medicines for ireland

Code of Practice

Medicines for Ireland is the representative body for the generics, biosimilar and value-added pharmaceutical industry in Ireland. Its member companies include both manufacturers and suppliers of prescription and non-prescription medicines. Our members provide the essential medicines that Irish patients, healthcare professionals and healthcare systems rely on to treat the most acute and chronic ailments covering a wide range of diseases from cardiovascular, to diabetes and cancer. Better access to the most effective therapies means millions more patients are getting better and living longer, while healthcare inequalities are being reduced. As a leading partner for better healthcare, we aim to improve the health and wellbeing of all Irish patients through better access to high quality affordable medicines.

Medicines for Ireland is a member of Medicines for Europe. Medicines for Europe is the official trade association for the European generic, biosimilar and value-added pharmaceutical industries, representing, supporting and developing our common scientific and technical interests within the European Union, Europe as a whole as well as between the European Union and third countries. Medicines for Europe has established a Code of Conduct on Interactions with the Healthcare Community (The Medicines for Europe Code) which aims to set a framework of standards and principles that promotes trust, responsible behaviour, and respect, between pharmaceutical companies and the Healthcare Community, including Healthcare Professionals, Healthcare Organisations, patients and Patient Organisations. This version of the Medicines for Ireland Code supersedes all prior versions of the Code and should be read in conjunction with the latest version of the Medicines for Europe code.

1. Introduction

Medicines for Ireland and our parent association Medicines for Europe are committed to ensure that all members advertising medicinal products aimed at both healthcare professionals and the public is conducted in a responsible, ethical, compliant and professional manner.

As a member of Medicines for Europe, all Medicines for Ireland members are committed to the ethical standards set out in Medicines for Europe Code of Conduct (www.medicinesforeurope.com). Medicines for Ireland has developed this supplementary Code of Marketing Practice to outline Irish specific requirements additional to the parent Medicines for Europe Code of Conduct. Both Codes should be read in conjunction and are intended to be a self-regulatory standard and are without prejudice to any existing or future legislation. Where there is any gap or inconsistency between standards, the stricter requirement shall always apply.

The Codes set out specific standards for pharmaceutical companies with regard to ethical and regulatory advertising and promotional interactions with the Healthcare Community. The Codes are not intended to address or regulate commercial terms and conditions relating to the price, sale and distribution of medicines, which must always be in compliance with applicable rules and requirements. The principles set forth in the Codes are mandatory and shall be implemented by all Members.

The advertising of medicinal products for human use within the European Union is governed by Titles VIII and VIIIa of Directive 2001/83/EC (as amended) and transposed into The Medicinal Products (Control of Advertising) Regulations, 2007 (S.I. No. 541 of 2007) which came into operation on the 23rd of July 2007. The Medicines for Ireland Code has been provided to guide implementation of the requirements of the legislative provisions governing the advertising of medicinal products in Ireland, (S.I. No. 541 of 2007). It is designed to be used in conjunction with the Regulations and is not a substitute for the Regulations. Certain sections of the Code are directly derived (verbatim) from the Regulations. If conflict between the two should arise, the requirements of the Regulations should take precedence.

2. Scope

2.1 This Code applies to any advertisement relating to a medicinal product where such product is the subject of a marketing authorisation or certificate of traditional-use registration in Ireland.

2.2 This Code is intended to support Marketing authorisation Holders (MAH) in the self-regulation of advertising.

2.3 This Code does not apply to:

2.3.1 The labelling of medicinal products and the accompanying package leaflets, (which are in compliance with Regulation 16 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007);
2.3.2 Correspondence which may be accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;
2.3.3 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;
2.3.4 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;
2.3.5 Information relating to human health or diseases, provided there is no reference, even indirect, to medicinal products. e.g. patient information or disease awareness campaigns carried out by pharmaceutical companies themselves or in conjunction with patients' associations;
2.3.6 Any advertisement relating to a registered homeopathic medicinal product;
2.3.7 Products which may be used as an accessory to medicinal products (e.g. saline solutions) and are not the subject of a marketing authorisation, provided there is no mention of a medicinal product;
2.3.8 Any advertisement relating to a medical device; or
2.3.9 Foodstuffs or food supplements which are not the subject of a marketing authorisation or certificate of traditional-use registration.

2.4 This code should be used in conjunction with Medicines for Europe code of conduct for the review and approval of advertising materials for medicinal products.

3. Definitions

3.1 'Advertising', in relation to a medicinal product, includes any form of advertising whether in a publication, or by display of a notice or point-of-sale material, or by means of a letter, press release or other document, or by the exhibition of a photograph or by way of a radio or television broadcast or via the internet. It also includes any form of door to door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products and including in particular:

- The advertising of medicinal products to the general public;
- The advertising of medicinal products to persons qualified to prescribe or supply them;
- Visits by medical sales representatives to persons qualified to prescribe medicinal products;
- The supply of samples of medicinal products;
- The provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind;
- The sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products;
- The sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith;
- The provision of donations or grants for charitable, not-for-profit or research purposes.

3.2 'Certificate of traditional-use registration' means a certificate of traditional-use registration which is for the time being in force and which has been granted by the HPRA under the Medicinal Products (Control of Placing on the Market) Regulations 2007 in respect of a traditional herbal medicinal product;

3.3 'Common name' in relation to a medicinal product means the international non-proprietary name, or, if one does not exist, the usual common name;

3.4 'Events' means all promotional, scientific or professional meetings (including virtual meetings via the use of online platforms), congresses, conferences, symposia, and other similar events including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies (each, an "Event"), organised or sponsored by, or on behalf of, a company. Meetings, congresses and conferences may be face to face, virtual (online platform) or a combination of both;

3.5 'Healthcare organisation' means any healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or through which one or more healthcare professionals provide healthcare services. Pharmacy businesses are healthcare organisations, though they may also be retailers. Wholesalers, distributors, and similar commercial intermediaries are not considered Healthcare Organisations.

3.6 'Patient organisation' means any not-for-profit organisations which are patient focused, and in which patients or carers form a majority of the governing body.

3.7 'Healthcare community' means any healthcare professionals, healthcare organisations, patients and patient organisations. Also includes any other person or organisation that is involved in the regulation, approval, control or supply of medicines, or that communicates about medicines in a professional capacity (for example a medical journalist, but excluding member company representatives) to healthcare professionals, healthcare organisations or patient organisations.

3.8 'Healthcare professional' means a person of any of the following classes:

- Registered medical practitioners,
- Registered dentists,
- Registered pharmacists,
- Registered nurses

3.9 'Herbal medicinal product' means any medicinal product, 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.

3.10 'Marketing authorisation' means an authorisation which is for the time being in force and which has been granted by the HPRA in accordance with the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) and includes a product authorisation, a parallel import licence, an authorisation granted by the Commission under Regulation (EEC) No. 2309/93 or Regulation (EC) No 726/2004 and an authorisation granted by the HPRA in accordance with Article 126a of the 2001 Directive;

3.11 'Medical device' (definition in accordance with Regulation 2017/745/EU) means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- Devices for the control or support of conception;
- Products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

3.12 'Misleading advertising' means any advertising which in any way, including its presentation, deceives or is likely to deceive the persons to whom it is addressed or whom it reaches and which, by reason of its deceptive nature, is likely to affect their economic behaviour or which, for those reasons, injures or is likely to injure a competitor;

3.13 'Promotional aid' means a non-monetary gift, that is inexpensive, relevant to the practice of medicine or pharmacy, and is made for a promotional purpose by a commercially interested party;

3.14 'Summary of product characteristics' means the information required to accompany any application for a marketing authorisation or certificate of traditional-use registration by Article 11 of the 2001 Directive.

3.15 'Scientific services' means a suitably qualified and trained department or individuals within a company (or outsourced where relevant) which may include Medical Information or other departments such as Pharmacovigilance, Regulatory or Quality Assurance.

3.16 A Transfer of Value can include anything of value, including monetary payments or in-kind benefits (such as travel, hospitality, etc) that is provided (or "transferred") by a company either directly or indirectly via a third-party intermediary acting at its direction.

4. General rules of advertising medicinal products

Marketing Authorisation

4.1 A medicinal product cannot be promoted prior to receipt of the marketing authorisation or certificate of traditional-use registration authorising its sale.

4.2 All product promotion must comply with the terms of the marketing authorisation or certificate of traditional-use registration.

Accuracy of advertisements

4.3 An advertisement in respect of a medicinal product must not be issued unless

- 4.3.1 All parts of the advertisement will comply with the information set out in the summary of product characteristics (SmPC) for the product.
- 4.3.2 The advertisement encourages the rational use of the medicinal product by presenting it objectively and without exaggerating its properties.
- 4.3.3 The advertisement is not misleading.
- 4.3.4 The advertisement must fully meet the requirements in S.I. 541 of 2017.

4.4 Information about medicinal products must be up-to-date, verifiable and accurately reflect current knowledge or responsible opinion.

4.5 Information about medicinal products must be accurate, balanced, fair, objective and must not mislead either directly or by implication.

Claims

4.6 All information in an advertisement must be capable of substantiation.

- 4.6.1 The use of statistics and technical data must be accurate and must not be presented in such a way as to exaggerate the validity of a claim.
- 4.6.2 Claims must not be exaggerated and the use of superlatives should be avoided.

4.6.3 Wording which implies superior or superlative status such as "number one", "leading", "largest" etc. must be capable of substantiation with market share data or similar proof.
4.6.4 The word "new" must not be used to describe a medicinal product which has been available in Ireland for more than 12 months.
4.6.5 The word "safe" must not be used without qualification. Medicinal products must not be promoted as being free from side effects, toxic hazards or risk of addiction.

4.7 Advertising materials must not claim or imply an endorsement where none exists.

4.7.1 Advertisers who use testimonials must be able to provide relevant supporting documentation and they must hold signed and dated proof for any testimonials they use.
4.7.2 Testimonials by persons named or depicted in an advertisement must only be used with the prior permission of those persons and only where such permission still holds.
4.7.3 Endorsements by fictitious or historical characters must not be presented as though they were genuine testimonials even in the presence of a disclaimer.
4.7.4 Consideration must also be given to Clause 5.5.6 of this Code regarding the use of endorsements/testimonials.

4.8 Advertising materials must not contain a statement that the marketing of the product has been approved by the HPRA, European Medicines Agency, European Commission, CHMP or other organisations.

Comparisons and References

4.9 Advertising materials must respect the principles of fair competition.

4.9.1 Other companies, their products, services or promotions must not be disparaged either directly or by implication.
4.9.2 Comparisons to other products must be fair and capable of substantiation.
4.9.3 An advertisement must not so closely resemble another as to be likely to mislead or cause confusion.

4.10 The clinical and/or scientific opinions of members of the healthcare professions must not be disparaged either directly or by implication.

4.11 When promotional material refers to published studies, clear references must be given.

4.12 References to the Primary Care Reimbursement Service (PCRS) in promotional material must be confined to including the relevant code number (the print size and typeface of which must be the same as that of the marketing authorisation number) and /or price.

4.12.1 Where reference is made to the prescribing of a product under the PCRS, the phrase "freely prescribable" or similar phrases suggesting a lack of restriction or restraint must not be used.
4.12.2 Where a product has been added or restored to the PCRS list, announcements, advertisements and other communications to this effect may include in the body of prescribing information, a statement that the product is "PCRS reimbursable" (or similar) provided that the print size of such statements is no larger than the rest of the text. Such a statement may be carried for no longer than twelve months from the date of the adding or restoring of the product to the PCRS list.
4.12.3 Reproductions of official documents, such as prescription forms, must not be used for promotional purposes unless the agreement of the appropriate State Organisation has been received.

Interpretation by target audience

4.13 Advertising materials must be prepared with a sense of responsibility to consumers and society and must not bring discredit upon or reduce confidence in the pharmaceutical industry.

4.14 Advertising material must not exploit the credulity, inexperience or lack of knowledge of the target audience.

4.15 An advertisement must not persuade or tend to persuade towards the unnecessary use of the product.

4.16 The design and presentation of advertising materials must allow them to be clearly understood. Where footnotes or small print sections are used, they must be of sufficient size and prominence and be easily legible.

4.17 Advertising materials must not cause fear or distress without good reason. In such cases, the fear aroused should not be disproportionate to the risk.

5. Advertising to the public

This section applies only to advertisements that are directed wholly or mainly at members of the public.

5.1 The advertising and promotion of prescription only medicines to the general public is prohibited (not applicable to any advertisement that forms part of a vaccination campaign relating to a vaccine or serum provided that such a campaign has been approved by the Minister).

5.2 Advertising to the public in respect of a controlled drug (as defined in Section 2 of the Misuse of Drugs Act [No. 12 of 1977, as amended]) is prohibited. This should be borne in mind when preparing advertising for consumer healthcare medicines, some of which may contain controlled substances, e.g. codeine, dextromethorphan.

5.3 Consideration should be given to the Medicinal Products (Control of Paracetamol) Regulations [S.I. No. 150 of 2001] in conjunction with the Medicinal Products (Prescription and Control of Supply) Regulations [S.I. No. 540 of 2003] when preparing advertising materials for medicinal products containing paracetamol.

5.4 An advertisement aimed at the general public must be set out in such a way that it is clear that the message is an advertisement and that the product is a medicinal product;

5.5 Advertisements intended for members of the general public must not contain material which:

5.5.1 Gives the impression that a medical consultation or surgical operation is unnecessary, by offering or by suggesting a treatment by mail (telephone, e-mail or any other electronic means of communication);

5.5.2 Suggest that the effects of a product are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to those of another treatment or medicinal product;

5.5.3 Recommends that the health of a subject can be enhanced by taking a medicinal product;
5.5.4 Suggests that the health of the subject could be affected by not taking the medicinal product (not applicable to any advertisement that forms part of a vaccination campaign relating to a vaccine or serum provided that such a campaign has been approved by the Minister);
5.5.5 Is directed exclusively or principally at children;
5.5.6 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;
5.5.7 Suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
5.5.8 Suggests that in and of itself, the safety or efficacy of a product is since it is natural;
5.5.9 Might, by description or detailed representation of a case history, lead to erroneous self-diagnosis;
5.5.10 Refers, in improper, alarming or misleading terms to claims of recovery;
5.5.11 Uses, in improper alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or the action of a medicinal product on the human body or parts thereof; or
5.5.12 Is intended to influence consumers in ways of which they are not consciously aware.

Full advertisement

5.6 An advertisement aimed at the public must contain the following minimum information:

5.6.1 The name of the medicinal product;
5.6.2 The common name of the medicinal product where there is only one active ingredient. Where there is more than one active ingredient, it is not necessary to list the common names, however, inclusion of all the common names is not considered a breach of the Code;
5.6.3 The information necessary for the correct use of the medicinal product. This requirement is interpreted to mean that one or more indications for use of the product should be presented in the advertisement.
5.6.4 A warning to read carefully the instructions on the package leaflet or outer label as appropriate (in the case of an audio or visual promotion there must be an overprint or an audible statement which recommends that the consumer reads the instructions carefully);
5.6.5 Where the product is a traditional herbal medicinal product, the following statement "Traditional herbal medicinal product for use in [one or more therapeutic indications for the product] exclusively based on long standing use".

Reminder advertisement

5.7 An exemption from Clause 5.6 may be appropriate where an advertisement is intended as a reminder does not contain any claim and consists solely of:

5.7.1 The name of the product, its international non-proprietary name, where such exists, and/or the trademark.
5.7.2 Advice to read carefully the instructions on the package leaflet or on the label as appropriate.

Prohibition of supply of medicinal products to the public for promotional purposes

5.8 Sale or supply of any medicinal product for promotional purposes to members of the general public is prohibited. This applies to marketing authorisation or certificate of

traditional-use registration holders or any person acting on their behalf, and persons who in the course of their business manufacture medicinal products or sell medicinal products by wholesale or any person acting on their behalf.

5.9 A company must not promote to the general public or be associated with any prize competition or other scheme which is intended to encourage the unnecessary use of a medicinal product.

6. Advertising to persons qualified to prescribe or supply

The provisions of section 6 apply only to advertisements that are directed wholly or mainly at persons qualified to prescribe or supply medicinal products. Such advertisements may be categorised as follows:

- Full advertisements (where the purpose is to provide sufficient information on which to reach a decision on prescribing or dispensing a medicinal product)
- Reminder advertisements (where the purpose is to remind a person qualified to prescribe or supply of the availability of a medicinal product)
- Promotional aids such as pens & pads.
- Refer to 6.1 and 6.2 for detailed information regarding full and reminder advertisement.

Full advertisement

6.1 A full advertisement aimed at persons qualified to prescribe or supply must contain the following in a clear and legible manner in a position readily accessible to the reader:

6.1.1 Essential information compatible with the summary of product characteristics and abbreviated prescribing information (API) which is in accordance with the current version of the summary of the product characteristics is required for full advertisements. The API must include a date of preparation or date of last revision;

6.1.2 The name of the product, and a list of the active ingredients using the common name placed immediately adjacent to the most prominent display of the name of the product.

6.1.3 The classification for the sale or supply of the product e.g, 'medicinal product subject to medical prescription' (POM), 'retail sale through pharmacies only' (P) or 'supply through general sales' (GSL);

6.1.4 One or more of the indications for the use of the product compatible with the terms of the marketing authorisation or certificate of traditional-use registration;

6.1.5 A clear statement of the entries in the summary of product characteristics relating to adverse reactions, precautions, and relevant contra-indications;

6.1.6 A clear statement of the entries in the summary of product characteristics relating to the dosage and method of use relevant to the indications shown. The method of administration must be given if this is not obvious;

6.1.7 The name and address of the holder of the marketing authorisation or certificate of traditional-use registration, or the business name and address of the part of the business responsible for placing the product on the market;

6.1.8 The marketing authorisation or certificate of traditional-use registration number of the medicinal product;

6.1.9 Where the product is a traditional herbal medicinal product, the following statement "Traditional herbal medicinal product for use in [one or more therapeutic indications for the product] exclusively based on long standing use";

6.1.10 The date on which the above were generated or last updated;

6.1.11 Details on how to report adverse events. e.g., "Adverse events should be reported. Reporting forms and information can be found on the HPRA website (www.hpra.ie), or by emailing medsafety@hpra.ie";

6.1.12 Include a statement to refer to the summary of product characteristics for full prescribing information.

Advertisements intended only as a reminder

6.2 An abbreviated advertisement that is intended solely as a reminder aimed at persons qualified to prescribe or supply must contain the following:

6.2.1 The name of the product, its international non-proprietary name(s) where such exists, and/or the trademark;

6.2.2 The classification for the sale or supply of the product. i.e., 'medicinal product subject to medical prescription', 'retail sale through pharmacies only' or 'supply through general sales';

6.2.3 The name and address of the holder of the marketing authorisation or certificate of traditional-use registration, or the business name and address of the part of the business responsible for placing the product on the market;

6.2.4 A statement which clearly indicates that additional information is available on request or in the summary of product characteristics relating to the product;

6.2.5 Where the product is a traditional herbal medicinal product, the following statement "Traditional herbal medicinal product for use in [one or more therapeutic indications for the product] exclusively based on long standing use"; and

6.2.6 The date on which the above were generated or last updated.

The indication(s) of the product may be included in an abbreviated advertisement.

Exemptions for Promotional Aids

6.3. The conditions set out in Section 6.1 and 6.2 above are not applicable to an advertisement relating to a medicinal product which is on a promotional aid if;

- The advertisement consists solely of the name of the product, its international non-proprietary name and/or the trademark;
- The advertisement is intended exclusively as a reminder;
- The promotional aid is intended for supply only to persons qualified to prescribe or supply medicinal products the company name or trading style may appear along with the name of the product.
- The company name or trading style may appear along with the name of the product.

6.3.1 Where promotional aids fall under the definition of a medical device, they must bear the appropriate CE mark in accordance with the current Medical Device Legislation.

Written material accompanying promotions

6.4 Any written material sent to a healthcare professional as part of a promotion of a medicinal product must comply with the requirements of either Clause 6.1 or 6.2 above as appropriate.

6.4.1 Any information provided must be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his/her own opinion of the therapeutic value of the medicinal product.

6.4.2 Such written material must not include any quotations, references or tables or other illustrative matter from a medical journal or other scientific work unless it is accurately reproduced, and the precise sources of the information are indicated.

Distribution of promotional material to persons qualified to prescribe or supply

6.5 Promotional material must only be distributed to healthcare professionals in accordance with the following conditions:

6.5.1 Where it is reasonable to assume they would have an interest in the subject matter taking into consideration that:
- Promotional material must be tailored to the audience to whom it is directed. For example, promotional material devised for general practitioners may not be appropriate for hospital doctors
- Any information designed to encourage the use of medicinal products in clinics, industrial concerns, clubs or schools must be addressed to the appropriate healthcare professional.

6.5.2 Excessive distribution and volume of promotional material is considered inappropriate.

6.5.3 Mailing lists should follow General Data Protection Regulation requirements and must be kept up-to-date and any requests from a healthcare professional for removal from a mailing list must be complied with promptly and no name should be stored except at the HCPs request or with their permission unless the holding of such details is required in the ordinary course of business.

6.5.4 Consideration should be given to exposed mailings, envelopes or wrappers used to distribute promotional material to healthcare professionals. Such materials must not carry any details which could be regarded as inappropriate advertising to the general public (refer to Section 5).

6.5.5 The use of faxes, text messages, emails and other electronic communications for promotional purposes is unacceptable without the prior consent of the recipient.

Medical Sales Representatives

6.6 The following requirements apply to the conduct of medical representatives:

6.6.1 A medical representative who promotes medicinal products to persons qualified to prescribe or supply such products must on request, be able to supply a hard copy of the product current summary of product characteristics (SPC) or refer the HCP to the SPC on an up-to-date accessible electronic compendium, website or publication.

6.6.2 A medical representative must report to the relevant department, established by the marketing authorisation holder, any information about the use of the products he/she promotes, with reference to any adverse reactions reported by healthcare professionals during their visits.

6.6.3 Companies must provide their medical representatives with training and ensure they possess sufficient scientific knowledge to enable them to present information on the company's products ethically and with appropriate accuracy and detail.

6.6.4 A high standard of ethical conduct is expected of medical representatives in the execution of their roles. Compliance with all relevant requirements of the Code is mandatory.

6.6.5 Medical representatives must not mislead as to their identity.

6.6.6 Medical representatives must not use any inducement or subterfuge to gain an interview. They must not pay, under any pretext, for access to a healthcare professional. (See section 6.7 inducements and hospitality.)

6.6.7 Medical representatives are required to employ sufficient security measures to safeguard medicinal products in their possession. (See section 615 on free samples)

6.6.8 Medical representatives must only use the telephone or similar electronic means to promote medicinal products to healthcare professionals when prior arrangement has been made with the individuals concerned.

6.7 Meetings between companies and Healthcare Professionals (including employees of healthcare organisations) can be mutually beneficial. Meetings may be held for educational, scientific or research purposes, and promotional purposes. Reasonable hospitality may be provided in connection with such meetings in accordance with this Code.

6.7.1 Depending on the nature of the meeting, hospitality may include accommodation, meals and drinks, and must always be necessary, incidental, reasonable, and secondary to the main purpose of the meeting. Unrelated hospitality or entertainment, not connected to any work-related meeting, is prohibited.

6.7.2 Hospitality may be offered at sales promotion events /professional and scientific events provided such hospitality is reasonable in level and;

- Is strictly limited to the main purpose or scientific objective of the event, and
- Is not extended to persons other than healthcare professionals, except in those rare instances where a service provider with a disability genuinely requires a carer to enable them to travel.
- Not include sponsoring (see 6.14 Sponsorship and Donations).

6.8 A meeting should be held in a location that makes the most logistical sense considering the location of the attendees or resources necessary for the meeting. This could include major transport hubs and cities with appropriate infrastructure.

6.9 Venues must be appropriate and conducive to the main purpose of the meeting. Appropriate venues may include clinical, laboratory, educational, conference or healthcare settings, or business locations such as business hotels or conference centres. Luxury hotels, resorts, venues known for their entertainment or recreational value, or extravagant venues are never appropriate.

6.10 Hospitality must be reasonable and proportionate, and never lavish or luxurious. It must only be offered to people who qualify as participants in their own right. Travel should always be on the most direct and logical route, considering costs to the company. Stopovers (except where logistically unavoidable)., recreation, side trips and trip extensions funded or facilitated by a company are prohibited. Arrival and departures should, whenever logistically possible, coincide with the beginning and end of the meeting. Flights should be booked in economy class; business class may only be compensated in exceptional circumstances, where justifiable.

6.11 Companies must not provide or fund any food or drinks for individual virtual attendees at a meeting. If sponsoring a meeting where some delegates and/or company representatives are attending virtually, companies may provide or fund appropriate food and drinks only for those healthcare professionals who are physically present as a group in an appropriate meeting location.

6.12 In the course of promoting medicinal products, companies may occasionally provide educational materials, medical utility items and inexpensive promotional items (e.g. a pen) to a Healthcare Professional. It is prohibited to promise or offer such items, gifts, financial advantage or benefit in kind unless it is inexpensive, relevant to the Healthcare Professionals professional duties and ultimately benefit patients, patient care or the practice of medicine or pharmacy. Such items should never provide as a personal benefit

or to offset the operating costs of a Healthcare Professionals professional practice and must never be provided as a means of improperly influencing Healthcare Professionals. When medical utility items are needed during public health emergencies or disaster relief, deviations from this clause will be permissible. In general, the recipients will be healthcare organisations or governmental agencies rather than individual healthcare professionals, and such benefits in kind will be disclosable as donations.

6.13 The provisions outlined above will not prejudice the negotiation of prices, margins and discounts in the ordinary course of business provided such prices, margins and discounts are incorporated in the sales invoice of such negotiations.

Sponsorship and Donations

6.14 The prohibition of the giving of gifts/financial advantage in the course of medicinal product promotion shall not preclude a company from providing support in the form of educational, research or employment grants, donations or sponsorship of equipment, provided that the following conditions are complied with:

- The company must be in receipt of a written request from a healthcare professional or institution (for example, a practice, medical centre, clinic, hospital or recognised charity) for the specific type of support provided. Sufficient information must be obtained to establish that there is a genuine need for such support and that it does not offset the routine practice costs of the recipient.
- Support must be paid directly to an institution rather than to an individual healthcare professional;
- Any such support must not be linked in any way with product promotion. No commitment must be sought or given in relation to the prescribing, supply or use of the company's products;

In certain circumstances, companies may proactively donate if:

- all other requirements of Medicines for Europe Code of Conduct section 6.7 are met; and
- the donor company does not have, and is not reasonably likely to have, any commercial interest in relation to the recipient organisation's activities.

Deviations from this clause for the purposes of public health emergencies or disaster relief will be permissible only to the extent agreed upon by Medicines for Europe.

Free Medical Samples

6.15 A free sample of a medicinal product can only be supplied to a healthcare professional qualified to prescribe such product and only where the following conditions are satisfied:

6.15.1 The sample is provided on an exceptional basis only and for the purpose of acquiring experience in dealing with such a product. It must not be provided to induce prescribing, sale, supply, or administration of medicinal products.

6.15.2 The number of such samples of each product that may be supplied to any one recipient in any one year shall be limited and, in any case, shall not exceed six in number. The provision, to a prescriber, of up to six samples per annum of different strengths of the same product is permitted. The limit of six applies to each marketing authorisation.

6.15.3 The supply of any such sample is made only in response to an unsolicited written request, signed and dated, by the healthcare professional;

6.15.4 The supplier of such samples maintains an adequate system of control and accountability;
6.15.5 Each such sample is no larger than the smallest presentation of the product on the market;
6.15.6 Each such sample is marked "free medical sample – not for sale" or words to the like effect;
6.15.7 Each such sample is accompanied by a copy of the summary of product characteristics or reference to the SPC on an up-to-date accessible electronic compendium, website or publication.
6.15.8 It is not permitted to supply free medical samples of the following medicinal products:

- A product which is a controlled drug under Section 2 of the Misuse of Drugs Act 1977; as amended by Misuse of Drugs Act 2016
- Antidepressants;
- Hypnotics;
- Sedatives;
- Tranquillisers.

7. Digital Marketing

General Guidance on Digital Marketing

7.1 Digital Marketing describes communication through channels such as social media sites (e.g. Facebook, Instagram, Google Plus), Online video platform (e.g. YouTube), Blogs (Tumblr, Micro press), microblogs (e.g. Twitter), user forums, Wikipedia, use of digital games, digital platforms developed with users, emails and services such as SMSs which are sent through mobile devices.

7.1.1 Information provided at the digital platform should have suitable references and be made available on request.
7.1.2 Any product claims made on digital platform recordings should be substantiated with references made available on request.
7.1.3 Digital platforms must have a homepage, clearly linking to the following information:

- Identity of the digital platform owner. This may include logos, company name, and contact details such as address, email and telephone number(s) details.
- Purpose of the digital platform
- Target audience(s) (e.g., healthcare professionals, public etc).

7.1.4 Procedures should be in place to review and approve information related to medicinal products placed on the digital platform in accordance with this Code and relevant legislation. A process for regular and documented review of the information should be in place as applicable.
7.1.5 Information that could be interpreted as prescription medicine promotion must not be made easily accessible to the general public.
7.1.6 The balance of safety and efficacy information provided on company websites should be maintained.
7.1.7 Procedures for monitoring digital platforms for adverse events and product complaints should be in place. Procedures should also be in place to monitor and deal with other complaints or inappropriate content.
7.1.8 It is necessary to ensure compliance with the Code when referencing other digital platforms. When linking to other websites, ensure that at the time of linking, that the

website is in compliance with the Code. Clearly state where the linked website is an independent third-party website which is not under the control of the company.

7.1.9 Avoid linking to content on platforms such as blogs or forums which undergoes constant change.

7.1.10 Should message boards be available on digital platforms, as companies do not have full content control, they should clearly express their right to remove certain messages.

7.1.11 All email databases should be held in accordance with the General Data Protection Regulations and include clear information on how to be removed as applicable.

7.1.12 Measures should be in place to archive content such that it can be easily retrieved in the future e.g., in the event of objections being raised regarding non-compliance.

7.1.13 Companies should have a clear policy for company employees regarding social media use.

- Such policy should ensure that individual employee interactions with the company's social media (including forwarding, retweeting, comments and likes) do not bring content to the attention of inappropriate audiences.
- Companies must be careful to ensure that materials and information on social media are available only to appropriate recipients and that each post is acceptable when read as a standalone communication.

7.1.14 No email recipient should be able to view the email addresses of other recipients and all relevant data protection legislation should be adhered to.

7.1.15 Respect and transparency are essential in all communications and mechanisms should be in place to prevent unwanted or abusive messages.

7.1.16 Companies should bear in mind that digital platforms are simply a channel of communication, and that requirements applicable to physical meetings or other forms of media apply also to digital and virtual interactions. Companies must ensure that their representatives use only approved materials, whether the interaction is a conventional meeting or online.

Digital marketing to the Public

7.2 The following guidance is to be followed for digital marketing to the public:

7.2.1 There should be no information which can be interpreted as promotion of prescription medicines

7.2.2 The phrases "Information placed on this digital platform is not intended as a substitute for consultation with your healthcare professional" and "Please consult your healthcare professional for further information" should be considered where appropriate on the home page and other pages on platforms intended for the public.

7.2.3 E-newsletters or e-zines aimed at the public cannot advertise prescription medicine-related content to non-healthcare professionals.

Digital marketing to Healthcare Professionals

7.3 Digital marketing to HCPs should be conducted as follows:

7.3.1 Access to website sections and other digital channels aimed at healthcare professionals should be restricted and must clearly indicate content that is intended only for healthcare professionals, including measures to prevent access of others (e.g. password-protected, active confirmation of HCP status by users, restriction warnings).

7.3.2 A digital platform may contain information aimed at both HCPs and the public, however, it should be segregated into separate sections, with clear warnings related to the HCP section such as "This section is intended for healthcare professionals only'' or some similar phrase.

7.3.3 A set of rules should be stated clearly on the website for platforms in which it is possible for HCPs to exchange views. Should a breach of these rules occur (such as the discussion of off-label use), the company should immediately remove the material and advise the contributor that such discussion is not permissible on a company sponsored/controlled forum.

7.3.4 On electronic banner advertisements where there is insufficient space, the viewer should be directed to where they can find the required information. The direction and / or button must be prominent and clearly legible. Linking directly to the SmPC on an up-to-date accessible electronic publication is advised. The hyperlink must be direct.

Third Party Digital Platforms Funded by Companies

7.4 Where companies fund or support Third party digital platforms, the following applies:

7.4.1 A written contract should be in place outlining both parties' responsibilities. This should include pharmacovigilance responsibilities as well as control of the digital platform content to ensure compliance with the Code and relevant legislation.

7.4.2 Where the third-party digital platform is aimed at the public, the digital platform must not promote prescription medicines to the public. The written contract should clearly outline this requirement.

8. Disclosure of Transfers of Value

8.1 Transparent relations and interactions between companies and Healthcare Professionals/ Organisations and Patient Organisations help to prevent unethical and illegal behaviour. In this regard Medicines for Ireland adopts the Medicines for Europe Code which requires member companies to disclose Transfers of Value that could potentially pose a conflict of interest and should encourage the recipients of the transfers of value to disclose them, where such disclosure would be in the best interest of patients or the public, further specified below. A company must disclose transfers of value made by third parties on its behalf, if the company knows or has access to the identities of the recipient(s). These indirect transfers of value are to be treated for disclosure purposes as though they were made directly by the company. It is the responsibility of each member company to disclose Transfer of Value either publicly or directly to specific stakeholders. Disclosure may be via the member company website, and/or on a central platform, or by direct provision of Transfer of Value data.

8.1.1 Companies must publish disclosure data relating to the following transfers of value (whether directly or indirectly funded) made to healthcare professionals, healthcare organisations or patient organisations:

- Fee for service (excluding associated expenses) except fees paid in connection with research & development activities or anonymous market research;
- Registration fees to attend a third-party congress/conference;
- Travel and accommodation provided to delegates to attend a meeting – including third party meetings, company organised meetings and site visits;
- Grants and donations, both financial and in-kind, to organisations that are part of the healthcare community;

- Sponsorship of healthcare organisations' and patients organisations' activities and events.

8.2 The Period and frequency of disclosure are as follows:

8.2.1 The reporting period for transfer of value disclosures is the full calendar year.
8.2.2 Disclosure data must be published annually.
8.2.3 Companies should disclose as early as possible, and by no later than 30 June of the year following the reporting period.

8.3 Transfers of Value shall be disclosed on an individual, named basis:

8.3.1 Transfers of Value to Patient Organisations:

Fee for service

- The amount disclosed for each patient organisation is the total of all honoraria for the reporting period.
- Expenses directly related to performance of the contracted service (for example travel, accommodation and meals) are not disclosable
- For each organisation, companies must include a brief description of the nature of the services provided.

Support in the forms of grants, donations and sponsorship of activities and events

- The amount disclosed for each patient organisation is the total of all sponsorship support and contributions in the reporting period made in accordance with clauses 6.1 and 6.7 of the Medicines for Europe Code.

For each patient organisation, companies must include a brief description of the nature of the sponsorship or contribution(s) (for example to fund a disease awareness day, to cover the cost of a newsletter, or general support for the organisation's running costs).

- The description of the nature of the transfer of value must be sufficiently complete to enable a member of the public to understand what the arrangement between the company and the recipient was.

8.3.2 Transfers of Value to Healthcare Professionals:

Fees for service

- Fees paid in connection with research & development activities or market research, are excluded from the scope of this disclosure. The market research exception in respect of fees applies only to genuinely anonymous market research where it is not possible for the company to know or deduce the identity of respondents.
- The amount disclosed for each healthcare professional is the total of all honoraria for the reporting period in exchange for the provision of services, such as serving as an expert on an advisory board, speaking at a company-organised educational event, participating in a focus group, etc.
- Expenses directly related to performance of the contracted service (for example travel, accommodation and meals) are not disclosable.

Support to attend meetings as a delegate

- In this category, 'support' refers to transfers of value during the reporting period in the form of:
  - Registration fees to attend a third-party congress/conference, including virtual meetings;
  - Travel and accommodation to attend a meeting including third party meetings, company organised meetings and site visits.
- Companies must choose one of two options for presenting their disclosures in this category (see Medicines for Europe Code of Conduct for full details):
  Option 1 – disclosing how many events each named healthcare professional has been supported to attend, without giving any financial information

Option 2 – disclosing the total cost of each specific meeting, and the total number of healthcare professionals supported to attend, without naming the delegates

8.3.3 Transfers of Value to Healthcare Organisations:

Fees for services

- The amount disclosed for each healthcare organisation is the total of all honoraria for the reporting period.
- Expenses directly related to performance of the contracted service (for example travel, accommodation and meals) are not disclosable.

Grants and donations

- The amount disclosed for each healthcare organisation is the total of all contributions in the reporting period made in accordance with clause 6.7 of the Medicines For Europe Code.
- For each healthcare organisation, companies must include a brief description of the nature of the contribution(s) (for example research grant, equipment donation, product donation) and, where not obvious, its purpose (for example "to increase lung cancer screening capacity" or " to support pandemic relief").
- In-kind contributions to a healthcare organisation must be disclosed as fair market value, even if the donating company has written off all or part of the value in its own books.

Sponsorship of activities and events

- The amount disclosed for each healthcare organisation is the total of all sponsorships for the reporting period made in accordance with clause 6.1 of the Medicines For Europe Code.

8.4 Along with its disclosure, each company must publish a note summarising the methodology which they have applied in preparing the disclosure and identifying Transfers of Value for each category. The methodological note should also explain the treatment of:

- multi-year contracts;
- taxes, including whether or not VAT has been included;
- currency and exchange rate where applicable;
- issues related to the timing and amount of transfers of value for the purposes of disclosure, for example, the company's approach where an event happened during the reporting year (so liability to pay was incurred) but the speaker has not yet invoiced the company.

9. Compliance with the Code

9.1 Marketing authorisation holders and holders of certificates of traditional-use registration have primary responsibility for ensuring that their advertising is in conformance with all relevant legislation.

9.2 Marketing authorisation holders and holders of certificates of traditional-use registration must establish a Scientific Service responsible for information about its medicinal products.

9.3 The Scientific Service includes suitably qualified personnel and will be responsible for:

9.3.1 Approving all advertising materials and related activities before use. They must have examined the final version of all such advertising and that it is in accordance

with the Code and applicable legislation. Documentation of approval should be retained;

9.3.2 Maintaining a sample of all advertising with records of those to whom it was distributed, the method and date of first distribution. Advertising materials should be retained for a period of three years from their cessation of use;

9.3.3 Provide, upon request from the HPRA, details of any advertisement or proposed advertisement generated by the marketing authorisation holder

9.3.4 Ensuring that, any decision taken by the HPRA in relation to an advertisement relating to a medicinal product is immediately complied with.

9.3.5 Compiling and collating all information, whether received from medical sales representatives or from any other source, relating to the medicinal products promoted by the marketing authorisation holder;

9.3.6 Ensuring medical sales representatives are given adequate training and have sufficient scientific knowledge to enable them to provide information which is as precise and as complete as possible about the products they promote;

9.3.7 Ensuring medical sales representatives have available summaries of product characteristics that is available as a hard copy or on an up-to-date accessible electronic publication, for each medicinal product that he or she presents to health professionals;

9.3.8 Ensuring that medical sales representatives transmit information about the use of the medicinal products that he or she advertises, including any adverse reactions reported by healthcare professionals.

9.3.9 Ensuring that Information related to medicinal products have been reviewed and authorised to ensure Code compliance. Such information should be regularly reviewed, and where necessary updated, with clear references to the last revision date for each section, page and/or article, as applicable.

9.4 Marketing authorisation holders should establish Standard Operating Procedures outlining how they implement compliance with the Medicines for Europe and Medicines for Ireland Codes and the relevant legislation and should include in the company self-inspection programme.

10. Enforcement procedures

10.1 Member companies are accountable for addressing and correcting infringements of the Medicines for Europe Code and the Medicines for Ireland Code and are encouraged to report potential violations.

10.2 Enforcement is managed by a self-regulatory process. Occasionally a national association may transfer a claim to the Medicines for Europe Secretariat for adjudication. However, companies may not appeal the enforcement decisions of national associations, whose appeal process is final.

10.3 Non-member companies, healthcare organisations, patient organisations healthcare professionals, members of the public, company employees or other stakeholders may make a complaint following the process below.

10.4 Where it is in the best interests of an individual complainant to withhold their identity from the company alleged to be in breach, they may raise the complaint directly to the national association or to the Medicines for Europe Secretariat, who must protect the complainant's confidentiality. Individual complainants who wish to remain completely anonymous in accordance with Directive (EU) 2019/1937 (the 'Whistleblower Directive')

are encouraged to report their concerns to the competent local regulator or to the relevant company's whistleblowing hotline.

Inter-company dialogue

10.5 A complainant who believes that a company has violated this Code should in the first instance report the alleged violation to the company in breach, at an appropriate level of seniority. The two parties shall work to resolve the matter between themselves, in good faith and in the spirit of the Medicines for Ireland and Medicines for Europe Codes. Inter-company dialogue is confidential between the parties and the correspondence should be limited to what is necessary to discuss and where possible resolve the alleged violation.

Formal complaint

10.6 If they cannot resolve the matter to their mutual satisfaction, member companies may escalate it to the Medicines for Ireland Secretariat. The complainant must submit a detailed written complaint.

10.7 Non-member companies healthcare organisations, patient organisations, healthcare professionals, members of the public, or other stakeholders may escalate their complaint by reporting to the HPRA Advertising Compliance Group if inter party dialogue did not result in resolution.

Advertising Compliance Group
Compliance Department
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre, Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353 1 676 7836
Email: compliance@hpra.ie

Case preparation

10.8 Upon receipt of a complaint, the Medicines for Ireland Secretariat will coordinate preparations for a hearing. The parties to the complaint must comply with all deadlines for information and responses advised by the Secretariat.

Complaint hearing

10.9 Complaint cases are heard by a review committee of three people who have no conflicting interests with the parties involved in the matter. The complainant and the respondent company are entitled to be represented. The review committee will adjudicate on the complaint and put its findings in writing

Findings and sanctions

10.10 Following the conclusion of the case and if applicable any appeal, a company found in breach of the Code must take corrective actions to immediately stop the non-compliant activities or practices. To prevent recurrence of the breach, the company must implement any further remedial measures imposed by the review committee.

10.11 The committee may recommend further sanctions against a member in egregious or repetitive cases, or in circumstances where a company's activities have been such as to potentially bring the pharmaceutical industry or the generics and biosimilars sector into disrepute. In these circumstances, Medicines for Ireland members may, in accordance with Medicines for Ireland's bylaws and the applicable legislation, expel a company from membership.

medicines for ireland

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