Irish Pharmaceutical Healthcare Association

IPHA SELF-CARE ADVERTISING CODE VERSION 6.1

EFFECTIVE 01 JUly 2022

#InnovateForLife

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Irish Pharmaceutical Healthcare Association

We partner for better health through innovative medicines, vaccines and technologies.

1. PHILOSOPHY OF THE VOLUNTARY CODES, FUNDAMENTAL PRINCIPLES & LEGAL OBLIGATIONS

1.1 This is a voluntary Code and it is not intended to be read or construed as a document giving rise to legal rights or obligations, nor does it envisage that the rules of legal procedure should apply in the operation of its provisions. The essence of this Code is the unequivocal acceptance of its principles and procedures by agreement. A decision in favour of, or against, the advertising by a company by the Code Committee does not exclude the need for compliance with any laws in relation to the advertising of medicines and in particular does not exclude the application of the Medicinal Products (Control of Advertising) Regulations 2007 (S.I. 541 of 2007), as amended, nor other applicable legal statutes.

1.2 In compiling this Code, reference has been made, and regard had, to the law governing the advertising of traditional herbal and other medicines together with the Codes adopted by other organisations.

1.3 All companies trading in Ireland are bound by the laws of Ireland.

1.4 The application of this Code applies to the activities of member companies, affiliates non-membersignatories to this Code and partners of member companies, acting within Ireland or directing activities towards Irish consumers.

2. ACTIVITIES OF COMPANIES

2.1 The activities of companies that fall within scope of this Code must never be suchas to bring disrepute upon the Consumer Healthcare Industry, undermine confidence in medicine advertising or prejudice public confidence in consumer healthcare products.

Interpretative Guidance

1.1 A The objective of this Code is to ensure the highest possible standards in the promotion and advertising of consumer healthcare products where the objective is to influence the supply, sale or purchase by a consumer. Activities carried out on behalf of, and material used by, a company in Ireland must adhere to the requirements of this Code.

1.1.B Companies are encouraged to engage in resolution via intercompany dialogue before utilising the IPHA Code Committee for formal resolution when activities concern IPHA member companies, partners of member companies, affiliates or non-member signatories to this Code.

1.2 A Recognition is made by this Code to the role of other complementary bodies such as the Advertising Standards Authority for Ireland (ASAI) which provides a self-regulatory Code of Standards for Advertising and Marketing Communications in Ireland.

1.4A Companies have a responsibility to ensure that the activities of their affiliates and global companies adhere to the requirements of this Code when material or activities are conducted within Ireland or make reference to the availability or use of the medicine in Ireland.

2.1A A ruling of a breach of this clause is a sign of particular censure. Examples of activities that are likely to be in breach of Clause 2.1 include those that prejudice consumer safetyand/or public health, inadequate action or failure to comply with an undertaking of the Code Committee, and multiple breaches of a similar and serious nature within a short period of time.

3. SCOPE AND DEFINITION OF TERMS

3.1 In this Code the term "medicine" means a medicinal product as defined in Council Directive 2001/83/EC, as amended, and which is intended for human use.

3.2 The term **"traditional herbal medicine"** or **"traditional herbal medicinal product"** means a herbal medicinal product as defined in the Medicinal Products (Control of Advertising) Regulations 2007 (S.I. 541 of 2007).

3.3 The term ''herbal medicine'' means any medicine, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.

3.4 The term "consumer healthcare product" includes products defined as medicines and traditional herbal medicines.

3.5 The expression "product authorisation" or "marketing authorisation" means a licence granted or renewed by the Health Products Regulatory Authority in accordance with the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. 540 of 2007), as amended, or an authorisation granted or renewed by the European Commissionin accordance with Regulation 726/2004/EC, as amended, laying down Community procedures for the authorisation and supervision of medicines.

3.6 The expression "certificate of traditional-use registration" means a certificate of traditional-use registration granted by the Health Products Regulatory Authority in accordance with the Medicinal Products (Control of Placing on the Market) Regulations 2007, as amended, in respect of a traditional herbal medicine.

3.7 The term "advertising" includes any form of advertising, whether in a publication, or by the display of any notice, or by means of any letter (whether circular or addressed to a particular person via mail [including electronic means of communication]), press release or other document, or by words inscribed on any article, or by the exhibition of a photograph, or by way of sound recording, sound broadcasting or television or in any other way includingthe use of audio-visual materials such as films, video recordings, animations, data storage services and the like. It also includes any form of door-to-door information, electronic information, canvassing activity or inducement designed to promote the supply, sale or consumption of consumer healthcare products.

3.8 This Code has no application to advertisements regarding prescription only medicines. Any activity targeted towards health professionals with the intention of encouraging the prescription of a consumer healthcare product are governed by the IPHA Code of Practice for the Pharmaceutical Industry, regardless of the legal status of the product.

3.9 This Code does not cover:

(i) the labelling of consumer healthcare products and the accompanying package leaflets as required by law;

(ii) correspondence, which may be accompanied by material of a non-promotional nature, needed to answer a specific question about a particular consumer healthcare product;

(iii) factual, informative announcements and reference material relating, for example, to pack changes, adverse reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no medicine claims;

(iv) books, journals, periodicals and other publications that are imported into the State and which contain advertising which is not intended for or directed at persons residentin the State;

(v) information relating to human health or diseases, provided there is no reference, even indirect, to consumer healthcare products;

(vi) homeopathic medicines and food supplements.

(vii) medical devices.

(viii) genuine independent user generated content online without any influence from a company whether direct or indirect.

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4. GENERAL PROVISIONS

4.1 Advertising must encourage the rational use of a medicine by presenting itobjectively and without exaggerating its properties. The advert must not be misleading.

4.2 Companies must establish a Scientific Service to compile and collate all information relating to the safety of their products.

4.3 In addition to compliance with legal obligations, this Code must be observed and enforced in the spirit as well as in the letter.

4.4 Companies are expected to have an established copy approval process to ensure rigour with the requirements of this Code and ensure a sample of all advertising material is retained.

4.5 Advertisements that feature both medicines and non-medicines must make it clear which claims apply to which products.

4.6 For Point of Sale material generated by companies, such as Free Standing Units, medicines in these units must be kept at least 1.2 metres above the ground.

5. PROVISIONS FOR MEDICINES

5.1 A medicine must not be promoted prior to the granting of the product authorisation permitting its sale or supply.

5.2 The promotion of a medicine must be consistent with the terms of its productauthorisation.

(i) Press releases aimed at Healthcare Professionals must be non-promotional. Promotional press releases aimed at the public must make it clear that they are advertisements.

5.3 A Company shall not:

(i) promote to the general public or be associated in any way with any prize competition, or other activity, which is intended to encourage the unnecessary use of a Consumer Healthcare Product;

(ii) promote or be in any way associated with any other schemes which are intended to encourage the sale of a Consumer Healthcare Product if in the opinion of the Code Committee, they are likely to introduce any hazard to the consumer or to lower the tone of the Industry;

(iii) offer to refund money to dissatisfied users;

(iv) offer or supply any samples of medicines to the general public.

The provisions of this Section shall not be construed in a manner inconsistent with a person's statutory or other legal rights relating to the sale of goods and supply of services.

Interpretative Guidance

4.1A Long-term use, or use once the condition has been resolved, can be promoted provided it is supported by the product's SmPC or technical documentation, e.g. for the treatment of atopic dermatitis. However, advertising cannot normally suggest that it is good practice to use a consumer healthcare product for a prolonged period of time, when the conditionhas been resolved, or when further advice needs to be sought. Advertising must not encourage the purchase of excessive amounts of consumer healthcare products.

4.4 A The archive of sample material must make clear to whom advertising material is addressed, the method of dissemination and the date of first dissemination.

4.5 A Companies may be required to include a statement such as 'Product Y is a medicine'.

5.1A The applicability of this clause applies equally to the terms, text, method and visuals used within the advertising.

5.1 B This clause prohibits the use of "teaser" advertising.

5.2 A Advertising for the use of a product for prevention is only permitted if this is in line with the product authorisation.

5.2B Products containing antihistamines and/or sympathomimetics may be advertised to the public, provided that there is a recommendation that the consumer seeks further advice from their doctor or pharmacist.

6. PROVISIONS FOR TRADITIONAL HERBAL MEDICINES

6.1 Medicinal claims may not be made with regard to herbal medicines prior to traditional-use registration or granting of a marketing authorisation.

6.2 The promotion of a traditional herbal medicine must be consistent with the product's Registration or Marketing Authorisation (which includes the therapeutic indication(s) listed on the product's SmPC).

6.3 Advertising must make it clear that the product is a traditional herbal medicine.

6.4 Where the indication states "Traditionally used for…" or similar wording, this information must be stated in advertising material. Claims such as "clinically proven" or "effective in…" are not acceptable as registration for traditional-use is based exclusively on long-standing use.

6.5 Advertisements for traditional herbal medicines must not imply superiority over medicines which are subject to Marketing Authorisations.

6.6 Advertising shall not infer safety due to the product being natural or herbal.

Interpretative Guidance

6.3A Advertising must not mislead consumers as to the strength of evidence which supports a traditional herbal medicine's therapeutic benefits.

6.3 B For traditional herbal medicines the following claims are likely to be acceptable:

- 'Brand X is a registered traditional herbal medicine'
- 'Brand X is an authorised traditional herbal medicine'
- 'authorised as a traditional remedy for the treatment of…'
- 'Traditional herbal medicine 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'.

6.3 C The following claims would not be acceptable:

- 'Approved by the HPRA/Department of Health'
- 'Approved by the HPRA/Department of Health for the treatment of…'"

6.3D Advertising for traditional herbal medicines must not mislead consumers regarding the strength of evidence which supports the product's therapeutic benefits. The Traditional Herbal Medicines Registration Scheme is based on a demonstration that the product (or a comparable product) has been used as a medicine for at least thirty years; normally fifteen of which have to have been within the European Union. The Registration Scheme is only open to herbal medicines which are not able to obtain a Marketing Authorisation due to there being insufficient scientific evidence of the product's effectiveness.

7. CONTENT OF ADVERTISEMENTS

7.1 All advertisements and advertising activities must be genuine, accurate and truthful. All information provided or presented must be fair, balanced, capable of substantiation, be based on an up-to-date evaluation of all the evidence and reflect this evidence accurately and clearly.

7.2 All advertisements must be easily intelligible to the consumer and must not mislead either directly or indirectly. They must encourage the rational use of the consumer healthcare product by presenting it objectively and without exaggerating its properties.

7.3 Any illustration contained in an advertisement shall be regarded as an integral part of the advertisement.

7.4 All advertising must conform both in text and illustration to canons of good taste.

7.5 An advertisement must not:

(i) offer any consumer healthcare product or treatment for a serious disease or condition which requires medical treatment by a healthcare professional;

(ii) refer to chronic conditions or contain any offer to make a diagnosis or prescribe treatment by correspondence;

(iii) denigrate or attack unfairly any other products, goods or services;

(iv) make reference to competitors by brand name, nor rest on claims that a product does not contain a given ingredient which is in common use in competitor products in any way which may give the impression that the ingredient is generally unsafe or harmful;

(v) contain any exaggerated claim, direct or implied, or claim or imply the cure of any illness as distinct from the relief of symptoms of any ailment, disease or illness;

(vi) make claims based on safety without qualification, and it must not be stated that a product has no side effects, toxic hazards or risk of addiction.

(vii) use words such as “magic”, “miracle”, “mystical”, “secret active ingredient” etc. in connection with the claims made for the consumer healthcare product;

(viii) in any way induce or tend to induce fear;

(ix) persuade or tend to persuade towards the unnecessary use of a consumer healthcare product;

(x) be such as to deliberately use visual or aural intimations intended to influence consumers in ways of which they are not consciously aware;

Interpretative Guidance

7.2A When showing before and after pictures of a consumer using a consumer healthcare product, the visuals must reflect the evidence held as to the level of benefit that the average user could expect.

7.3A Companies should note that any text on shelf-ready packaging is likely to be viewed as advertising rather than labelling.

7.4A Care must be taken as to the impression that advertising material conveys (in line with the spirit of this Code), and in the use of medical terminology to ensure it does not mislead or confuse.

7.5A (i) Advertising must not discourage consumers from seeking medical or pharmacy advice.

7.5B (iii) Other companies, their products, services or promotions must not be disparaged directly or by implication.

7.5C (xiii) Care must be taken if editing a testimonial to ensure that the original meaning is not lost.

7.5D (xiii) Companies, their employees or agents must not develop and use testimonials regarding their own products.

7.5E (xiii) Testimonials are not appropriate substantiation for claims relating to safety, performance or intended use.

7.5F (xiv) If only a specific aspect or use of a product is new, advertising must make clear which aspect is new.

xi. contain any reference to a doctor other than a person who is registered in the Register of Medical Practitioners in Ireland or is a person entitled to be so registered or to hospital tests unless such reference can be substantiated by independent evidence and can be properly used in that manner;

xii. contain the words "college", "clinic", "institute", "laboratory" or similar terms unless an establishment corresponding to the description used does, and can be shown to, exist;

xiii. use testimonials in an advertisement except where they are limited to the genuine views of the user and an official or a certified copy is available with a signed and dated release of the person giving it.

Testimonials shall not be used in an advertisement for more than three years after the date on which they were produced by the users and shall not contain anything contrary to the provisions of this Code;

xiv. make use of the word "new" or confer an element of "newness" to any medicine which has been generally available or use in a therapeutic indication, which has been generally promoted in Ireland for more than 12 months;

xv. include top parity claims unless all similar over-the-counter medicines, both branded and generic, have been considered, and evidence supports that no other medicine has superiority over the named medicine in a given area, e.g. efficacy, speed of action, duration of action, etc.

7.6 All advertisements for traditional herbal or other medicines must comply with the requirements of the Medicinal Products (Control of Advertising) Regulations 2007 (S.I. 541 of 2007), as amended, and in particular:

(i) **Format of the advertisement**

The advertisement must be set out in such a way that it is clear that the message conveyed is an advertisement and that the product is clearly identified as a traditional herbal or other medicine.

(ii) **Reminder Advertisements**

In the case of an advertisement to the general public which is intended only as a reminder (i.e. which does not contain any claim), the advertisement shall consist solely of:

(a) the name of the medicine or its international non-proprietary name or the trademark and;

(b) advice to carefully read the instructions on the leaflet contained within the package or on the label, as the case may be (Annex I);

Interpretative Guidance

7.6A (i) Advertising must be clearly distinguishable from editorial matter or official correspondence, for example through the use of different typeface, emboldened borders, clear prominent statements that the content is advertising material when it may not be immediately obvious to viewers or recipients. This requirement applies to all media, whether in print or digital.

7.6C (iii)(c): In assessing legibility, the following points should be considered:

- the essential information must be large enough to be clearly legible and must be in proportion to the rest of the text. Companies must consider the distance from which a consumer might be viewing the advertisement. (Please refer to the media-specific guidance below.)
- the essential items must be placed horizontally and not vertically, or spiralling around the advertisement.
- attention must be paid to issues such as contrast between text and background, font style and print quality.
- the essential information must be placed prominently so that consumers are likely to notice it. It must not be placed on part of the advertisement or website that consumers are unlikely to view. For example, where a print advertisement includes details of a promotion, the medicines essential information should usually be placed before the terms and conditions of the promotion (each advertisement will be examined on a case-by-case basis.)

7.6D (iv)(b) The following terms are not thought to indicate a guarantee and are therefore generally acceptable:

- Claims which are preceded by 'may' or 'helps', for example,

  'may' (e.g. 'may relieve your symptoms for 24 hours')

  'helps' (e.g. 'helps get rid of pain')

  'could' (e.g. 'could relieve your symptoms for 24 hours')

(iii) The full advertisement shall contain the following minimum information:

(a) the name of the traditional herbal or other medicine, as well as the common name if the product contains only one active ingredient;

(b) information necessary for the correct use of the medicine;

(c) an express and legible invitation to carefully read the instructions on the leaflet contained within the package or on the label, as the case may be (Annex I); and

(d) if it is a traditional herbal medicine the words "Traditional herbal medicine for use in…" followed by a statement of one or more therapeutic indications for the product compatible with the terms of the certificate of traditional-use registration for that product, followed by the words, "exclusively based upon long-standing use".

(iv) No advertisement shall contain any material which:

(a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;

(b) suggests that the effects of taking the traditional herbal or other medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicine;

(c) suggests that the health of the subject can be enhanced by taking the traditional herbal or other medicine;

(d) undermines current healthy lifestyle advice;

(e) suggests that the health of the subject could be affected by not taking the traditional herbal or other medicine (this prohibition shall not apply to vaccination campaigns provided that such campaigns have been approved by the Minister);

(f) is directed exclusively or principally at children;

(g) might result in harm to children or which exploits their credulity;

(h) leads the public to assume that the traditional herbal or other medicine has some special property or quality which is in fact unknown or unrecognised;

(i) makes claims of uniqueness unless it is significantly different from traditional herbal or other medicines on the market;

(j) claims that the traditional herbal or other medicine advertised will promote sexual virility or be effective in treating sexual weakness (unless it is authorised for such an indication) or habits associated with sexual excess or indulgence or any ailment, illness or disease associated with those habits;

- Claims that make it clear that the cessation of symptoms applies to one specific episode, usually in the past tense (e.g. "Six weeks ago I had a verruca, now it has gone").

- Claims that make it clear that they refer to the process of treating a condition/ symptoms, rather than guaranteeing that the condition/symptoms will be completely resolved should be acceptable (e.g. 'to help clear congestion', 'to help take the itch out of insect bites', 'to help the cessation of diarrhoea'). Please note that such claims will be examined on a case-by-case basis.

- In some circumstances, instructional phrases or directions may be viewed as instructions to change behaviour rather than product guarantees. For example, 'Stop smoking' is healthy lifestyle advice and does not necessarily imply guaranteed efficacy. However, 'Stops coughing' featured next to a cough medicine pack shot is likely to be seen as a product guarantee, as would 'Stops scratching'.

7.6E (iv)(b) Examples of when this would be applicable include advertisements for products intended to assist consumers in giving up smoking which should make reference to the requirement for willpower in order to quit smoking successfully, or that products to help people loose weight should be used as part of a calorie-controlled diet and exercise.

7.6F (iv)(f) For the purposes of this Code, a child is someone under the age of 18. Advertising must not depict children using, or within reach of, consumer healthcare products withoutadult supervision unless it is appropriate and safe for them to do so. Advertisements featuring cartoons, characters and designs that are likely to be particularly attractive to children must be avoided.

7.6G (iv)(k) "Celebrities" include those individuals who are generally well-known in the public domain.

7.6H (iv)(m) Claims may not refer to a product being natural unless all of its components are naturally occurring.

7.6I (iv)(n) Advertising must advocate the cautious use of any medicine in pregnancy.

7.7A For comparative advertising, the following claim would be considered acceptable 'the only soluble pain reliever that works for up to 6 hours', where the only other products with this duration of action are solid dose tablets and capsules. However, the following claim would not be considered acceptable 'the only pain relief tablet that works for up to 6 hours', where there is a capsule that has the same duration of action.

(k) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity status, could encourage theconsumption of traditional herbal or other medicines;

(l) suggests that the traditional herbal or other medicine is a foodstuff, cosmetic orother consumer product;

(m) suggests that the safety or efficacy of the traditional herbal or other medicine isdue to the fact that it is natural;

(n) suggests that the traditional herbal or other medicine may be used in pregnancyunless use is clearly supported;

(o) could, by giving a description or detailed representation of a case history, lead to erroneous self-diagnosis;

(p) refers, in improper, alarming or misleading terms, to claims of recovery;

(q) uses 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 consumer healthcare product on the human body or parts thereof.

7.7 It is acceptable to make comparative statements, provided they are balanced and fair, they do not refer to an identifiable product or treatment and there is sufficient evidence to support them.

8 RESPONSIBILITY OF ADVERTISERS

8.1 An advertiser will be held responsible for the contents and form of any advertisement which may appear with his authority in connection with his products (Annex II).

8.2 Member and non-signatory companies to this Code must ensure effective, appropriate training is provided to all relevant staff concerned with the drawing up or distribution ofadvertising or activities covered by this Code.

8.3 Companies shall ensure their contracted third parties (including advertising and public relation agents etc.) that are commissioned to engage in promotional activities withinscope of this Code are provided with effective, appropriate training on the requirements described herein.

8.4 Advertisers shall keep available for supply on request a sample of all advertising emanatingfrom his or her undertaking together with information indicating the audience to whom it was addressed, methods of dissemination and date of first dissemination as well as substantiating material relative to any claims made in any advertisement. Such materialshall be made available to the Code Committee.

9 ONLINE ACTIVITIES

9.1 Information placed on the internet outside Ireland, placed there by an Irish company or withthe authority of such a company, that is directed to Irish consumers or makes reference to the availability or use of a consumer healthcare product in Ireland will come within scope ofthis Code, and must be reviewed and authorised to ensure Code compliance.

9.2 The requirements for advertising of products apply equally to advertisements that appear online. Care must be taken to ensure all the necessary information for advertisements to the public is provided to visitors, including that which is detailed in Clause 8.5.

9.3 Websites directed towards young adults must be careful not to encourage access and use by children.

9.4 Companies must ensure that they have appropriate monitoring in place where dynamic content can be added to a platform for which the company has ownership or control. This includes having and making available a moderation policy for acceptable content and theremoval of inappropriate content that may be in breach of the letter or spirit of this Code, may encourage irrational or inappropriate use of a consumer healthcare product (includinguse for an unlicensed or non-registered indication), is in bad taste or is likely to cause offence, may constitute bullying, etc.

9.5 Digital platforms owned or within the control of member companies must clearly providethe identity of the owner of the platform with relevant contact information (physical and electronic addresses, contact number(s)).

9.6 Company procedures must be in place to ensure that digital platforms that they own, or which are within their control are monitored for adverse events on a regular basis and in line with regulatory requirements, and how to manage complaints.

9.7 All data protection legislative requirements must be adhered to including ensuring the security of personally identifiable information and providing notices on how to "unsubscribe" as applicable.

9.8 Due diligence must be taken when companies link visitors to other digital platforms to ensure compliance with the requirements of this Code and the national advertising legislation. It must be clear to a user whether the link is to a company sponsored site oran independent site and when they are leaving a platform owned or in the control of a company for an external platform.

Interpretative Guidance

10.1 A Activities within scope include websites, social media sites, pay-per-click advertising and banner advertisements. Genuine user generated posts e.g. reviews that have not been influenced by a company are not within scope of this Code unless adopted and used by a company. Companies are advised to have a clear policy regarding social media use by company employees.

10.3 A When advertising to young adults, special care is needed to promote a responsible and cautious approach to self-medication.

10.4 A Companies should consider adding disclaimers that the views expressed on certain dynamic areas, e.g. message boards, are those of individual contributors and may not represent the views of the advertiser.

10.4 B The following are examples of entries that should be removed when message boards are moderated (this is not an exhaustive list):

- entries that suggest use of the product amongst groups for whom the product is contraindicated e.g. due to age or other medical conditions.
- entries suggesting that the directions for use do not need to be adhered to.
- entrieslikely to lead consumers to make an erroneous self-diagnosis.
- entries that discourage consumers from seeking professional advice when it would be pertinent to do so.
- entries that mislead as to the nature of the product or its ingredients.
- entries that suggest the product is side-effect free, or that use the word 'safe'.
- entries that suggest use of the product during pregnancy unless the product is authorised for use in pregnancy.
- entries that unfairly denigrate other products, ingredients or types of treatment.
- entries that suggest that a product can be used alongside other products (such as other medicines or alcoholic drinks) where this is not appropriate.

10.8A A clear notification through the use of a "pop-up box" to inform visitors that they are being redirected to an external platform can be considered. The appropriateness of redirecting visitors to such platforms must always be considered, and companies may be held responsible for content that may amount to advertising for one of their products. Companies must therefore ensure that all the necessary requirements that surround the advertising of their products apply.

10 ENFORCEMENT OF THE CODE

10.1 For inter-company complaints, it is required that every reasonable effort is made to resolve differences between the companies directly. Only after such efforts have been exhausted shouldthe matter be referred to the Code Committee for resolution.

10.2 The Code Committee shall be constituted as follows:

i. An independent legally qualified Chairperson at the invitation of the IPHA Consumer Healthcare Division.

ii. Two nominees of the IPHA Consumer Healthcare Division, one with medical or pharmaceutical expertise.

iii. One nominee from the non-IPHA member signatories to this Code.

iv. A nominee of the Institute of Advertising Practitioners in Ireland.

v. A nominee of the Pharmaceutical Society of Ireland.

vi. A nominee of the Advertising Standards Authority for Ireland.

10.3 When the Complainant is a signatory to this Code, the following requirements must be satisfied for a complaint to be considered valid:

i. the complaint must be in writing, fully cross referenced, of good quality and with relevant passages highlighted;

ii. it must specify those clauses of the Code which are alleged to have been breached;

iii. submission of an electronic version is acceptable. If submitted in hardcopy, seven bound copies of the complaint must be supplied. The Complainant must also provide the following in writing:

a) an unqualified undertaking to comply with every reasonable request of the Code Committee;

b) confirmation of acceptance of the final decision of the Code Committee (althoughthe company may reserve the right to have recourse to law, should it consider that route necessary). Failure by the Complainant to provide the required written undertaking of compliance and confirmation of acceptance of the Decision of the Code Committee, if relevant, will result in the Complaint not being processed further.

10.4 In the case of all other Complainants e.g. members of the public, healthcare professionals (other than those working directly for, or on behalf of, a company etc) the complaint must be submitted in writing. The Code Committee will examine the complaint in detail and determine which clauses of the Code have been breached. The Complainant's identity will not be disclosed without the Complainant's permission. However, anonymous complaints will not be accepted.

10.5 Proceedings before the Code Committee shall be informal.

10.6 The Code Committee shall determine its own rules of conduct and procedure and mayappoint a recording secretary. It will be deemed constituted with a quorum of three.

10.7 If a Committee member is employed by a company directly involved in a complaint, either as Complainant or Respondent, that member may not participate in the Code Committeeestablished to consider it. Furthermore, it is recognised that, on occasion, members of the Committee that are not employed directly by a company involved in a complaint may have some degree of conflict of interest (e.g. direct competitor, same therapeutic area etc.).However, it may not be feasible to require such a member to stand down. A member of the Code Committee must declare his or her interest to enable the Chairperson to make an appropriate decision. Confidentiality must be maintained.

11 RESOLUTION AND HEARING OF COMPLAINTS

11.1 The expeditious resolution of complaints by the Code Committee and the adoption of its findings in any case is accepted by all parties involved in a complaint as a fundamental principle under the provisions of this Code. The Complainant may withdraw the complaint at any time up until IPHA has received the response from the Respondent. However, the Complainant may only withdraw their complaint if they have identified a valid reason to believe that the Respondent did not breach the Code and such justification has been provided, in writing, to the Chair. If a complaint is withdrawn before it has been sent to the Respondent, the Respondent will not be informedabout that complaint. Where the Code Committee Chairperson is of the view that the alleged breach is serious, he or she may choose to continue the investigation of the matter.

11.2 The process commences when a valid complaint is received at the IPHA offices. A copyof the complaint is sent to the company alleged to have breached the Code (i.e. the Respondent) who is requested to:

i. provide a written response within 10 working days;

ii. provide an unqualified undertaking that the company will comply with every reasonable request of the Code Committee;

iii. confirm that the company will accept the final decision of the Code Committee (although it may reserve the right to have recourse to law should it consider that routenecessary).

iv. if responding in hardcopy, supply seven bound copies of the response.

11.3 A meeting of the Code Committee will be arranged within 30 working days of the date of receipt of a valid complaint (i.e. whether or not the Respondent has replied). The Code Committee will issue a final decision within 10 working days of its last meeting. Both the Respondent and the Complainant will be issued with a copy of the decision at the same time. The names of the members of the Code Committee hearing the complaint may onlybe made available to either party subsequent to the completion of a case and only upon request.

11.4 The Respondent will have 10 working days from the date on which the decision is issued to confirm in writing its intention to comply with any recommendations or sanctions imposed. Failure by the company concerned to do so will result in the matter being referred to the IPHA Board of Directors.

11.5 The above time frame for the Code complaints procedure can be shortened or lengthenedat the discretion of the Code Committee Chairperson, depending on the issues presented and the availability of the Chairperson and Committee members.

11.6 Where the Code Committee, having considered a complaint, has found that the Code has been breached it shall, without prejudice to the right of any affected party to have the matter resolved through the judicial process, have the authority to:

i. require the company concerned to cease the practice found to be in breach of the Code and take all necessary steps to avoid a similar breach in the future;

ii. reprimand the company for the breach of the Code;

iii. order the recovery of material found to have been in breach of the Code;

iv. order the correction of inaccurate information by way of direct contact or by publication of a corrective notice in terms approved by the Code Committee;

v. order the immediate publication of the decision in whole or in part and specify how and to whom the decision is to be communicated;

vi. in the case of difficult and/or persistent breaches of the Code, refer the matter to the Minister for Health;

vii. recommend to the IPHA Board of Directors suspension or expulsion from IPHA of the offending party;

viii. advise the Advertising Standards Authority for Ireland (and any other group it sees fit) of its findings and recommend that the subscribers to that Authority should not acceptthe advertisement which has been found to be in breach of the Code. This list is not exhaustive and other sanctions may be applied.

11.7 A Publication of Findings will be created which will contain the number of complaints heard by the Code Committee each year. A summary of each complaint upheld in whole or part will be provided, including the names of companies found to have breached the Code. However, where there are no complaints no report will be created.

A copy of the Publication of Findings shall be sent to:

- all members of IPHA's Self-Care Division

- all non-IPHA member Code signatories

- the Minister for Health and Department of Health

- the Health Products Regulatory Authority

Annex I

GUIDELINE ON THE USE OF A CAUTIONARY WARNING IN ADVERTISEMENTS FOR CONSUMER HEALTHCARE PRODUCTS

An express and legible invitation to carefully read the instructions on the leaflet contained within the package, or on the label, must be included. The invitation must be clear and must not be obscured or disguised in any way by the content, design or format of the advertisement. Any colour may be used so long as the colour does not interfere with legibility. In the case of a television advertisement the warning must appear on the screen for a minimum of four seconds regardless of the length of the advertisement.

Annex II

IPHA'S CHECKLIST FOR ADVERTISEMENTS FOR CONSUMER HEALTHCARE PRODUCTS

- ☐ Advertising promotes the responsible use of consumer healthcare products.
- ☐ Advertising does not precede the granting of a product authorisation or certificate of traditional-use registration or technical registration (as applicable dependent on product).
- ☐ Advertising is clear as to its nature and is distinguishable from any editorial matter.
- ☐ Claims are in line with the product's SmPC or technical documentation.
- ☐ Claims are accurate, balanced, substantiated and easily understood by consumers.
- ☐ Text and visuals do not undermine current healthy-lifestyle advice, and do not suggest that health can be enhanced by using the product (or could be negatively affected by not using it).
- ☐ Advertising is unlikely to cause unwarranted anxiety.
- ☐ Advertising is unlikely to lead consumers to make an incorrect self-diagnosis.
- ☐ Advertising does not overemphasise therapeutic response to using a product, nor contain or suggest any guarantees.
- ☐ There are no claims based on safety or side effects.
- ☐ Any use of the word "new" is appropriate in line with the relevant time period(s).
- ☐ Care is taken with any indication of a product being "unique".
- ☐ Only appropriate reference is made to use of the product in pregnancy.
- ☐ Any claims based on the product being "natural" does not infer product safety due to the product or its ingredients being natural or herbal.
- ☐ If both medicines and non-medicines are advertised together, it is made clear which claims and which essential information apply to each product.
- ☐ Any comparisons made are fair and capable of substantiation.
- ☐ Competitor products, companies or their activities are neither denigrated nor discredited.
- ☐ There are no claims that the product is better than or equal to another treatment or product.

- ☐ There are no claims based on the product being free of ingredients present in competitor products which suggests that ingredient is generally unsafe or harmful.
- ☐ There is no reference to competitor brand names.
- ☐ Any top parity claims are specific as to the aspect or superiority and consider all over-the-counter products, including generics.
- ☐ The messaging and visuals are unlikely to be particularly attractive to children.
- ☐ Any testimonials are genuine, are not in use beyond three years, remain up to date and comply with the requirements of the Code.
- ☐ For television advertising, an appropriate indication of time change isprovided before the person appears to have improved unless the effect is immediate.
- ☐ Full advertisements must provide:
    - o the name of the consumer healthcare product
    - o the non-proprietary name if the product contains only one active ingredient
    - o information necessary for the correct use of the product
    - o an express and legible invitation to carefully read the instructions on the leaflet contained within the package or on the label, e.g. “Always read the label/leaflet”
        - o For THMs, the words “Traditional herbal medicine for use in [specify one or more therapeutic indications for the product compatible with the terms of certificate of traditional-use registration] exclusively based on long-standing use”.
- ☐ Reminder advertisements:
    - o the full product name, non-proprietary name or trademark
    - o advice to carefully read the instructions on the leaflet contained within the package or on the label.
- ☐ The essential information is presented legibly and is sufficiently prominent.
- ☐ Advertising for traditional herbal medicines makes it clear that the product is a traditional herbal medicine.

Annex III

IPHA OPINION ON AN ADVERTISEMENT'S COMPLIANCE WITH THE IPHA CODE

Upon request, IPHA will provide its opinion on the compliance of non-prescription medicine advertising aimed at the public, exclusively for IPHA member companies and code signatories. Those availing of the service are expected to have reviewed the advertisement against the requirements of this Code and to have those requirements fully incorporated. IPHA provides an opinion not a definitive statement of compliance with the Code and the service is available without charge.

To avail of the service the following must be submitted to amybrophy@ipha.ie:

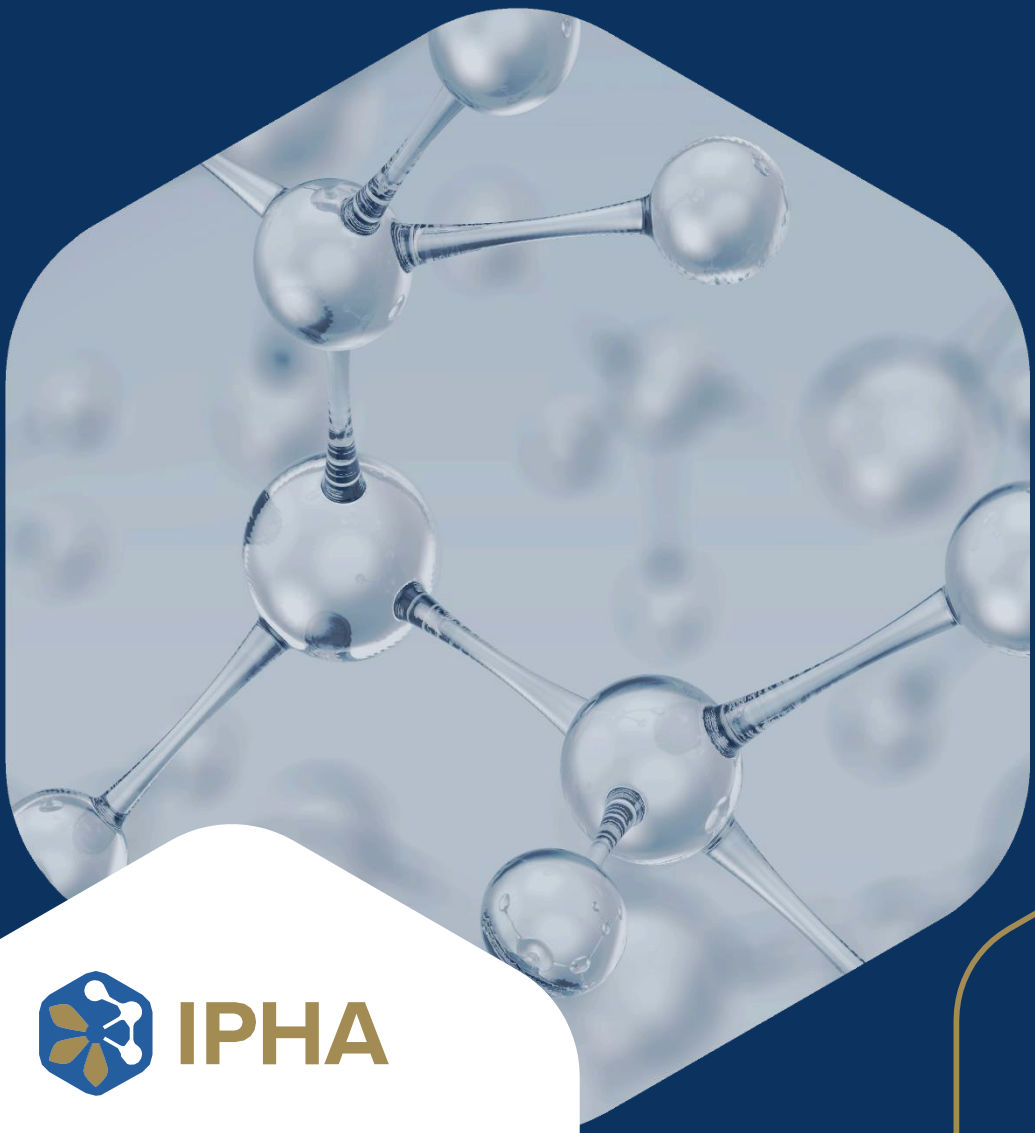
- Advertisement (script, story board, etc)
- Summary of Product Characteristics (SmPC)
- Product Specific Details (Part 1 of the license or screenshot of the 'promotion status' section of www.hpra.ie for that medicine)
- If required to substantiate a claim, the Package Leaflet and /or pack shot, journal paper etc.

Note that while IPHA commits to a response within 15 working days the review will not commence until a full submission has been received.

Example of excellent substantiation

The claim was that the product 'acts quickly not only to...'

The substantiation for the claim was that the approved carton stated that the product was 'Fast acting' and an electronic version of the approved carton was provided.



IPHA

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