HEALTH FOOD MANUFACTURERS' ASSOCIATION

CODE OF ADVERTISING PRACTICE

(Abridged Edition)

HFMA Code of Advertising Practice
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This booklet is an abridged version of the HFMA Code of Advertising Practice, providing essential information for non-members of the Association.

Members of the Association are provided with a copy of the complete document, containing information on borderline issues and regulatory considerations.

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INTRODUCTION

The Health Food Manufacturers' Association (HFMA), founded in 1965, is the authoritative and responsible voice for the UK natural products industry and promotes, protects and defends the general interests of members of the industry and promotes high standards of product manufacture and presentation to ensure consumer safety, responsible and informative communications and compliance with applicable legislation. We represent around 125 manufacturers and suppliers of specialist health products, notably food supplements, herbal products, natural remedies, sports nutrition products, natural cosmetics and health foods.

This Code, administered by HMFA CLEAR CHECK® accredited compliance service[1], was established as a focus for industry self-regulation in terms of product advertising and promotional standards. The underlying principle of the Code is for labelling and advertising to be presented in a considered, fair, legal and truthful manner.

Compliance with this Code of Advertising Practice, in spirit as well as in principle, is a condition of HFMA membership. With the exception of broadcast advertising, members are required to submit product labels and advertising to the public for pre-vetting by a CLEAR CHECK™ Code Administrator, as follows:

- labelling and advertising materials for food supplements
- labelling and advertising materials for 'functional foods' (foods associated with health claims)
- labelling and advertising materials for foods for specific groups
- labelling and advertising materials for cosmetic products
- advertising materials for licensed medicinal products (includes those with marketing authorisations, registered traditional herbal medicines, homeopathics, products with licences of right)

The principles of the Code apply to all advertisements, including those directed to the trade and health professional, and, whilst pre-vetting of these materials is not mandatory, it is strongly recommended that they also be submitted.

In the case that copy has been vetted and agreed by an alternative association or regulatory body, evidence of this must be provided. Evidence of MHRA authorisation is required for medicinal products.

Submitted copy is treated as confidential and is not disclosed to anyone outside CLEAR CHECK™ without prior permission.

The Code Administrators provide comprehensive advice on all aspects of materials that fall within the scope of the Code, including the labelling and advertising of food supplements, foods and cosmetics, and the advertising of medicinal products in the UK. The focus of the service is on assisting members to present their products within the established legal framework and industry codes and guidelines. General guidance on classification and determining suitable claims for products outside the scope of the Code may also be provided on request.

For the purposes of the Code, the term 'advertising' means the making of a representation in any form in connection with a trade, business or profession in order to promote the supply of goods or services and includes:

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[1]Surrey and Buckinghamshire Trading Standards have assessed HFMA CLEAR CHECK® service for its food standards support and concluded that "The quality level has been independently reviewed and in our opinion is likely to provide users of those services with a defence of 'having taken all reasonable precautions and exercised all due diligence". Contact HFMA CLEAR CHECK® for more details.

- magazine and newspaper advertising (text and illustrations)
- leaflets, brochures and direct mailings & other electronic or printed material
- advertorials
- posters
- point of sale materials
- television and radio commercials
- product-related websites
- on-line advertisements
- video and audio tapes/discs
- press releases
- films and other recordings
- verbal representations by commercially interested parties
- on-line marketing communications (e.g. social media content) which falls under the control of the marketing company

There are many other areas for which the manufacturer or distributor is legally responsible, related to, for example, product safety and manufacturing practices that are not covered by the Code. Companies should make sure they are conversant with applicable legislation, and clearly understand their responsibilities in this regard. A company is responsible for ensuring that all applicable legal requirements are complied with.

To complement the Code and assist members, various guidance notes, including for example on the labelling of food supplements, have been compiled; these are available to members via the HFMA website.

PROCEDURE FOR HFMA CLEAR CHECK® REVIEW OF MATERIAL

Submission of material

Submissions of labelling and advertising material for review should include, as appropriate/applicable:

- A copy of the material including visuals (which may be in outline form)
- Details of approval of the relevant material from another UK self-regulatory body, certification body, MHRA or trading standards office, if applicable
- A full quantified list of all ingredients if the product is not licensed
- In the case of advertisements, an indication of where the advertisement is to appear or how it is to be distributed or presented
- For medicinal products, a copy of the relevant parts of the product licence/registration. Any subsequent variation/s made by the licensing authority must also be notified
- Any other information that impacts on labelling which would not otherwise be known, for example, the presence of irradiated ingredients in foods, novel food status

Substantiating evidence for claims must be supplied for consideration upon request by a Code Administrator.

Process and scope of review

The material submitted is reviewed by a Code Administrator for compliance with the principles of this Code of Advertising Practice, with reference to:

- the relevant labelling or advertising regulations
- the terms of the marketing authorisation or product licence/registration, where applicable
- government and industry guidelines
- other relevant codes of practice

Advice on any required/recommended alterations is then provided. Where available, the Code Administrator will provide guidelines and checklists on subjects relevant to the material submitted. In the case of issues not clearly defined in the regulations, current industry practice and the current approach of the authorities are taken into account to determine the suitability of a proposal.

Note that the following areas are outside the scope of the Code and are not routinely considered as part of the review:

- accuracy and efficacy of formulation, except in relation to appropriateness of claims
- the safety of ingredients and finished product
- the accuracy of declared quantities in final product
- the accuracy of GM status claims and other negative-presence claims
- the determination of novel ingredient/food status
- the content of any referenced websites, publications or similar [separate review of these materials can be carried out]

Agreement and the review stamp

When agreement has been reached on suitable copy, the copy is returned stamped with a reference number.

The review stamp conveys compliance with the principles of the HFMA Code of Advertising Practice and is provided based on current scientific opinion and current regulatory and industry practice. Until a body of case law has been built up to form the basis of an authoritative statement, advice on the law and application of the regulations can be given as informed opinion only.

The review stamp does not constitute an endorsement or approval of the product or services offered, nor should it be regarded as a guarantee of the legality of the product. It remains the responsibility of the manufacturer/supplier/importer to ensure that the product placed on the market meets its claims.

Appeals

In the event that agreement cannot be reached with the Code Administrator, an appeal may be made to the Advertising Committee, with whom ultimate responsibility for interpretation of the Code rests.
Appeals applications should be directed to the HFMA Executive Director at Head Office, with notice given to the Code Administrator concerned. Strict confidence is maintained throughout the proceedings.

Resubmission

Copy should be resubmitted for review every two years if it is still in use. At times, changes in the law, codes of practice or interpretation may necessitate an earlier review.

CHARGES

An hourly consultation rate is applied to all HFMA CLEAR CHECK® services, billed in 15 minutes increments. Telephone discussions and product-related meetings of longer than ten minutes duration (5 minutes for non-members of the HFMA) are chargeable at the hourly rate.

Details of the current fee structure may be obtained by contacting the HFMA office. Any changes made are notified by the HFMA Secretariat.

Invoices are issued monthly for payment within 30 days of the invoice date.

HFMA CODE of ADVERTISING PRACTICE

PRINCIPLES OF THE CODE

1. General

1.1 The Code is applied in spirit, which means that the intention behind the principles as well as the exact wording is taken into account. It is not enough that there is an interpretation of the presentation of material that meets the requirements of the Code; no reasonable interpretation should contravene it.

1.2 Information provided should not be misleading, for example by the inclusion of false or exaggerated information. Misleading information in one part of an advertisement is unacceptable even if it is modified or contradicted in another part, including illustrations.

1.3 Information should not deceive the consumer, even if the information is factually correct, for example by the omission of material details, or exert undue influence, causing the consumer to take a different action.

1.4 Information should not claim or infer that a product has particular characteristics or functions which it does not in fact possess.

1.5 Labelling and advertising materials should be easy to understand and clearly legible.

1.6 All descriptions, claims and comparisons which relate to any objectively ascertainable facts must be capable of substantiation.

1.7 Material must be prepared taking the perception of the receiver into account. The impression obtained from a quick glance is considered along with that obtained from a detailed reading. Images, illustrations, sounds, shapes, the wording chosen and the use of emphasis are examples of the factors considered to determine the overall impression gained from the material.

1.8 Advertising should be set out taking account of the principles relating to taste and decency, should not be offensive and should not exploit the lack of knowledge or experience of the reader (e.g. by use of complicated scientific terminology).

1.9 Unsolicited questions from journalists, health practitioners, the trade or members of the public may be replied to truthfully and fully, either verbally or by a personal letter. However, responses to solicited enquiries are considered extensions of advertisements and the usual restrictions apply, including the prohibition on medicinal claims for unlicensed products. Solicited enquiries include those resulting from telephone help-lines or ‘further information’ offers on labels or in advertisements.

1.10 No labelling or advertisement should encourage or condone, directly or indirectly, the indiscriminate, unnecessary or excessive use of the product in question.

1.11 Advertisements must be clearly distinguishable from editorial matter, for example by labelling as an advertising feature or advertorial.

1.12 Advertisements for products must not be placed or accepted on the basis that they are to be positioned in juxtaposition to editorial matter which suggests that the products are suitable for purposes for which they may not be advertised.

1.13 No advertisement shall denigrate or attack unfairly any other products, goods, individuals, competitors or services.

1.14 No advertisement shall denigrate orthodox medicine or orthodox drugs.

1.15 Advertising shall not suggest that normal good health can be affected by not taking the product.

1.16 Advertising shall not suggest that the effects of taking a product are guaranteed.

1.17 Advertising should not be directly targeted at children or induce children to ask their parents or other adults to purchase the advertised product for them.

1.18 Advertisements should not falsely represent the business as a consumer (for example; a company website carrying comments supposedly from consumers but which have been drafted by employees of the business).

1.19 Information provided in labelling and advertising must not claim or imply copy has received approval or endorsement by the HFMA.

1.20 Advertising should not bring the health products industry into disrepute.

2. Claims and Comparisons

2.1 Unlicensed products, including food supplements, must not be presented for medicinal use in labelling, advertising or promotion. This prohibition also applies to advertisements addressed to the trade. Words, phrases or visuals must not claim or imply the treatment, cure or prevention of any ailment, illness or disease.

2.2 Exaggerated claims, direct or implied, are not acceptable. Words such as 'magic', 'mystical', 'miracle' or 'wonderdrug' should not be used.

2.3 Negative claims, that is claims that a product does not contain a given ingredient, should only be used in cases where the ingredient mentioned is likely to be found in similar products and should not be given in a manner which gives the impression that the ingredient is generally unsafe or harmful.

2.4 Slogans and abbreviated claims which, because of brevity or for any other reason, are capable of misinterpretation shall be used only in association with copy that clearly indicates their meaning.

2.5 No advertisement shall, by statement or implication, suggest that a product contains some unknown active principle.

2.6 Advertisements should not suggest that the safety or efficacy of a product is due to the fact that it is ‘natural’.

2.7 Care should be taken in the use of the word 'natural' or similar terms, used unqualified to describe a product or its ingredients. Made, or derived, from natural sources, may be the more appropriate description. In advertisements for products which combine ingredients from natural sources with synthetic ingredients, the term 'natural' must be used only in reference to those constituents to which it applies.

2.8 Advertisements should not imply that a product is wholly or mainly of a herbal nature unless the active ingredients consist wholly or mainly of parts of plants.

2.9 A product described as 'unique' should have properties or active ingredients which set it apart from others in the market.

2.10 A product may not use the word 'new' for more than one year following introduction to the market. To justify such a description the advertiser must be able to demonstrate the existence of real novelty in effect or formulation or presentation.

2.11 Medicinal and food supplement products may be described as palatable or nice to eat, provided this is purely to inform the consumer and not couched in terms which might encourage excessive or unnecessary use of the product.

2.12 No claims that the taking of a product is unaccompanied by side effects may be made. This does not prohibit claims that a product does not cause specified side effects (such claims must be backed by robust and suitable evidence). Claims should also take account of any side effects of the non-active ingredients.

2.13 No claim shall be made based on the fact that a product is legally available without a prescription.

2.14 All comparisons shall be balanced, fair and supportable. Comparisons shall not unfairly denigrate or discredit a competitor product, ingredient or treatment. Superiority claims must be supported by direct comparative tests or similar and where applicable make it clear the aspect of the product or marketers performance that is being claimed to be superior.

2.15 Comparisons with identifiable competitors should be between products meeting the same need or intended for the same purpose and should be based on objective criteria (one or more material, relevant, verifiable and representative feature, e.g. price, market share, quality) and be presented in a manner which does not mislead. Consumers must have access to the information on which the comparison is made.

2.16 Comparisons that do not identify the product which is being compared, such as comparisons between a marketers own products should be clear, fair and not misleading.

2.17 Subjective claims should be clearly set out as representing the views of the individual or business.

2.18 Advertising should not describe a product as ‘free’ or similar if the consumer has to pay anything other than the unavoidable cost of responding to the offer and the collection or delivery of the product.

2.19 Green/environmental claims must be clear, accurate, relevant and not misleading and presented in a manner which indicates if the claim applies to the complete product, a component of the product or to the packaging.

3. Endorsements, Testimonials and Recommendations*

3.1 An advertisement for a food or food supplement product should not suggest that the product is recommended by a member of the medical, dental, pharmaceutical or related professions. Illustrations of any person who might appear to be a doctor, dentist, pharmacist, nurse or member of any related profession are not permitted.

3.2 Recommendations or endorsements of food products by national associations of medical, nutrition or dietetic professionals and health-related charities may be permissible where relevant national rules apply.

3.3 Recommendations from medical, para-medical or scientific specialists on a cosmetic ingredient or product or a general message on hygiene or beauty are acceptable, provided they are established on the basis of adequate and appropriate evidence.

3.4 Any material in testimonials which is contrary to this Code must not be used.

3.5 Marketers must hold documentary evidence that a testimonial or endorsement is genuine and retain contact details of the person who provided it. Permission for use of the testimonial must be obtained.

3.6 Copies of testimonials must be made available if the Code Administrator requires them.

3.7 Testimonials and copies of press articles may not be used to make claims for a product which the advertiser himself may not make.

3.8 Testimonials should represent the genuine views of the user. If the testimonial is shortened, care should be taken that the original meaning is not changed in any way.

3.9 The writers of testimonials may not be identified as members of any of the health care professions.

3.10 Use of symbols or logos must not imply that a product has achieved the required relevant third-party endorsement when it is not the case

[**** Medicines Law prohibits the inclusion of testimonials or other promotional material in labelling and package leaflets of medicinal products]***

4. Promotional Activities for Unlicensed Products

4.1 Any material that accompanies or is available in association with unlicensed products, in any commercial setting, should not make claims which are not permitted for the product or its components [for example; a book written by a 3rd party which discusses lifestyle choices relating to disease risk reduction but which is placed next to commercial product; the

availability of clinical scientific papers on a commercial website marketing food supplements]

4.2 If the labelling or advertisement for a product also mentions or offers for sale printed or electronic material (e.g. a book, disc or similar), or includes an internet address or quick response code, the content of the relating information will be treated as an extension of the advertisement and subject to the same rules.

4.3 Printed or electronic material making generic claims may not be placed in a commercial environment in juxtaposition to (or in association with) a product for which the claims made by the accompanying copy could not be made.

4.4 Seminars held to describe the medicinal properties of generic substances must not refer to or depict products and this includes product displays, product give-aways and the presence of catalogues or other advertisements for products. The advertisements for the seminar may not mention or depict products.

4.5 Articles, brochures, hand-outs etc. by companies describing the medicinal properties of generic substances, must not mention or be associated in any way with products.

4.6 Products that are not medicines should not be grouped together with medicines under any general indication such as 'Herbal Remedies' which could give the impression that they are medicines. This applies in all retail situations, including on commercial websites.

5. Principles Specific to Foods and Food Supplements

The principles detailed in sections 1-4 of the Code also apply to marketing communications relating to food supplements

5.1 Any fancy name used in addition to the legal name must not make a prohibited or misleading claim for the product.

5.2 Trade-marked/brand names that can be construed as a nutrition or health claim may be used if authorised or accompanied by a relevant authorised claim. However, products bearing trademarks or brand names which do comply with applicable legislation but which existed before 1st January 2005 may benefit from a defined transition period (to 19th January 2022) after which time the appropriate legislative requirements will apply.

5.3 Terms such as 'natural', 'fresh' and 'pure' should be used in accordance with guidelines issued by the UK competent authorities from time to time.

5.4 Industry agreed warnings for food supplements containing certain ingredients, including vitamin A, vitamin K and iron, are to be applied as appropriate.

5.5 Advisory statements as agreed with the UK competent authority for food supplements containing high levels of certain vitamins and minerals are to be applied as appropriate.

5.6 Only permitted nutrition claims and authorised health claims may be made, in accordance with applicable legislation or in line with any guidelines issued by the UK competent authorities.

5.7 Health claims should only be made for the nutrient, substance, food or food category for which they have been authorised and not for the food product or food supplement that contains them.

5.8 A degree of flexibility of the wording of health claims is allowed, provided that its aim it to help consumer understanding, taking into account factors such as linguistic and cultural variations in the target population. Where alternative wording is used it should convey to the consumer the same meaning as that of the authorised claim.

5.9 General and non-specific health claims, such as 'supports well-being', 'hair care' can be made but only where accompanied by a relevant authorised health claim.

5.10 Where a health claim is made the product label, or if none the product advertising, must make clear the importance of a balanced and varied diet and healthy lifestyle.

5.11 Claims should not imply that normal foods cannot provide a healthy diet or that there is widespread vitamin or mineral deficiency.

5.12 Advertisements and labelling for food supplements should avoid any suggestion that supplements can take the place of a well-balanced diet.

5.13 Food supplements may be presented to safeguard nutrient levels in the diet but advertisements should not suggest that it is necessary for ordinary healthy adults to supplement their diet.

5.14 The labelling, presentation and advertising of food supplements shall not state or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

5.15 Health claims must not make reference to the rate or amount of weight loss.

5.16 Health claims which make reference to recommendations of individual doctors or health professionals and associations other than national associations of medical, nutrition or dietetic professionals and health-related charities to which national rules apply, are prohibited.

5.17 Claims which compare the nutritional content of a food supplement with a food (e.g. Supplement X provides as much vitamin C as 4 oranges) are not permitted.

6. Principles Specific to Cosmetic Products

The principles detailed in sections 1-4 of the Code also apply to marketing communications relating to cosmetic products

6.1 The cosmetic function of the product, unless obvious from the presentation or advertising copy, must be clearly stated.

6.2 Claims made in the presentation and advertising of a cosmetic product (e.g. labelling, name, trademark, text, graphics and visuals) should not state or imply that the product has functions or characteristics which it does not possess.

6.3 Medicinal claims should not be made for a cosmetic product, however, claiming a secondary preventative purpose for a cosmetic product may be feasible in certain circumstances; the use of such claims will require to be assessed on a case-by-case basis.

6.4 Claims that no animal tests have been carried out are only permitted if the manufacturer and his suppliers have not carried out or commissioned any animal tests on the finished cosmetic product, or its prototype, or any of the ingredients the product contains, or used any ingredients that have been tested on animals by others for the purposes of developing new cosmetic products.

6.5 Claims, either direct or implied, for a cosmetic product must conform to the list of common criteria developed by the European Commission: legal compliance, truthfulness, evidence support, honesty, fairness and informed decision-making, and associated best practice guidance for claim substantiation evidence.

6.6 The responsible person for a cosmetic product is obliged to ensure claims are justifiable.

6.7 Words such as 'cosmeceutical', which makes a pharmaceutical implication, should be avoided.

6.8 Claims regarding the efficacy of sunscreen products are required to take account of the recommended principles adopted by the European Commission.

7. Principles Specific to Medicinal Products

The principles in sections 1-3 of the Code should also be taken into account

7.1 General Principles on Advertising and Promotion to the Public

7.1.1 Advertisements which offer to treat cancer, or to prescribe a remedy for its treatment, or to give advice relating to treatment are prohibited.

7.1.2 Advertising to the public for a prescription only medicine (POM) is not permitted.

7.1.3 Advertising must be set out in such a way to make it clear that the message is an advertisement and that the product is a medicinal product.

7.1.4 Claims made in advertisements must be consistent with the product's Summary of Product Characteristics and must not promote a medicine for uses outside the scope of the therapeutic indications listed on the approved SPC or data sheet. This includes claims relating to the clinical effect of the product as well as claims relating to speed, mode and duration of action etc.

7.1.5 Advertisements should not refer to any medicine as 'essential'.

7.1.6 An advertisement for a medicinal product should not contain a suggestion that it is recommended by a member of the medical or allied health professions, by scientists, or by persons who are none of these but who, because of their celebrity could encourage the consumption of medicinal products.

7.1.7 No advertisement should suggest that a medicinal product is a foodstuff, cosmetic or other consumer product. It is acceptable to indicate that a product is palatable but the advertising shall make it clear the product is a medicine.

7.1.8 An advertisement for a medicinal product should not suggest the effects of taking a medicine are better than, or equivalent to, those of another treatment or medicinal product, if it is possible to identify the brands being compared.

7.1.9 Advertising shall not contain any offer to diagnose, prescribe or treat by correspondence, telephone, facsimile or electronic communication.

7.1.10 Advertisements should not suggest that health can be enhanced by taking the medicinal product or that health could be affected by not taking the product.

7.1.11 Advertising should not state or suggest that the effects of taking a medicinal product are guaranteed.

7.1.12 Advertisements should not encourage unnecessary, indiscriminate or excessive use of any medicine.

7.1.13 Advertising shall not contain improper, alarming or misleading claims of a recovery.

7.1.14 Advertising should not suggest that a product does not have any side-effect or that its safety or efficacy is due to the fact it is 'natural'. It is acceptable to indicate the absence of a specific side effect if that effect is common amongst other, similar products.

7.1.15 Advertising shall not in any way tend to induce unjustified concern that the reader is suffering from any illness, ailment or disease, or that without treatment they may so suffer or suffer more severely.

7.1.16 Advertising shall not contain any material which gives the impression that a medical consultation or surgical operation is unnecessary. It shall not discourage those who see it or hear it from seeking medical advice.

7.1.17 Advertising shall not be directed exclusively or principally at children (under 16's).

7.1.18 No advertisement for a medicinal product should contain material which might, by a description or detailed presentation of a case history, lead to erroneous self diagnosis.

7.1.19 Advertisements should not imply, directly or indirectly, that the normal incidents of the human condition, such as fatigue or irritability, require continuous treatment by medicines.

7.1.20 Advertisements should not use, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body, or parts thereof.

7.1.21 Care should be exercised to ensure that advertisements do not cause lay persons to be confused by the use of medical or invented terminology or other information unsuitable for the lay public.

7.1.22 In the case of promotional aids to the public, without claims, which serve solely as a reminder (e.g. t-shirts, pens, mugs) then only the brand name need be listed i.e. the general information for advertising is not required.

7.1.23 Medicines shall not be promoted to the public with the offer to refund money to dissatisfied users.

7.1.24 Supply of samples of medicinal products for promotional purposes, by the licence or registration holder and anyone acting on their behalf (e.g. distributors), by pharmacies, retailers or similar forms of commercial undertaking and those acting with their consent or on their behalf, to any member of the public, is prohibited. This includes the provision of vouchers/coupons to enable the consumer to obtain product for free or at an unreasonably low cost.

7.1.25 Advertisements should not state that a product has been approved or endorsed by the MHRA or Department of Health or any other relevant body. Advertisers may state that a medicinal product is licensed or authorised.

7.2 Essential information in consumer advertising

Consumer advertising for medicinal products must incorporate the following. This does not apply to products with Product Licences of Right (PLRs), Homeopathic products registered under the Simplified Scheme, or materials without promotional claims (i.e. those just bearing the brand or product name):

a) The name of the product.

b) Information necessary for correct use of the medicinal product, i.e. the product indications, or at least one indication for use, consistent with the SPC plus any additional information specifically required for the product.

c) The name of the active ingredient (if the product contains only one active ingredient). Provision of a pack shot which is sufficiently large enough for the active ingredient to be clearly legible fulfils the requirement. If the product name includes the name of the active there is no need to list the active ingredient separately.

d) A clear and legible instruction to 'always read the label' if the label carries full consumer information. If information is instead provided on an in-pack leaflet, advertising copy must direct the consumer to 'always read the leaflet'.

Essential information must be clearly legible, placed prominently, be in a print size in proportion to the rest of the copy and placed horizontally.

7.3 Additional principles specific to Traditional Herbal Medicines (THMs)

7.3.1 Advertisements for THMs must make it clear that the product is a traditional herbal medicine.

7.3.2 All advertisements for THMs must include the following statement:
'Traditional herbal medicinal product for use in *[specify one or more indications for the product consistent with the terms of the registration*] exclusively based on long standing use as a traditional remedy.' [When placed in the body of the advertisement rather than as a footnote this text meets with the requirement to include an indication of use of the product]

7.3.3 Advertising for THMs must reflect the approved indication, accurately and in its entirety, for the product and not mislead the consumer as to the benefits that can be obtained from using the product.

7.3.4 Claims must be clearly set out in the context that the indication is based exclusively on longstanding use [e.g. traditionally used as a remedy for xx; long history of use as a traditional remedy for xx]

7.3.5 Advertising for THMs must not mislead consumers regarding the strength of supporting evidence for the therapeutic benefits of the product. Claims such as 'effective for' or 'clinically/scientifically proven', 'relieves xx' are unacceptable.

7.3.6 Advertising must not state or imply that a THM has been granted a marketing authorisation or that the benefits of the THM are comparable with those of a medicine which has a marketing authorisation. It is acceptable to state that a THM is a registered or authorised traditional herbal medicine.

7.3.7 Claims that a herbal medicinal product is 'organic' may only be made for products that have been certified by an approved Certification Body as meeting organic standards applicable to the production of herbal medicines.

7.4 Additional principles for Homeopathic Medicines registered under the Simplified Scheme or authorised under National Rules Scheme

7.4.1 **Homeopathic products registered under the Simplified Scheme**

(a) The content of advertising is limited to the information that is permitted for inclusion on the product label [Ref: Schedule 28, Human Medicines Regulations 2012]
No other information can be included.

(b) Mention of any specific therapeutic indication is not permitted.

7.4.2 **Homeopathic products authorised under the National Rules Scheme**

(a) Advertising may include the homeopathic use.

(b) Claims must be consistent with the authorised indication and clearly state that the product is *a homeopathic medicinal product used within the UK homeopathic tradition for* xx [the stated indication].

(c) Claims should be set out in the context of traditional use.

(d) Advertising must not imply that the efficacy of a product is based on clinical data or that efficacy has been demonstrated. Claims such as 'effective for', 'works to relieve' is not acceptable.

7.5 Principles for Medicines, including homeopathic medicines with Product Licences of Right

7.5.1 Products with PLRs may only be advertised to the consumer in accordance with the provisions of the Medicines (Labelling and Advertising to the Public) Regulations 1978 (SI 1978/41).

7.5.2 The promotion of a product for any disease listed in the relevant schedules to the regulations is not permitted, except where specific requirements are complied with.

7.5.3 Advertising must not include any reference to the Commission on Human Medicines, the Advisory Board on the Registration of Homeopathic Products, the MHRA or the Licensing Authority.

ANNEX I

CONTACT DETAILS

Aromatherapy Trade Council (ATC)
PO Box 219
Market Rasen LN8 9BR
Tel: 01673 844672
E-mail: info@a-t-c.org.uk Website: www.a-t-c.org.uk

The Advertising Standards Authority Ltd (ASA) /
The Committees of Advertising Practice (CAP)
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Website: www.gov.uk/government/organisations/department-of-health

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Tel: 020 7276 8829 (general enquiries help line)
Email: helpline@foodstandards.gsi.gov.uk
Website: www.food.gov.uk
Website FSA in Wales: www.food.gov.uk/wales
Website FSA in Northern Ireland: www.food.gov/norther-ireland

Food Standards Scotland
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ANNEX II

Food Supplements – Mandatory vitamin & mineral cautions

The provision of the following is mandatory for HFMA members

Vitamin A
The following warning notice should appear on the labels of all supplements providing more than 800µg of preformed Vitamin A (as retinol, i.e. not as beta carotene) daily:
'This product contains Vitamin A. Do not take if you are pregnant or likely to become pregnant except of the advice of a doctor or ante-natal clinic'

Vitamin K
Products providing more than 100µg of Vitamin K in the daily intake should carry the following warning:
'If you are taking anti-coagulants (blood thinners) do not take this product except on the advice of a doctor.'

Iron
For supplements where the total iron content of the package is equal to or in excess of 200mg, the following warning should be given:
'This product contains iron, which, if taken in excess, may be harmful to very young children. Keep out of sight and reach.'

Vitamins and Minerals provided in excess of EVM recommended level
The EVM (UK Expert Group on Vitamins and Minerals) recommendations of 2003 indicated potential safety issues with long term intakes of a limited number of vitamins and minerals [Vitamins C & B6, Nicotinic acid, Iron, Calcium, Magnesium, Zinc, Manganese, Phosphorus, Beta-carotene] when provided at above certain levels.

To enable the continued presence of applicable supplements on the UK market HFMA has agreed the use of **advisory statements** to be applied to labels of those products where the recommended daily intake provides in excess of the EVM level.

Label advisory statements and re-formulations in response to EVM findings, May 2004

Nutrient	**Threshold to trigger statement** (recommended daily amount)	**Label advisory statement/reformulation**
Vitamin C	> 1000 mg	'[This amount of Vitamin C]* may cause mild stomach upset in sensitive individuals'
Iron	> 20 mg	'[This amount of Iron]* may cause mild stomach upset in sensitive individuals'
Calcium	> 1500 mg	'[This amount of Calcium]* may cause mild stomach upset in sensitive individuals'
Magnesium	> 400 mg	'[This amount of Magnesium]* may cause mild stomach upset in sensitive individuals'
Beta-carotene	1) >7 mg 2) See footnote[1]	1) Encourage reformulation to ≤ 7 mg/day 2) Label statement: '[Beta-carotene]* should not be taken by heavy smokers'
Nicotinic acid	> 20 mg	1) Encourage reformulation to nicotinamide

		2) If nicotinic acid is used, label statement: '[This amount of Nicotinic acid]* may cause skin flushes in sensitive individuals'
Zinc	> 25 mg	Label statement: 'Long term intake [of this amount of zinc]* may lead to anaemia'
Manganese	See footnote[2]	Label statement: 'Long term intake [of this amount of manganese]* may lead to muscle pain and fatigue'
Phosphorus	> 250 mg	Label statement: '[This amount of Phosphorus]* may cause mild stomach upsets in sensitive individuals'
Vitamin B6	> 10 mg > 100 mg	Label statement: 'Long term intakes [of this amount of vitamin B6]* may lead to mild tingling and numbness' Encourage reformulation to lower daily amount

Notes on Table

* For single nutrient products, the words in square brackets may be deleted.

[1] Government officials considered that the labels of all food supplements containing beta-carotene should carry the advisory statement '[Beta-carotene]* should not be taken by heavy smokers.' Industry considered that this should only be on products recommending a daily amount > 7mg. This footnote is for information only.

[2] Government officials considered that the labels of all food supplements recommending a daily amount greater than 0.5mg manganese should carry this advisory statement. Industry considered that this statement could only be justified on products recommending a daily amount greater than 4mg. This footnote is for information only.

Notes

a) No vitamins are completely stable and they deteriorate at different rates. Amounts of vitamins are added to food supplements during manufacture to compensate for losses during shelf life. For very labile nutrients, such as vitamin C, the threshold values above refer to the declared amount and manufacturers will strive to use only the necessary quantities in the products to ensure 100 per cent of the declared value at the end of shelf-life.

b) All sources of nutrients in a product should be taken into account when declaring the quantities of nutrients and deciding if the trigger level for an advisory statement has been exceeded.

c) These advisory statements are based on current evidence and are subject to change in the light of new evidence and advice.

The Department of Health has published a guidance document [Label advisory statements and suggested reformulations] to reflect this agreement
https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs

The final EVM report was published in 2003; copy can be found at:
http://cot.food.gov.uk/cotreports/cotjointreps/evmreport/

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