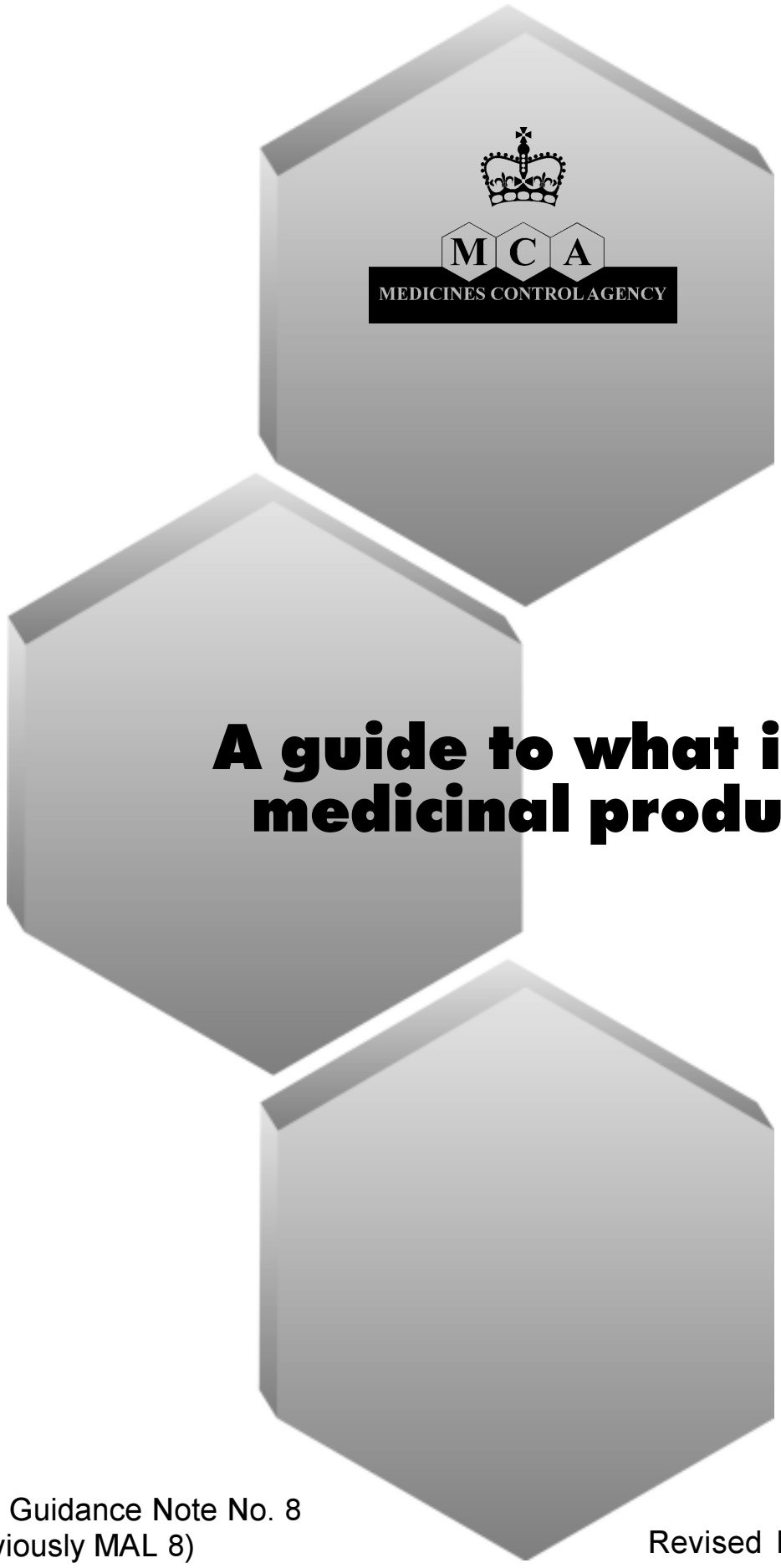

A guide to what is a medicinal product

MCA Guidance Note No. 8
(Previously MAL 8)

Revised December 2000

A GUIDE TO WHAT IS A MEDICINAL PRODUCT

December 2000

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INTRODUCTION

The Medicines Control Agency

1. To protect public health, and on behalf of the UK Licensing Authority, the Medicines Control Agency (MCA) regulates medicinal products for human use in accordance with the European Community's pharmaceutical directives and UK law. The MCA may be called on to determine if a product is a "medicinal product". If it does so determine, then unless an exemption applies, it is subject to the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994, as amended, ("the Regulations") and the Medicines Act ("the Act").

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" to which Chapters II to V of Directive 65/65/EEC apply must not be placed on the UK market unless it has a marketing authorisation (product licence) granted by the European Commission or by the UK Licensing Authority. The Act similarly provides that, unless exempt, any other "medicinal product" must not be sold or supplied without a marketing authority. A marketing authorisation or product licence is only granted for a product which meets statutory standards of safety, quality and efficacy.

3. The status of many products on the "borderline" between medicinal products and food supplements, cosmetics or medical devices can be difficult to determine. This Guidance has been developed and revised to explain how and on what basis the MCA decides whether products are medicines or not. It includes guidance on the statutory procedures in Regulation 3A of the Regulations introduced by the Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 2000 [SI 2000/292].

4. Following a thorough assessment of the status of a product, which may include review of an earlier provisional determination, the MCA may give notice that it has finally determined that a product ***is*** a medicinal product, and require compliance with the law. If compliance is not obtained voluntarily, the MCA's Enforcement Group will investigate and take whatever action is necessary. Enforcement options include a formal caution, or prosecution in the criminal courts for a breach of medicines legislation, in either case usually following a determination made in accordance with the procedure in Regulation 3A of the Regulations.

Cosmetic Products

5. The Cosmetics Directive 76/768/EEC, as amended (implemented in the UK by the Department of Trade and Industry (DTI) as the Cosmetic Products (Safety) Regulations 1996 (SI 1996/2925) as amended), harmonises the requirements for cosmetics in the European Community to achieve free trade in cosmetics whilst ensuring that the products are safe and consumers are not misled. It prohibits, or places restrictions on, certain ingredients and defines a cosmetic product. The definition envisages that a cosmetic product may have a secondary preventative, (but not curative), purpose. When deciding whether or not a product

on the borderline between cosmetics and medicines ***is*** a medicinal product, the MCA will apply the tests set out in Directive 65/65/EEC, having regard to whether or not the product falls within the definition of a cosmetic product in Cosmetics Directive 76/768/EEC. The legal status of products in other member states will also be taken into account.

6. A minority of products may potentially satisfy the definitions of "a medicinal product" ***and*** "a cosmetic product". The MCA will decide whether to classify such a product as a medicinal product on a case by case basis and taking into account all relevant factors in its presentation and constitution.

Food products, including dietary supplements

7. "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 MCA as a medicinal product unless it contains one or more ingredients generally regarded as medicinal and indicative of a medicinal purpose. If the MCA determines that such a product is not a medicine, it will be regulated under food law. Food law includes, for example, a prohibition on claims to treat, prevent or cure disease. An MCA determination that a product is not a medicine does not amount to an approval that the product may legally be sold under food law.

8. In the case of products on the borderline between food and medicine, this Guidance should be read together with relevant guidance issued by the Local Authority Co-ordinating Body on Trading Standards (LACOTS), and with reference to the Joint Health Claims Initiative's published Code of Practice. A "food for a particular nutritional purpose" is defined by, and subject to the provisions of, Directive 89/398/EEC, (implemented into UK law by the Food Labelling Regulations 1996, as amended) and includes "dietary foods for special medical purposes" (as defined by Directive 1999/21/EC, implemented into UK law by the Medical Foods (England) Regulations 2000), the Foods for Special Medical Purposes (Scotland) Regulations 2000, the Medical Food Regulations (Northern Ireland) 2000, and the Medical Food (Wales) Regulations 2000.

Herbal remedies

9. "Herbal remedies" are medicinal products and defined in Section 132 of the Medicines Act. They must be licensed unless an exemption applies, for example, one of those in Section 12 of the Medicines Act. Please note, however, that Section 12 exemptions do not apply to a herbal remedy on open sale if any name(s) other than those of the herbal constituent(s) are given to the remedy, or if it is sold or supplied with any written recommendations for use. A herbal remedy exempt from licensing is also exempt from the need for a manufacturer's or wholesale dealer's licence, but is subject to the other requirements of the Act, in particular as to labelling.

Medical devices

10. Some products may be on the borderline between medicinal products and medical devices. Medical devices are subject to the controls of Directive 93/42/EEC, implemented in the UK by the Medical Devices Regulations (SI 1994/3017) or the Active Implantable Medical Devices Regulations (SI 1992/3146). These cases are decided after considering the intended purpose of the product taking into account the way it is presented, and the method by which the principal intended action is achieved. In the case of a medical device, the principal intended

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. However, where a product achieves its principle intended purpose by pharmacological, immunological or metabolic means, it is a medicinal product. Advice on the legislation which covers medical devices can be obtained from the Medical Devices Agency, whose address and telephone number appears in **Appendix 2** (page 17) to this Guidance.

WHAT *IS* A MEDICINAL PRODUCT?

Definition

11. Article 1 of Directive 65/65 EEC defines a *"medicinal product"* as:

(a)"Any substance or combination of substances presented for treating or preventing disease in human beings or animals.

(**b) Any substance or combination of substances which may be administered to human beings or animals with a view to making a diagnosis or to restoring, correcting or modifying physiological function in human beings or animals is likewise considered a medicinal product."**

(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 it as a medicinal product. *[Upjohn 1989]:* "**Directive 65/65 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."**

MCA policy and practice

12. Although the above definition must be applied throughout the EC, it is for individual Member States to do so in respect of products within their borders. This is the basis on which the MCA, 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 do so has been confirmed by a judgement of the Court of Appeal *(R. v. Medicines Control Agency ex parte Pharma Nord (UK) Limited 1998)*. The Master of the Rolls, Lord Woolf, and his colleagues did not accept the argument that only a court could decide what is or is not a medicinal product. The judgement included the following:

"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."

13. The MCA 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 MCA will gather all available information that may have a bearing on the issue. Generally, this will include asking the manufacturer, importer or distributor for full details of the product's composition, presentation and purpose.

14. The MCA 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 8 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.

"Presented"

Paragraph (a) of the definition

15. Sub-paragraph *(a)* of the definition is concerned with the *presentation* of the product. In assessing whether a product is *"presented for treating or preventing disease"*, the MCA considers, in context, any claims (implicit as well as explicit) which are made for it, and with reference to its presentation as a whole, not in isolation. 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

16. A product for which claims are made to treat or prevent disease comes within the first limb of the definition of a medicinal product. Claims of relief from symptoms, or to cure, remedy or heal a specific disease or adverse condition of body or mind will also be regarded as medicinal claims. In context, **s*tress, 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. 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 in pharmaceutical form 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.

Claims to "maintain" health

17. The MCA does not consider claims to ***"maintain"*** or ***"help to maintain"*** or *"support"* health or a healthy lifestyle, as medicinal in themselves. Nor, if such claims are made in relation to *healthy bodily functions or organs*, is the MCA likely to consider them as presenting the product for treating or preventing disease. In general, the MCA is only likely to consider ***"health maintenance"*** claims as medicinal if they suggest or imply that a product, perhaps 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.

18. These are as follows:

- *all claims made for the product*, both explicit and implicit, including any made on linked "helplines" or in linked publications. "Implicit" claims may include product names. The MCA is committed to considering each product on its merits, and in the round, and it is not possible to produce more than an indicative list of the kind of claims that the MCA 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** (page 13)**.** The MCA 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 a third party on behalf of the supplier;

- *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 MCA as a medicinal product under the first limb of the definition, but *not* under the second limb

19. The MCA may determine that a product is a medicine *solely* because *it falls within the* ***first ("presentation")*** *limb of the definition.* This reflects the importance the ECJ attaches to protecting vulnerable 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."** However, in cases where it is presentational factors *alone* which bring the product within the definition of a medicinal product, the MCA will take into account any action being taken about "medicinal" claims by the authorities responsible for enforcing "food" or "cosmetic" law, in order to avoid double jeopardy. In the event that compliance is not achieved within a reasonable period of time by such action, or the outcome is unsatisfactory, the MCA will consider taking action under medicines law.

"Function"

Paragraph (b) of the definition

20. 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. Although a product may contain nutritional ingredients, if it also contains an active ingredient which has an established use as a medicine in the UK, the MCA may still determine that the product is a medicinal product because it satisfies this limb of the definition. Where there is doubt or dispute whether the recommended dosage level of the active medicinal ingredient is "therapeutic" or not, the MCA will seek the advice of its medical and pharmaceutical assessors.

21. Many herbs have an established or accepted use as medicines. For example, as a bronchodilator ***(Ephedra*)**, a respiratory stimulant ***(Lobelia***), a sedative ***(Valerian),*** a defence against colds and 'flu ***(Echinacea***), an anti-depressant ***(St. John's Wort)***, a diuretic ***(Boldo***), or an aphrodisiac ***(Yohimbe bark***). The MCA will generally consider products containing ingredients like these in therapeutic doses to be medicinal products on the basis that they *"may be administered with a view to … modifying physiological function in human beings"*.

22. It is important to remember that although a product may *not be presented as, or claim to be* a medicinal product, the MCA may still determine that it is a medicinal product if it contains substances with properties which indicate that it *"may be administered … with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings…"*.

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

23. These are as follows:

- *the pharmacological properties of the ingredient(s*) and any significant effect(s) they have on physiological function in humans;

- *the product promotional literature*, including testimonials and any literature issued by a third party on behalf of the product supplier;

- *the product form*, (capsule, tablet, etc.) and *the way it is to be used*;

- *the presence of essentially similar licensed or exempt medicines* on the UK market.

- *any claims*, explicit or implicit, which although they may not be claims "*for treating or preventing* [a specific] *disease"* could suggest to the average consumer that the product can be taken "*with a view to … restoring, correcting or modifying physiological functions in human beings …"*.

DETERMINATION PROCEDURE IN CASES OF URGENCY

24. Generally, determinations of the status of a product will follow the new statutory determination procedure set out in ***regulation 3A*** of the Regulations and described in the following sections. However, in exceptional circumstances, the MCA is empowered to determine that a product is a relevant medicinal product without following the statutory determination procedure if there are reasons why it would not be appropriate to follow the procedure. 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.

In such cases, a final determination will be issued by Special Delivery without delay and requiring compliance with ***Regulation 3 (1)*** of the Regulations.

Provisional determinations

25. In all other cases where the MCA is of the opinion that a product without a marketing authorisation, and not otherwise exempt is a relevant medicinal product, the MCA will give notice by Special Delivery 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 MCA 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 representations are made

26. 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 avail itself of the opportunities under the statutory procedure to make representations, the MCA (on behalf of the Licensing Authority) will consider the product again, and make and issue a final determination by Special Delivery, 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 them. It will be asked to notify the MCA of its compliance with the final determination within two weeks. The MCA also has power to issue a notice under regulation 3A(6) of 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 has been granted in respect of the product. Breach of such a notice is an offence under Paragraph 1A of Schedule 3 to the Regulations, if the product is a relevant medicinal product.

The Independent Review Panel

27. The Panel will consider written and oral representations against the Licensing Authority's provisional determination that a product is a medicinal product within the meaning of Article 1 of Directive 65/65 EEC. It will apply the relevant legal provisions and precedents to the evidence before it. It may take further evidence from the MCA 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.

28. The Panel operates independently of the MCA. The Chairman will be legally qualified and supported by members appointed by the Licensing Authority for their expertise and standing in relevant disciplines or areas of business. Members will be required to follow a code of practice, which amongst other things will stipulate 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.

29. 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.

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

Written Representations Procedure

31. The Review Panel will consider the company's written representations and a written submission by the MCA. 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 within one week. 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 further week. 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

32. 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 MCA will also provide a written report for the Panel to consider.

33. At the hearing the company may, at the discretion of the Chairman, field expert and other witnesses to give evidence on its behalf. The MCA 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 MCA representatives, and may adjourn to a later date in order to seek additional information or advice.

34. 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.

35. Once the Panel has completed its deliberations, it will aim to advise the Licensing Authority within one week. The Licensing Authority, having considered the advice, will aim to issue its final determination by Special Delivery, again giving reasons and enclosing a copy of the panel's advice, within a further week. 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.

36. There will be instances where the final determination will have wider application. In these cases, before coming to its final determination, the 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 3A(6) of the Regulations

37. All final determinations will be sent by Special Delivery. 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 MCA of its intention to comply, giving details, within two weeks. The MCA also has power to issue a notice under regulation 3A(6) of 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 has been granted in respect of the product. Breach of such a notice is an offence under paragraph 1A of Schedule 3 to the Regulations *if* the product *is* a relevant medicinal product.

Publication of final determinations

38. 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 MCA proposes to publish.

MARKETING AUTHORISATIONS (PRODUCT LICENCES)

39. Guidance on marketing authorisations is provided in Guidance Note 81 and should be read alongside the "Notice to Applicants" (Volume II of the Rules Governing Medicinal Products in the European Community, ref. 111/5944/94, published January 1995). These can be ordered from the MCA's Eurodirect Publications Office, 10-2, Market Towers, 1 Nine Elms Lane, London SW8 5NQ (enquiries on 020 7273 0352, fax 020-7273 0353, e-mail info@mca.gov.uk).

APPENDIX 1 WORDS AND PHRASES

The words and phrases listed below have all contributed to a determination by the MCA that products they were associated with were medicines. 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 MCA 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. Other words and phrases may make a contribution to a MCA determination that a product they are associated with is a medicine.

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 the immune system"	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 on the metabolism.
"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.
"Can lower cholesterol"	In context, a high level of cholesterol may be an adverse condition, and a claim to lower it may suggest that the product can treat that adverse condition, and may be administered with a view to having a significant effect on the metabolism.
"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 (successfully) 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 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 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 or 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/pubic 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)
2 Torrington Place
London
WC1E 7HW

Tel: 020 7580 5555
Fax: 020 7580 4072

Aromatherapy Trades Council (ATC)
PO Box 387
Ipswich
1P2 9AN

Tel: 01473 603630
Fax: 01473 603630

Association of British Pharmaceutical Industry (ABPI)
12 Whitehall
London
SW1A 2DY

Tel: 020 7930 3477
Fax: 020 7747 1416

The Ayurvedic Company of Great Britain (TAPASI)
81 Wimpole Street
London
W1G 9RF

Tel: 020 7224 6070
Fax: 020 7224 6080

Ayurvedic Trade Association
C/o 6 Chiltern Street
London
W1M 1PA

Tel: 020 7706 0070
Fax: 020 7706 0060

British Herbal Medicines Association (BHMA)
3 Wickham Road
Boscombe
Bournemouth
Dorset
BH7 6JX

Tel: 01453 751389
Fax: 01453 751402

British Institute of Regulatory Affairs (BIRA)
7 Herons Quay
Marsh Wall
London
E14 9XN

Tel: 020 7538 9502
Fax: 020 7515 7836

Broadcast Advertising Clearance Centre
200 Gray's Inn Road
London
WC1X 8HF

Tel: 020 7843 8265
Fax: 020 7843 8154

Chinese Medicine Association of Suppliers
8th Floor
87-90 Albert Embankment
London
SE1 7UD

Tel: 020 7587 6700
Fax: 020 7587 6720

Cosmetics, Toiletry & Perfumery Association Limited (CTPA)
Josaron House
5/7 John Princes Street
London
W1M 9HD

Tel: 020 7491 8891
Fax: 020 7493 8061

Department of Trade and Industry
Consumer Safety Unit
1 Victoria Street
London
SW1H 0ET

Tel: 020 7215 5000

Food Standards Agency
PO Box 30080
Elephant & Castle
London
SE1 6YA

Tel: 0845 7573012
Fax: 020 7972 2340

Health Food Manufacturers Association (HFMA)
63 Hampton Court Way
Thames Ditton
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