



Code of **Standards of Advertising Practice** for the Consumer Healthcare Industry

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The Irish Pharmaceutical Healthcare Association (IPHA) represents the international research-based pharmaceutical industry in Ireland. Its member companies include both manufacturers of prescription medicines and non-prescription, or Consumer Healthcare, medicines.

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Introduction

This Code of Standards of Advertising Practice for the Consumer Healthcare Industry (the 'Code of Standards') has been prepared by the Irish Pharmaceutical Healthcare Association (IPHA) with a view to securing the universal acceptance and adoption of high standards of advertising of medicinal products which may be purchased by individuals without the presentation of a prescription. Acceptance and observance of the provisions of the Code of Standards are a condition of membership of the IPHA. Non-member companies are also invited to accept and observe the Code of Standards. Companies observing the Code of Standards acknowledge that its provisions are to be applied in the spirit, as well as in the letter.

The advertising of medicinal products for human use in the European Union is governed by Council Directive 2001/83/EC, as amended. The Code of Standards fits into the general framework established by Article 97 Paragraph 5 of this legislation, which recognises the role of voluntary control of advertising of medicinal products by self-

regulatory bodies and recourse to such bodies. The Code of Standards also incorporates changes arising from the Medicinal Products (Control of Advertising) Regulations 2007 (S.I. 541 of 2007). The Minister for Health, as provided for under Regulation 26 of the aforementioned regulation, endorses the parts of the IPHA Code of Standards that are derived directly (verbatim) from the aforementioned regulation.

This Code of Standards has been provided to help in the implementation of the requirements of the legislation. It is designed to be used in conjunction with, and is not a substitute for, the relevant legislation.

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1. Philosophy of the Voluntary Codes

This is a voluntary Code and 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 of Standards 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 medicinal products and in particular does not exclude the application of the Medicinal Products (Control of Advertising) Regulations 2007 (S.I. 541 of 2007).

2. Fundamental Principles and Legal Obligations

- 2.1 In compiling this Code of Standards, reference has been made, and regard had, to the law governing the advertising of all medicinal products and to the Codes adopted by other organisations.
- 2.2 All companies trading in the Republic of Ireland are bound by the laws of the Republic of Ireland.

3. Interpretation and Scope

- 3.1 In this Code of Standards, the term “medicinal product” means a medicinal product as defined in Council Directive 2001/83/EC, as amended, and which is intended for human use. Medical devices and food supplements are not within the scope of this Code of Standards and are not dealt with by IPHA. The Advertising Standards Authority for Ireland (ASAI) is the appropriate body for concerns regarding medical device advertisements. However, companies should only commence a formal ASAI complaint once attempts at intercompany resolution have been exhausted and

provided that the complainant has notified the other company of its intention to move from intercompany resolution to formal ASAI complaint.

- 3.2 In this Code of Standards, "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 including the 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 medicinal products.
- 3.3 Any illustration contained in an advertisement shall be regarded as an integral part of the advertisement.
- 3.4 The expression 'product /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 Commission in accordance with Regulation 726/2004/EC, as amended, laying down Community procedures for the authorisation and supervision of medicinal products.
- 3.5 The expression "Consumer Healthcare Medicine" means any medicinal product which is intended for use as human medication or for general health care and which may be purchased by individuals without the presentation of a prescription issued by a registered Healthcare Professional (HCP).
- 3.6 This Code of Standards has no application to advertisements regarding prescription only medicinal products, treatments or appliances addressed to or sent directly to registered HCPs, published in HCP journals or in any of the relevant trade journals.

3.7 The Code of Standards does not cover:

- (i) The labelling of medicinal products and the accompanying package leaflets
- (ii) Correspondence, which may be accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;
- (i) 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 product claims;
- (ii) 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 resident in the State;
- (iii) Information relating to human health or diseases, provided there is no reference, even indirect, to medicinal products;
- (iv) Traditional herbal medicinal products or homeopathic medicinal products.

4. General Provisions

- 4.1 A medicinal product should not be promoted prior to the granting of the product authorisation permitting its sale or supply.
- 4.2 The promotion of a medicinal product must be consistent with the terms of the relevant product authorisation.
- 4.3 The holder of the authorisation in respect of a medicinal product shall establish within their undertaking a Scientific Service to compile and collate all information relating to that product.
- 4.4 The advertisement must not mislead. It should encourage the rational use of the medicinal product by presenting it objectively and without exaggerating its properties.

- 4.5 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.
- 4.6 In addition to compliance with legal obligations, this Code of Standards must be observed and enforced in the spirit as well as in the letter.
- 4.7 With the exception of any advertisement that is part of a vaccination campaign relating to a medicinal product which is a vaccine or serum (and provided that the campaign has been approved by the Minister) the advertising of a prescription only medicine, or a drug that is a controlled drug under section 2 of the Misuse of Drugs Act 1977, as amended, to the public is not permitted.

5. Contents of Advertisements

- 5.1 All advertisements must be accurate and truthful.
- 5.2 All advertisements must be easily intelligible to the consumer.
- 5.3 All advertisements must comply with the requirements of the Medicinal Products (Control of Advertising) Regulations 2007 (S.I. 541 of 2007) 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 medicinal product.

- (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 product or its international non-proprietary name or the trademark and;
- (b) advice to read carefully the instructions on the leaflet contained within the package or on the label, as the case may be (Annex I);

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

- a) The name of the medicinal product, as well as the common name if the product contains only one active ingredient;
- b) An express and legible invitation to read carefully the instructions on the leaflet contained within the package or on the label, as the case may be (Annex I).

(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 medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;
- (c) suggests that the health of the subject can be enhanced by taking the medicinal product;
- (d) suggests that the health of the subject could be affected by not taking the medicine (this prohibition shall not apply to vaccination campaigns provided that such campaigns have been approved by the Minister);

- (e) is directed exclusively or principally at children;
- (f) might result in harm to children or which exploits their credulity;
- (g) leads the public to assume that the medicinal product has some special property or quality which is in fact unknown or unrecognised;
- (h) claims that the product, medicine or treatment 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;
- (i) 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 the consumption of medicinal products;
- (j) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
- (k) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;
- (l) could, by giving a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- (m) refers, in improper, alarming or misleading terms, to claims of recovery;
- (n) 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 medicinal product on the human body or parts thereof.

5.4 An advertisement must not:

- (i) bring disrepute upon the Consumer Healthcare Industry, undermine confidence in advertising or prejudice public confidence in medicinal products;
- (ii) offer any Consumer Healthcare Medicine or treatment for a serious disease or condition which requires medical treatment by a healthcare professional;
- (iii) refer to chronic conditions or contain any offer to make a diagnosis or prescribe treatment by correspondence;
- (iv) denigrate or attack unfairly any other products, goods or services;
- (v) 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;
- (vi) 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;
- (vii) use words such as "magic", "miracle", "mystical" or "secret active ingredient" in connection with the claims made for the product or treatment;
- (viii) in any way induce or tend to induce fear;
- (ix) persuade or tend to persuade towards the unnecessary use of a 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;
- (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 the Code of Standards.

6. Responsibility of Advertisers

- 6.1 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).
- 6.2 Advertisers shall inform their contracted third parties (including advertising and public relation agents etc.) commissioned to engage in promotional activities of the requirements under this Code of Standards and provide them with training on it.
- 6.3 Advertisers shall keep available for supply on request a sample of all advertising emanating from 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 material shall be made available to the Code Committee.

7. Competitions, Public Schemes and Samples

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 Medicine;
- (ii) Promote or be in any way associated with any other schemes which are intended to encourage the sale of a Consumer Healthcare Medicine 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 medicinal products 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.

8. Inter-Company Resolution

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

9. Code Committee

9.1 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/ pharmaceutical expertise.
- (iii) One nominee from the non-IPHA member signatories to the Code of Standards.
- (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.

9.2 When the Complainant is a signatory to the IPHA Code of Standards, 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 of Standards which are alleged to have been breached;
- (iii) If submitted in hardcopy, seven bound copies of the complaint must be supplied.

The Complainant must also provide the following in writing:

- (i) an unqualified undertaking to comply with every reasonable request of the Code Committee;

- (ii) confirmation of acceptance of the final decision of the Code Committee (although the 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.

- 9.3 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 of Standards have been breached. The Complainant's identity will not be disclosed without the Complainant's permission. However, anonymous complaints will not be accepted.
- 9.4 Proceedings before the Code Committee shall be informal.
- 9.5 The Code Committee shall determine its own rules of conduct and procedure and may appoint a recording secretary. It will be deemed constituted with a quorum of three.
- 9.6 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 Committee established 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 should declare his or her interest to enable the Chairperson to make an appropriate decision. Confidentiality must be maintained.

10. Resolution and Hearing of Complaints

- 10.1 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 of Standards. The Complainant may withdraw the complaint at any time up until IPHA has received the response from the Respondent. If a complaint is withdrawn before it has been sent to the Respondent, the Respondent will not be informed about 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.
- 10.2 The “clock” starts when a valid complaint is received at the IPHA offices. A copy of the complaint is sent to the company alleged to have breached the Code of Standards (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 route necessary).
 - (iv) If responding in hardcopy, supply seven bound copies of the response.
- 10.3 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 only be made available to either party subsequent to the completion of a case and only upon request.

- 10.4 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/ sanctions imposed. Failure by the company concerned to do so will result in the matter being referred to the IPHA Board of Directors.
- 10.5 The above time frame for the Code of Standards complaints procedure can be shortened or lengthened at the discretion of the Code Committee Chairperson, depending on the issues presented and the availability of the Chairperson and Committee members.
- 10.6 Where the Code Committee, having considered a complaint, has found that the Code of Standards 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 of Standards and take all necessary steps to avoid a similar breach in the future;
 - (ii) Reprimand the company for the breach of the Code of Standards;
 - (iii) Order the recovery of material found to have been in breach of the Code of Standards;
 - (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 of Standards, 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 accept the advertisement which has been found to be in breach of the Code of Standards.

This list is not exhaustive and other sanctions may be applied.

- 10.7 A Code of Standards 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 of Standards.

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

- All members of IPHA's CHC Division
- All non-IPHA member Code of Standards 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 Medicines

(Reference: Clauses 5.3 (ii)(b) and 5.3(iii)b of this Code of Standards)

An express and legible invitation to read carefully 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 opinion on an advertisement's compliance with the IPHA Code of Standards

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 the Code of Standards and to have those requirements fully incorporated. IPHA provides an opinion not a definitive statement of compliance with the Code of Standards 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 licence 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

Claim 1: Acting quickly not only to ...

Substantiation for Claim 1: The approved carton states:

- 'Rapidly...'
- 'Fast acting'

(A pdf version of the approved carton was also provided)

Notes



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