

# **A GUIDE TO WHAT IS A MEDICINAL PRODUCT**

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## A GUIDE TO WHAT IS A MEDICINAL PRODUCT

<b>CONTENTS</b>	<b>Page</b>
Introduction .....	4
Cosmetic Products .....	4
Food Products including Food Supplements.....	5
Herbal Medicinal Products .....	6
Medical Devices .....	7
What is a Medicinal Product? .....	8
Paragraph (a) of the definition.....	9
Paragraph (B) of the definition.....	11
Determination Procedure in cases where the Statutory Procedure is not appropriate .....	12
The Statutory Procedure .....	13
Final Determinations Following Review.....	15
Publication of Final Determinations .....	15
The Internet .....	15
Marketing Authorisations.....	16
Registrations for Traditional Herbal Medicinal Products.....	16
Homoeopathic Medicinal Products .....	16
What To Do If You Are Not Sure If A Product Is Medicinal.....	16
Appendix 1 Words And Phrases .....	17
Appendix 2 Useful Addresses .....	21

## INTRODUCTION

### The Medicines and Healthcare products Regulatory Agency

1. To protect public health, and on behalf of the UK Licensing Authority, the Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicinal products for human use in accordance with the European Community's medicinal products directive (Directive 2001/83/EC, as amended, "the Directive") and UK law. The MHRA may be called on to determine if a product is a "medicinal product". If it does so determine, then unless an exemption applies, the product is subject to the Human Medicines Regulations 2012 [SI 2012/1916] ("the Regulations").
2. The 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, traditional herbal registration or certificate of registration as a homoeopathic product granted by the European Commission or by the UK Licensing Authority. A marketing authorisation or registration is only granted for a product which meets statutory standards of safety, quality and efficacy, whilst products registered as traditional herbal medicines or as homoeopathic medicines have to meet statutory standards of safety and quality. Traditional herbal medicinal products are required to demonstrate *plausible* efficacy alongside other criteria.
3. The status of many products on the "borderline" between medicinal products and food supplements, biocides, cosmetic products or medical devices can be difficult to determine. This Guidance explains how, and on what basis, the MHRA decides whether products are medicines or not. It includes guidance on the review procedures in Part 9 of the Regulations. This latest version of Guidance Note 8 is updated to reflect the consolidation of medicines legislation effective from 14 August 2012 and clarifies the MHRA's position on traditional herbal medicinal products.
4. 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's Enforcement Group investigates and takes enforcement action as necessary. Enforcement options include, but are not confined to, a formal caution, or prosecution in the criminal courts for a breach of medicines legislation. The MHRA enforcement strategy can be found at <http://www.mhra.gov.uk/home/groups/ei/documents/websiteresources/con084796.pdf>. In many, but not all cases, the determination is made in accordance with the procedure set out in Regulations 159-164 of the Human Medicines Regulations 2012.

### Cosmetic products

5. The Cosmetics Directive 76/768/EC, as amended (implemented in the UK by the Cosmetic Products (Safety) Regulations 2008 (SI 2008/1284) as amended, harmonises the requirements for cosmetics in the European Community to achieve free trade whilst ensuring that the products are safe and consumers are not misled. It prohibits, or places restrictions on, certain ingredients within a product and also defines what a cosmetic is. The definition envisages that a cosmetic product may have a secondary preventative (but not curative), purpose. When deciding whether or not a product on the

borderline between cosmetics and medicines is a medicinal product, the MHRA will apply the tests set out in Directive 2001/83/EC. If a product falls within the definition of a cosmetic and within the definition of a medicinal product it will be classified as a medicinal product (*Delattre* 1991, C-369/88). The regulatory status of products in other Member States will also be taken into account. Directive 76/768/EC is being repealed and will be replaced by Directive 1223/2009/EC from July 2013.

Article 1(1) of the Cosmetics Directive defines 'Cosmetic Product' as

“any substance or preparation intended to be placed in contact with the various 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 and/or correcting body odours and/or protecting them or keeping them in good condition.”

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

### **Food products including food supplements**

7. The definition of food in the Food Safety Act 1990 is that used in Article 2 of EC Regulation 178/2002;

*“...food (“or foodstuff”) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans...”*

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

“Food” includes any food, drink or food supplement that is part of the diet. Any ingested product which is not a medicinal product is a “food”, including articles and substances of no nutritional value. A product which the average consumer would regard as something to be eaten, drunk or chewed as part of his/her diet for example, because of its taste, flavour, or nutritional value 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 may be regulated under food law. 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.

8. Food law includes a prohibition on claims to treat, prevent or cure disease. An MHRA determination that a product is not a medicine does not automatically amount to an approval that the product may legally be sold under food law. Manufacturers and persons intending to place a product on the market as a food should seek confirmation from the Trading Standards Service of their Local

Authority that the product complies with all relevant food law including the Nutrition and Health Claims Regulations and the requirements of the Food Supplements Directive (Directive 2002/46/EC). This Directive was implemented in England by the Food Supplements (England) Regulations 2003. Separate, equivalent legislation has been made in Scotland, Wales and Northern Ireland. The directive and these regulations apply from 1 August 2005.

Food supplement is defined as:

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

The “upper safe level” referred to in Article 5(1)(a) of Directive 2002/46/EC is one of the factors which may be taken into account in setting maximum quantities of vitamins and minerals in food supplements. However, the concept of “upper safe level” is not relevant alone to the question of whether a product is a food supplement or a medicinal product. A product administered in quantities above or below the “upper safe level” may nonetheless be classified as a medicinal product if it falls within the definition in Article 1(2) of Directive 2001/83/EC (*HLH Warenvertriebs*, 2005 (C-211/03)). Advice on food supplements should be sought from the Department of Health either in writing (address provided in Appendix 2) or by using the web contact form at this location: [http://www.dh.gov.uk/en/ContactUs/DH\\_066319](http://www.dh.gov.uk/en/ContactUs/DH_066319)

9. In addition, we have been advised by the Food Standards Agency (FSA) that ingredients which do not have a history of significant consumption within the EU prior to 15 May 1997 may be subject to the controls of Novel Food Regulation (EC) 258/97. Advice on this point should be sought from the Food Standards Agency either in writing (address provided in Appendix 2) or by e-mailing using the following addresses: [novelfoods@foodstandards.gsi.gov.uk](mailto:novelfoods@foodstandards.gsi.gov.uk).

10. Products to provide nutritional support to athletes and persons who exercise (“sports supplements”) would normally be regarded by the MHRA as falling outside the definition of a medicinal product. However, products which make claims to treat or prevent disease and/or which significantly modify physiological functions by pharmacological, metabolic or immunological means are likely to fall within the definition of a medicinal product. Additional information on the borderline between medicines and sports supplements is available on the Borderline Products page of the MHRA website.

11. Products for persons wishing to lose weight (“slimming/dieting products”) would fall within the definition of a medicinal product if: (a) they make medicinal claims; (b) if they modify physiological functions by acting pharmacologically, immunologically or metabolically. However, 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.

## Herbal medicinal products

12. The Traditional Herbal Medicines Directive (Directive 2004/24/EC) was published on 30 April 2004 and implemented by the Medicines (Traditional Herbal Medicinal Products for Human Use)

Regulations 2005, which for the most part came into force on 30 October 2005 (Part 7 of the Human Medicines Regulations from 14 August 2012). Products which were legally on the UK market on 30 April 2004 were not legally required to comply with the Directive during a seven year transitional period. Post 30 April 2011, new products coming onto the market do need to be authorised. This means that unlicensed herbal remedies previously sold under Section 12(2) of the Medicines Act 1968 need to obtain either a traditional herbal registration (“THR”) or a marketing authorisation (“MA”) before they can be placed on the market. If a product has neither a THR or MA, it cannot be placed on the market after 30 April 2011. The MHRA has a policy position that products already legally placed on the market, for example, held by retailers before 30 April 2011, may continue to be sold through. The transitional protection did not apply to any products placed on the UK market at any time after 30 April 2004 onwards. Further details may be obtained from the Agency's website [www.mhra.gov.uk](http://www.mhra.gov.uk).

### Medical devices

13. Some products may be on the borderline between medicinal products and 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. These cases are decided after considering the manufacturer's intended purpose of the product taking into account the way it is presented, and the method by which the principal mode of action is achieved. In the case of a medical device, the principal mode of action is typically fulfilled by physical means (including mechanical action, physical barrier, replacement of, or support to, organs or body functions). Medical devices *may* be assisted in their function by pharmacological, immunological or metabolic means but not defined as their principal mode of action. Accordingly, where a product achieves its principal intended action by pharmacological, immunological or metabolic means, it is a medicinal product.

14. The classification principles relating to medical devices containing medicinal products remain the same irrespective of whether the medicinal product is 'pharmaceutical' or an 'herbal' medicinal product. It is possible that a product containing herbal substance(s) that have demonstrated a pharmacological action could be classified as a medical device, if the action of the herbal constituent is ancillary to the physical means by which the function of the product is mainly achieved. The notions of pharmacological action and physical means are important elements in reaching classification decisions when considering the borderline between a (traditional) herbal medicinal product and a medical device. Where a product's main action is a result of the action of the herbal ingredient exerting an intended effect by virtue of primarily pharmacological, immunological or metabolic means it may not be considered as a medical device. If such action is ancillary to the main purpose of the medical device then the herbal ingredient may be considered as a medicinal substance under classification rule 13.

15. General advice on the legislation which covers medical devices can be obtained from the MHRA website at [www.mhra.gov.uk](http://www.mhra.gov.uk) or from the Devices sector of the MHRA on telephone number 020 3080 6000. For specific advice on borderline issues for medical devices, please refer to Devices Bulletin 17, available on the MHRA website, or telephone 020 3080 7386. Alternatively you may write to the Devices sector of the MHRA (see address in Appendix 2).

## WHAT IS A MEDICINAL PRODUCT?

### Definition

16. Article 1 of Directive 2001/83/EC as *amended* defines a “medicinal product” as:

- (a) “Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; [*“the first limb”*]
- (b) Any substance or combination of substances which may be used in, or administered to, human beings, either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis” [*“the second limb”*]

*The paragraph identifications (a) and (b) are not part of the definition and are added here solely for ease of reference later on.*

Medicinal products may well fall under both limbs of the definition but the European Court of Justice (“ECJ”) has confirmed that falling under either limb is sufficient to classify a product as a medicinal product. [*Upjohn 1989 C-112/89*]: **“Directive 65/65 (now Directive 2001/83) provides two definitions of the term “medicinal product”: one relating to presentation, the other to function. A product is medicinal if it falls within either of those definitions.”**

### “Meaning of ‘Disease”

17. Council Directive 65/65 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products gives no definition of the terms ‘illness or disease’. The only possible definitions for those terms are those most commonly accepted on the basis of scientific knowledge.

[Case C-369/88 Delattre]

“disease” includes any injury, ailment or adverse condition, whether of body or mind”

[Regulation 8 of the Human Medicines Regulations 2012]

### MHRA policy and practice

18. European Community legislation on medicinal products is not fully harmonised. For this reason, it is possible that a product classified as a medicine in the UK may be classified as, for example, a food in another Member State. However, when reaching decisions on the status of products each Member State is obliged to follow the criteria set out in the judgments of the European Court of Justice.

This is the basis on which the MHRA, on behalf of the UK Licensing Authority, determines (subject to review by the courts), whether a product is a medicinal product. The Agency’s power to so determine



the classification of a product has been confirmed by a judgement of the Court of Appeal (*R. v. Medicines Control Agency ex parte Pharma Nord (UK) Limited 1998*). The Court ruled that it was acceptable for the Licensing Authority to determine whether or not a product is a medicinal product, having expert knowledge, the decision of the Licensing Authority being subject to review by the courts. The judgement noted:

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

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

20. 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 set out in paragraph 16 above;
- relevant ECJ and domestic Court precedents; and
- following an assessment of all the available evidence.

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

**“Presentation”**

### **Paragraph (a) of the definition**

21. Sub-paragraph (a) of the definition is concerned with the *presentation* of the product. 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 ECJ has placed considerable emphasis on the impression that consumers are likely to form as a result of the product’s presentation. [*Van Bennekom 1982*]: **“It is necessary to take the view that a product is presented for treating or preventing disease... whenever any averagely well-informed consumer gains the impression, which provided it is definite, may even result from implications, that the product in question should, regard being had to its presentation, have an effect such as is described by the first part of the EC definition.”**

## Claims to treat or prevent disease

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

23. 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 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

24. The MHRA does not normally consider claims to **“maintain”** or **“help to maintain”** or **“support”** health or a healthy lifestyle, as medicinal in themselves. 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.

## Factors particularly relevant to deciding whether a product is a medicine under the first limb of the definition.

25. These are as follows:

- all claims made for the product, both explicit and implicit, including any made on websites, linked “helplines”, testimonials or in linked publications. “Implicit” claims may include product names. The MHRA is committed to considering each product individually, and it is not possible to produce more than an indicative list of the kind of claims that the MHRA may decide are presenting the product as treating or preventing disease. However, it may be helpful to refer to the words and phrases listed in Appendix 1. The MHRA has previously decided that, in context - for example, when used in relation to a disease, illness or specific adverse condition - claims which included words like these were presenting products for treating or preventing disease, that is, as medicines;
- *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, 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.

**A product determined by the MHRA as a medicinal product under the first limb of the definition, but not under the second limb**

26. The MHRA may determine that a product is a medicine *solely* because *it falls within the first (“presentation”) limb of the definition*. This reflects the importance that the ECJ attaches to protecting consumers from products that could not deliver the claimed medicinal results. [Van Bennekom 1982, again]: **“The Directive thereby seeks to protect consumers not only from harmful or toxic medicinal products as such but also from a variety of products used instead of the proper remedies.”**

**“Function”**

**Paragraph (b) of the definition**

27. Sub-paragraph (b) of the definition is concerned with the **function and intended use of the product**, that is, whether the product “*may be administered... with a view to*” achieving a medicinal purpose.

The factors which are relevant in determining whether a product falls within the second limb of the definition have been considered by the ECJ, the judgment in *HLH Warenvertriebs*, 2005 (C-211/03) says:

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

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

Although a product may contain nutritional ingredients, if it also contains an active ingredient which means that the product overall has significant effect on human physiology, the MHRA may still determine that the product is a medicinal product because it satisfies this limb of the definition. Where there is doubt or dispute as to whether the recommended dosage level of the product is large enough to have a significant effect on the actual functioning of the body or not, the MHRA will seek the advice of its medical and pharmaceutical assessors.

28. Since the *Warenvertriebs* judgment a European system for regulating herbal medicinal products has come fully in to force. Under Directive 2004/24/EC herbal medicinal products can receive a certificate of registration instead of a marketing authorisation. The scheme is limited to herbal medicinal products for simple, self-limiting conditions with a history of traditional use of 30 years (of which 15 must be in the European Union). Registered products have the requirement for efficacy replaced by a requirement for plausible effect on the basis of long standing use and experience.

#### **Factors particularly relevant to deciding whether a product is a medicine under the second limb of the definition**

29. These are as follows:

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

#### **DETERMINATION PROCEDURE IN CASES WHERE THE STATUTORY PROCEDURE IS NOT APPROPRIATE**

30. Generally, determination of the status of a product will follow the statutory determination procedure set out in Regulation 159 of the Human Medicines 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 are where:

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

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

## THE STATUTORY PROCEDURE

### Provisional determinations

31. 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 homoeopathic medicinal product **and** not otherwise exempt is a relevant medicinal product, the MHRA will give notice (either by Special Delivery or by email) 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 representations about it to an Independent Review Panel (“the Panel”). It will ask the company for notice of any intention to make written or oral representations within four weeks of the provisional determination. In the case of **written representations**, the company will be expected to submit them to the Panel by a date not less than six weeks from the date of the provisional determination. In the case of **oral representations** to the Panel, the MHRA will, after consultation with the company, set a hearing date generally not less than eleven weeks from the date of the provisional determination. In either case, there is some scope to allow additional time for proper preparation of the company’s case.

### Final determinations if no request for review is made

32. 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 (either by Special Delivery or by email), 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 also 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.

## The Independent Review Panel

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

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

35. 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.

36. 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

37. 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, within a week of receiving the advice wherever possible. 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

38. 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 not later than one week before the hearing. If it is necessary to submit new evidence within one week of, (or at), 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.

39. At the hearing the company 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.

40. 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.

41. 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 (either by Special Delivery or by email), again giving reasons and enclosing a copy of the panel's advice, within a week wherever possible. 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.

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

## **FINAL DETERMINATIONS FOLLOWING REVIEW**

### **Notice under Regulation 161 or 162 of the Regulations**

43. 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**

44. 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 MHRA website [www.mhra.gov.uk](http://www.mhra.gov.uk) under 'Final Determinations'.

## **THE INTERNET**

45. Information on the internet about a product and its uses is not excluded from the definition of the term 'advertisement' in Regulation 7 of the Regulations. To help companies avoid bringing unlicensed

products within the definition of a medicinal product guidance on the use of the internet can be found at <http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedallicence/Borderlineproducts/index.htm#15>.

## **MARKETING AUTHORISATIONS**

46. Guidance on marketing authorisations is provided in the "Notice to Applicants" (Volume II of the Rules Governing Medicinal Products in the European Community) This can be obtained from [http://ec.europa.eu/health/documents/eudralex/index\\_en.htm](http://ec.europa.eu/health/documents/eudralex/index_en.htm).

## **REGISTRATIONS FOR TRADITIONAL HERBAL MEDICINAL PRODUCTS**

47. Guidance on the registration scheme for Traditional Herbal Medicinal Products can be found on [www.mhra.gov.uk](http://www.mhra.gov.uk) under 'Traditional Herbal Medicines Registration Scheme'.

## **HOMOEOPATHIC MEDICINAL PRODUCTS**

48. Guidance on the legislation which controls homoeopathic medicinal products and on the registration scheme can be found on [www.mhra.gov.uk](http://www.mhra.gov.uk) under 'Homoeopathic Medicines'.

## **WHAT TO DO IF YOU ARE NOT SURE IF A PRODUCT IS MEDICINAL**

49. Classification is carried out on a product by product basis. If you have looked at all the literature in the Guidance Note and on the website and you are still unsure, complete the advice request form which is available on the Agency's website at [www.mhra.gov.uk](http://www.mhra.gov.uk) under Borderline/How the MHRA determines whether a product is medicinal. 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.
“At the first sign of a spot...”	Implied claim to treat ‘spots’, an adverse condition.
“Avoids”	In context, may be a claim to prevent specific disease(s).
“Boosts”	In context, claim may tend to suggest that the product may be administered with a view to modifying physiological function and having a significant effect.
“Burns fat”	A claim that the product may be administered with a view to having a significant effect on the metabolism and modifying physiological function.
“Calm/calms/calming”	In context, may be a claim to sedate.
“Can benefit those who suffer from...”	A claim to treat or prevent disease in specific patient groups or in those at particular risk of specific diseases or adverse conditions.
“Clears”	In context, may be a claim to effectively treat or correct disease or an adverse condition.
“Clinical Trials Evidence”	Implied claim to (medicinal) efficacy in relation to disease or an adverse condition.
“Clinically proven”	An implied claim that the product has met the appropriate efficacy test in relation to disease or an adverse condition.
“Combats”	In context, a claim to work directly to treat, prevent or cure disease or an adverse condition.

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

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

“Treats/clears infestations”	In relation to humans, a claim to stop, treat or remove parasitic infestations such as head/body/public lice. An infestation of lice is an adverse condition.
“Treats/Treatment/Treating”	In context, these are claims to treat or prevent disease or an adverse condition.

## **APPENDIX 2 USEFUL ADDRESSES**

### **The Advertising Standards Authority Ltd (ASA)**

Mid City Place  
71 High Holborn  
London  
WC1V 6QT

Tel: 020 7492 2222  
Fax: 020 7242 3696  
E-mail: [enquiries@cap.org.uk](mailto: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](mailto:info@a-t-c.org.uk)

### **Association of British Pharmaceutical Industry (ABPI)**

12 Whitehall  
London  
SW1A 2DY

Tel: 020 7930 3477  
Fax: 020 7747 1411

### **British Herbal Medicine Association (BHMA)**

PO Box 583  
Exeter  
EX1 9GX

Tel: 0845 680 1134  
Fax: 0845 680 1136  
E-mail: [secretary@bhma.info](mailto:secretary@bhma.info)

### **Clearcast Ltd**

3rd Floor  
4 Roger Street  
London  
WC1N 2JX

Tel: 020 7339 4700

**Committee of Advertising Practice (CAP)**

Mid City Place  
71 High Holborn  
London  
WC1V 6QT

Tel: 020 7492 2200  
Fax: 020 7242 3404  
E-mail: [advice@cap.org.uk](mailto:advice@cap.org.uk)

**Cosmetics, Toiletry & Perfumery Association Limited (CTPA)**

Josaron House  
5/7 John Princes Street  
London  
W1G OJN

Tel: 020 7491 8891  
Fax: 020 7493 8061

**Council for Responsible Nutrition**

100 Pall Mall  
St James  
London  
SW1Y 5NQ

Tel: 020 7664 8970  
E-mail: [secretariat@crnuk.org](mailto:secretariat@crnuk.org) / web [www.crnuk.org](http://www.crnuk.org)

**Department of Health**

(Customer Service Centre)  
Richmond House  
79 Whitehall  
London  
SW1A 2NS

Tel: 020 7210 4850  
Fax: 020 7210 5952

**Department of Trade and Industry**

Consumer Safety Unit  
1 Victoria Street  
London  
SW1H 0ET

Tel: 020 7215 5000  
Fax: 020 7222 0612

**Food Standards Agency**

Aviation House  
125 Kingsway  
London  
WC2B 6NH

Tel: 020 7276 8000  
Fax: 020 7276 8833

**Chinese Medicine Association of Suppliers**

8th Floor  
87-90 Albert Embankment  
London  
SE1 7UD

Tel: 020 7587 6700  
Fax: 020 7587 6720

**Health Food Manufacturers' Association (HFMA)**

1 Wolsey Road  
East Molesey  
Surrey  
KT8 9EL

Tel: 020 8481 7100  
Fax: 020 8481 7101

**Medicines and Healthcare products Regulatory Agency  
(Devices Sector)**

Floor 5-M  
151 Buckingham Palace Road  
London  
SW1W 9SZ

Tel: 020 8030 7386

**The Organisation for Professionals in Regulatory Affairs (TOPRA)**

Bellerive House  
3 Muirfield Crescent  
London  
E14 9SZ

Tel: 020 7510 2560  
Fax: 020 7537 2003  
E-mail: [info@topra.org](mailto:info@topra.org)

**Proprietary Association of Great Britain (PAGB)**

Vernon House  
Scilian Avenue  
London  
WC1A 2QS

Tel: 020 7242 8331  
Fax: 020 7405 7719  
E-mail: [info@pagb.co.uk](mailto:info@pagb.co.uk)