outcomes of all patients having PRP injections for knee osteoarthritis, including details of the methods used to prepare and administer the PRP injections. NICE has identified relevant audit criteria and has developed NICE's interventional procedure outcomes audit tool Tools and resources | Platelet-rich plasma injections for knee osteoarthritis | Guidance | NICE (which is for use at local discretion).

The Procedure

2.3 PRP is prepared by a clinician or a technician. Blood is taken from the patient and centrifuged to obtain a concentrated suspension of platelets in plasma. Different preparation methods may affect the concentrations of platelets and the level of contamination with red and white blood cells.