



**Irish Pharmaceutical
Healthcare Association**

CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY

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© Irish Pharmaceutical Healthcare Association
7 Clanwilliam Terrace, Grand Canal Quay, D02 CC64
Tel: +353 (1) 6610018 Fax: +353 (1) 6610164
E-mail: info@ipha.ie
Websites: www.ipha.ie,
www.transferofvalue.ie,
www.medicines.ie



Irish Pharmaceutical Healthcare Association

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

INTRODUCTION

The Code has been prepared by the Irish Pharmaceutical Healthcare Association (IPHA) with a view to securing the universal acceptance and adoption of high standards of conduct in the interactions with healthcare professionals, healthcare organisations and patient organisations, and the marketing of medicine to healthcare professionals, whether intended for use under medical supervision or otherwise.

The advertising of medicine for human use in European Union Member States is governed by Council Directive 2001/83/EC of 6 November 2001, as amended. This Code of Practice fits into the general framework established by Article 97 Paragraph 5 of Directive 2001/83/EC as amended, which recognises the role of the voluntary control of advertising of medicine by self-regulatory bodies and recourse to such bodies.

The Code emphasises the importance of providing healthcare professionals with accurate, fair and objective information about medicine so that rational decisions can be made as to their use. Moreover, the Code accepts the principle that such information must be presented in a form and by ways and means which conform not only to legal requirements but also to professional standards of ethics and good taste.

Acceptance and observance of the provisions of the Code and its annexes are a condition of membership of the IPHA. Companies observing the Code also acknowledge that its provisions are to be applied in spirit, as well as in the letter.

GENERAL

The provisions of the Code fully reflect the standards of the July 2019 edition of the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code. IPHA is a member of EFPIA and compliance with the European Code is a requirement of all member associations of EFPIA.

This IPHA Code of Practice incorporates the provisions of the Medicine (Control of Advertising) Regulations 2007 (S.I. 541 of 2007) for the purposes of providing practical guidance in implementing the Regulations.

The Minister for Health, as provided for under Regulation 26 of the medicinal products (Control of Advertising) Regulations 2007 [the 'Regulations'], endorses the parts of the IPHA Code of Practice for the Pharmaceutical Industry, that are directly derived (verbatim) from the aforementioned Regulations.

This Code has been provided to help in implementing the requirements of the Regulations. It is designed to be used in

conjunction with the Regulations and is, by no means, a substitute for the Regulations.

ETHICAL PRINCIPLES

1. We keep **PATIENTS AT THE HEART OF WHAT WE DO**, therefore we:

- Continue to improve existing treatments and deliver innovative new medicines
- Support the common objective of timely access to medicines
- Maintain a dialogue to better understand the needs of patients
- Work with stakeholders including research communities to tackle healthcare challenges
- Continue appropriate collaboration with HCPs and others to support their role in treating patients

2. We act with **INTEGRITY**, therefore we:

- Engage with HCPs, HCOs and Patient Organisations only when there is a legitimate need
- Take into consideration the role and responsibility of stakeholders with whom we interact to avoid conflicts of interest or improper influence
- Consider the values, standards and decision-making processes of other stakeholders
- Support evidence-based decision making
- Facilitate access to medical education and help rapid dissemination of scientific information.

3. We act with **RESPECT**, therefore we:

- Are conscious of the importance of providing accurate, fair and objective information about medicines so that rational decisions can be made about their appropriate use
- Support the independence of the prescribing decisions of HCPs
- Assure mutual respect and independence, in terms of political judgment, policies and activities, in all partnerships with Patient Organisations
- Promote an attitude and environment of mutual regard for other stakeholders, taking into account differences such as cultures, views and ways of working

4. We are **TRANSPARENT** about our actions, therefore we:

- Share clinical trial data in a responsible way
- Publish details of the Transfers of Value made to HCPs and HCOs on www.transferofvalue.ie
- Publish details of financial support and significant non-financial support to Patient Organisations
- Clearly indicate pharmaceutical company sponsorship of any material relating to medicines and their uses

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PROVISIONS OF THE CODE

1. SCOPE & DEFINITION OF TERMS

- 1.1 The Code covers interactions with healthcare professionals, healthcare organisations and patient organisations, and the promotion to healthcare professionals of prescription-only medicine.
- 1.2 The term “promotion” means those marketing and informational activities coming under the control or authority of the company, the purpose of which is to induce the prescribing, supply, sale or consumption of the company’s medicine.

Promotion includes, for example, the activities of medical representatives; various aspects of sales promotion such as journal and direct mail advertising, the use of mail (including hardcopy, telephone, email, and other electronic means), the use of the internet, the use of audio-visual materials such as films, video recording, data storage services and the like, informational systems and exhibitions; and the provision of samples, gifts or hospitality.

- 1.3 The term “healthcare professional” means a person of any of the following classes:
 - (i) Registered medical practitioners
 - (ii) Registered dentists
 - (iii) Registered pharmacists

(iv) Registered nurses

- 1.4 The term “medicinal product” or medicine means means:

- (i) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings.
- (ii) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

- 1.5 The term ‘Healthcare Organisation (HCO)’ means any healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for a Patient Organisation (PO) within the scope of Annex III of this Code) whose business address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more HCPs or other relevant decision makers provide services. In addition to the specific provisions set out in the Code the following general conditions apply when working with a HCO:

- The public use of an HCO logo and/

or proprietary material by a Member Company requires written permission from that HCO. In seeking such permission, the specific purpose and the way in which the logo and/or proprietary material will be used must be clearly stated.

- Member Companies must ensure that their sponsorship is always clearly acknowledged and apparent from the outset. This can be achieved by clearly documenting or acknowledging the sponsors on relevant materials related to the activity.
- In addition, no member company may require that it is the sole funder or sponsor of an HCO or any of its programmes. Member Companies welcome broad funding and sponsorship of HCOs from multiple sources.

1.6 The term “marketing (or product) authorisation” refers to a medicine licence granted or renewed by the Health Products Regulatory Authority or the European Commission.

1.7 The Code is not intended to inhibit the exchange of medical and scientific information during the development of a product.

The term “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.

1.8 The term ‘medical education’ includes education related to human health and diseases and specific non-promotional training related to medicines. Medical education may include materials and activities.

1.9 The Code does not cover:

- the labelling of medicine and the accompanying package leaflets, which are subject to the provisions of the Medicine (Control of Placing on the Market) Regulations 2007 (S.I. 540 of 2007) as amended;
- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicine. Non-promotional, general information about companies (such as information directed to investors or to current/prospective employees), including financial data, descriptions of research and development programmes, and discussion of regulatory developments affecting the company and its medicine.
- 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;
- 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;
- information relating to human health or diseases provided there is no reference, even indirect, to medicine.

2. ACTIVITIES OF MEMBER COMPANIES

2.1 The activities of member companies that fall within the scope of this Code must never be such as to bring discredit upon or reduce confidence in the pharmaceutical industry.

3. MARKETING AUTHORISATION

- 3.1 A medicine must not be promoted prior to receipt of the marketing authorisation permitting its sale or supply.
- 3.2 The promotion of a medicine must be consistent with the terms of the marketing authorisation. All promotion must encourage the rational use of the medicine by presenting it objectively and not exaggerating its properties.
- 3.3 At independent international congresses or symposia held in Ireland, promotional material which appears on exhibition stands or is distributed to participants may refer to a medicine or indication for a medicine which is not the subject of an authorisation in Ireland (but which is so authorised in at least one Member State of the European Economic Area [EEA]) provided that the following conditions are observed:
 - (i) The meeting must be a truly international, scientific event with a significant proportion of the speakers and delegates from other countries;
 - (ii) To ensure that the promotional material does not promote the prescription, supply, sale or consumption of the medicine in Ireland, a clearly visible and legible statement must be included to the effect that the medicine is not authorised in Ireland or that it is authorised for different indications in this country;
 - (iii) Promotional material which refers to the prescribing information (indications, warnings etc.) authorised in other countries must include an explanatory statement indicating that licensing conditions differ internationally.

Promotional material for medicine which are not authorised in any EEA country at the time of the congress or symposium, may not be displayed or distributed to participants. Scientific papers on such medicine may, however, be provided in accordance with Clause 1.6 of the Code.

4. NATURE AND AVAILABILITY OF INFORMATION

- 4.1 Upon reasonable request, a company must promptly provide healthcare professionals with accurate and relevant information about the medicine which it markets.
- 4.2 Information about medicine must be up-to-date, verifiable and accurately reflect current knowledge or responsible opinion.
- 4.3 Information about medicine must be accurate, balanced, fair, objective and must not mislead either directly or by implication.
- 4.4 Information about medicines must be capable of substantiation. Such substantiation need not be provided however in relation to the validity of indications approved in the marketing authorisation.
- 4.5 Substantiation that is requested pursuant to Clause 4.4 must be provided without delay at the request of members of the medical and pharmacy professions including the members of those professions employed in the pharmaceutical industry.
- 4.6 When promotional material refers to published studies, clear references must be given.
- 4.7 In accordance with an agreement reached

between the IPHA and the Department of Health, the summaries of product characteristics (SmPCs) relating to individual medicine are included in www.medicines.ie which is made available free of charge in Ireland. The contents of the SmPCs in that electronic compendium are determined by the relevant marketing authorisations.

- 4.8 The provision of informational or educational materials is permitted provided **that** the materials are: (i) inexpensive; (ii) directly relevant to the practice of medicine or pharmacy; and (iii) directly beneficial to patient care. Such items may be company branded.

Materials provided for informational or educational reasons may include: scientific articles and items used to provide information about medicine (such as detail aids); patient education materials given to healthcare professionals for use with their patients, etc.

Companies may provide pens or paper exclusively during company-organised meetings, as long as they are inexpensive and not product branded.

Companies shall not distribute pens or paper at medical exhibition stands. Pens or paper included in conference bags shall not be branded (neither product nor company branded).

- 4.9 HCPs may be provided with items which are to be passed on to patients which may bear the name of a medicine and/or information about medicines only if such detail is relevant to the appropriate use of the medicine by patients who have been prescribed that medicine. Additionally, although items which are to be passed on to patients may not be issued at HCP exhibition stands, they may be exhibited

and demonstrated on those stands and requests for them accepted for later delivery. Patient support items may be provided to HCPs by those representing the company during the course of a visit or when requested by a HCP.

In limited circumstances patient support items may be made available for the use of HCPs even though they are not to be passed on to patients for them to keep. This is where their purpose is to allow patients to gain experience in using their medicines whilst under the supervision of a HCP. Examples include inhalation devices (with no active ingredient) and devices intended to assist patients to learn how to self-inject.

- 4.10 Items of medical utility aimed directly at the education of healthcare professionals and patient care may be provided if they are inexpensive and do not offset the routine business practice costs of the HCP. Such items may be company branded, only if the brand name is essential for the correct use of the medicine.

5. CLAIMS AND COMPARISONS

- 5.1 Claims for the usefulness of a medicinal product must be based on an up-to-date evaluation of all the evidence and must reflect this evidence accurately and clearly. Such claims must have prior medical review and approval.
- 5.2 Exaggerated claims must not be made and all-embracing claims must be avoided. Claims must not imply that a medicine, or an active ingredient, has some special merit, quality or property unless this can be substantiated.
- 5.3 The word "safe" must not be used

without qualification and it must not be stated categorically that a medicine has no side-effects, toxic hazards or risk of addiction (see also Clause 7.2).

- 5.4 The word “new” must not be used to describe any medicine which has been generally available, or therapeutic indication which has been generally promoted, in Ireland for more than 12 months.
- 5.5 Comparisons of medicine must be factual, fair and capable of substantiation. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by undue emphasis, by omission or in any other way.
- 5.6 The brand names of other companies’ medicine must not be used in comparison unless the prior consent of the companies concerned has been obtained.

6. DISPARAGING REFERENCES

- 6.1 Other companies, their medicine, services or promotions must not be disparaged either directly or by implication.
- 6.2 The clinical and/or scientific opinions of members of the healthcare professions must not be disparaged either directly or by implication.

7. TEXTUAL AND AUDIO VISUAL PROMOTIONAL MATERIAL

- 7.1 All promotional material issued by a marketing authorisation holder or with his authority, must be consistent with the requirements of this Code.
- 7.2 Where the purpose of promotional material is to provide persons qualified to prescribe or supply with sufficient information upon which to reach a decision for prescribing or for use, then the following minimum information, which must be compatible with the SmPC, must be given clearly and legibly and must be an integral part of the advertisement:
 - (i) The relevant marketing authorisation number and the name and address of the holder of the authorisation or the business name and address of the part of the business responsible for placing the medicinal product on the market;
 - (ii) 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;
 - (iii) One or more of the indications for the use of the product compatible with the terms of the marketing authorisation;
 - (iv) Recommended dosage, method of use and, where not obvious, method of administration;
 - (v) The classification for the sale or supply of the product;
 - (vi) Adverse reactions, warnings and precautions for use and relevant contraindications of the product;
 - (vii) A statement that additional information is available on request;

(viii) The date on which the above particulars were generated or last updated.

7.3 Where the purpose of the promotional material is to remind persons qualified to prescribe or supply of the availability and of the indication(s) of a medicine (i.e. a “reminder advertisement”), the following information, which must be compatible with the SmPC, must be included:

- (i) The name of the medicine, or the international non-proprietary name, where such exists, or the trademark;
- (ii) A statement which clearly indicates that further information is available upon request or in the SmPC;
- (iii) The name and address of the holder of the marketing authorisation or the business name and address of the part of the business responsible for placing the medicine on the market;
- (iv) The classification for sale or supply of the medicine.

The indication(s) for the medicine may also be included in a reminder advertisement.

All promotional material not falling within the category of “reminder advertisements” must comply with Clause 7.2.

7.4 Promotional material such as mailings and journal advertisements must not be designed to disguise their real nature. Where a company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble editorial matter.

7.5 All promotional material appearing in journals, the publication of which is paid for, secured or arranged by a company and referring by brand name to any product of that company, must comply with Clause 7.2 or 7.3 of this Code as

appropriate, irrespective of the editorial control of the material published.

7.6 Promotional material must conform, both in text and illustration, to canons of good taste and must be expressed so as to recognise the professional standing of the HCPs and not be likely to cause offence.

7.7 The names or photographs of healthcare professionals must not be used in promotional material without their permission nor in any way that is contrary to the ethical code of the appropriate profession.

7.8 Promotional material must not imitate the devices, copy, slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.

7.9 Where appropriate (for example, in technical and other informative material), the date of printing or of the last review must be stated.

7.10 Extremes of format, size or cost of promotional material must be avoided.

7.11 Postcards, other exposed mailings, envelopes or wrappers must not carry matter which might be regarded as advertising to the lay public or which could be considered unsuitable for public view.

7.12 Audio-visual material must be accompanied by all appropriate printed material so that all relevant requirements of the Code are complied with.

7.13 Material relating to medicines and their uses, whether promotional in nature or not, which is sponsored by a company must clearly indicate that it has been sponsored by that company and if that company had any input into the content of the material.

8. REFERENCES TO THE HEALTH PRODUCTS REGULATORY AUTHORITY AND RELATED ORGANISATIONS

- 8.1 Unless specific requirements with regard to distribution or use have been imposed, companies must not include in any promotional material, a statement that the marketing of the medicine has been approved or recommended by the Health Products Regulatory Authority or related organisations such as the European Medicines Agency (EMA), the European Commission or the Committee for Medicine for Human Use (CHMP).

9. REFERENCES TO THE PRIMARY CARE REIMBURSEMENT SERVICE

- 9.1 References to the Primary Care Reimbursement Service (PCRS) (or the GMS as it was previously known) 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.
- 9.2 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.
- 9.3 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.

- 9.4 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.

10. DISTRIBUTION OF PROMOTIONAL MATERIAL

- 10.1 Promotional material must only be sent or distributed to those categories of persons whose need for, or interest in, the particular information can be reasonably assumed.

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.

- 10.2 Any information designed to encourage the use of medicine in clinics, industrial concerns, clubs or schools must be addressed to the appropriate healthcare professional.
- 10.3 Restraint must be exercised on the frequency of distribution and on the volume of promotional material distributed.

The style of mailings is relevant to their

acceptability to healthcare professionals and criticism of their frequency is most likely to arise where their informational content is limited or where they appear to be elaborate and expensive.

10.4 Mailing lists must be kept up-to-date. Requests from healthcare professionals to be removed from mailing lists must be complied with promptly and no name should be restored except at the healthcare professional's request or with his/her permission.

10.5 The use of faxes, e-mails, automated calling systems, text messages and other electronic data communications for promotion is prohibited except with the prior permission, or upon the request, of the HCP.

11. REPRINTS, ABSTRACTS AND QUOTATIONS

(Such use is, of course, subject to the Law of Copyright)

11.1 All reprints of articles supplied to individual healthcare professionals in the course of promotion must comply with the provisions of Clause 7.2 or 7.3 16 as appropriate.

11.2 It is permissible to include in promotional material, reasonably brief abstracts of, or quotations from, articles, or accurately reproduced tables or other illustrative matter taken from the scientific literature and to include in such material references to authors' names in a bibliography of published works. In no case however, should authors' names be used in a prominent manner in promotional material.

11.3 Quotations from medical literature, or

from personal communications received from healthcare professionals, must accurately reflect the meaning of the author and the significance of the study.

12. COMPANY EMPLOYEES (DIRECT AND CONTRACTED)

12.1 The term "medical representatives" includes medical sales representatives, including personnel retained by way of contract with third parties, and any other company representatives who call on healthcare professionals, pharmacies, hospitals or other healthcare facilities in connection with the promotion of medicine.

12.2 Medical representatives must be provided with thorough training by the company which employs them and possess sufficient scientific knowledge to present information on the company's medicine in an accurate, complete and responsible manner. The contribution of the Medical Representatives Institute of Ireland in this respect (for example by the inclusion of the IPHA Code of Practice in its examination syllabus) is acknowledged.

12.3 During each visit medical representatives must give the person visited or have available for them, the most up-to-date version of the SmPC for each medicinal product they promote. Where the SmPCs are published in a compendium such as www.medicines.ie and this fact is drawn to the attention of the persons visited, this requirement is deemed to be satisfied.

12.4 All company employees must transmit to the Scientific Services established in their companies any information on adverse reactions reported to them by

the persons they visit.

- 12.5 Medical representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties. They must comply with all relevant requirements of the Code.

Medical Sales Representatives must, from the outset, take reasonable steps to ensure that they do not mislead as to their identity or that of the Member Company they represent.

- 12.6 Medical representatives must not employ any inducement or subterfuge to gain an interview. They must not pay, under any guise, for access to a healthcare professional.

This clause does not preclude the occasional provision of light refreshments/modest meals at a meeting organised by a medical representative. Such hospitality may only be provided to healthcare professionals and occur in a manner and venue conducive to information exchange and/or scientific education.

Payments to healthcare professionals to cover the cost of such hospitality are not allowed.

- 12.7 Medical representatives must ensure that the frequency, timing and duration of calls on healthcare professionals, or on hospitals, together with the manner in which they are made, are acceptable to the healthcare professionals and hospitals as appropriate and are not such as to cause inconvenience. The wishes of an individual healthcare professional, or the arrangements in force at any particular establishment, must be observed by representatives.

Medical representatives must always

endeavour to treat healthcare professionals' time with respect and if for any reason an appointment cannot be kept by the representative, the longest possible notice must be given.

- 12.8 Medical representatives must take adequate precautions to ensure the security of medicine in their possession.
- 12.9 Medical representatives must not use the telephone or similar electronic means to promote medicine to healthcare professionals unless prior arrangement has been made with the individuals concerned.

- 12.10 Companies are responsible for the activities of all their employees and must ensure that employees who are concerned in any way with the drafting or approval of promotional material (including employees of third parties contracted on behalf of the company) are fully conversant and compliant with the requirements of the Code.

Other third parties working for or on behalf of companies, (including advertising company executives, business consultants and market research companies), and those that do not act on behalf of companies (such as joint ventures and licensees) commissioned to engage in activities covered by the Code must also be fully conversant and compliant with the Code.

- 12.11 The provision of nursing services by a company must be undertaken in accordance with the guideline on the provision of nursing services by companies published in Annex II.
- 12.12 Companies must ensure that all regulatory obligations are met. In

particular their pharmacovigilance departments must be notified of all market research activities, Patient Support Programmes etc.

13.SAMPLES

13.1 Free samples of medicine shall not be supplied to any person who is not qualified to prescribe such product.

The supply of a sample means the supply of a medicine made otherwise than in connection with a clinical trial.

13.2 Where samples of medicine are distributed by a medical representative, the sample must be handed directly to a person qualified to prescribe such product or to a person authorised to receive the sample on their behalf.

Medical samples must not be provided as an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines, and must not be given for the sole purpose of treating patients.

13.3 The following conditions shall be observed in the provision of samples to a person qualified to prescribe such product:

- (i) Such samples are provided on an exceptional basis only (see (ii) to (vii) below) and for the purpose of acquiring experience in dealing with such a product;
- (ii) Such samples in respect of a medicinal product shall not exceed four in number per year and sampling shall not extend beyond the two years after he/she first requested samples of each particular new medicine. In this context, a new medicine is a product for which a new marketing authorisation has been granted, either following an initial marketing

authorisation application or following an extension application for new strengths/dosage forms that include a new indication. Extensions of the marketing authorisation to additional strengths/dosage forms for existing indications or pack sizes (number of units in the pack) cannot be considered as new medicines.

- (iii) Any supply of such samples must be in response to a signed and dated request from the HCP;
- (iv) An adequate system of control and accountability must be maintained in respect of the supply of such samples. This system shall also clearly establish, for each person supplied, the number of samples provided in application of the provision in Clause 13.3(ii);
- (v) Each sample shall be no larger than the smallest presentation on the market;
- (vi) Each sample shall be marked “free medical sample – not for sale” or bear another legend of analogous meaning;
- (vii) Each sample shall be accompanied by a copy of the most up-to-date version of the SmPC relating to that product in accordance with the requirements set out in Clause 12.3.

13.4 A person shall not supply a sample of a medicine which is a controlled drug under Section 2 of the Misuse of Drugs Act, as amended, or which is an anti-depressant, hypnotic, sedative or tranquilliser.

13.5 Samples sent by post must be packed so as to be reasonably secure against the package being opened by children.

13.6 Distribution of samples in hospitals must also comply with individual hospital regulations, if any.

14. GIFTS

- 14.1 No gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply by a company in relation to the promotion/ marketing of prescription medicines. This does not preclude any regulations for the time being in force relating to prices, margins and discounts.

15. GRANTS, HEALTHCARE SUPPORT SERVICES AND OTHER FORMS OF SUPPORT

- 15.1 Clause 14 shall not preclude a company from providing support in the form of educational, research or employment grants, donation or sponsorship of equipment for the betterment of patients, provided that the following conditions are complied with.

- (i) The company must be in receipt of a written request from a healthcare professional or institution (for example, a practice, medical centre, clinic or hospital) 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 business practice costs of the HCP. A written agreement, including details of the duration and nature of the support must be signed in advance of the commencement of the support.
- (ii) Support must be paid directly to an institution rather than to an individual healthcare professional;
- (iii) Employment grants provided directly or indirectly to HCOs are only permitted

for positions that are predominantly research based and for a defined period of time. Any request for funding should clearly outline the focus of the research, the output of the research work and the full cost of employment for the period in question.

- (iv) 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 medicine;
- (v) Any such support must be reasonable, modest and in proportion to the scale and scope of the HCP institution and must be likely to appear so to independent third parties.
- (vi) Companies must make public details of all Transfers of Value as outlined in Annex V.
- (vii) Companies should actively check that their support has been spent as intended. In particular, the written agreement must require that the HCP provides confirmation that the support has been spent as agreed.
- (viii) The funding confirmation 'Agreement' must specify the name of the HCO that the ToV payment can be disclosed against on the IPHA Transfer of Value website.
- (ix) Companies must obtain written confirmation of the authorised account for ToV payments from the CEO, Finance Director or other comparable role of the HCO.

- 15.2 A Healthcare Support Service (HSS) is defined as a process enhancement initiative or medical service support (e.g. patient compliance initiative, sharps bin service, disease identification, screening or genetic marker test, review of patient management/ treatment quality review etc.) provided by a pharmaceutical company that ultimately improves patient care and welfare. Further

guidance regarding Nursing Services provided by companies are detailed separately in Annex II.

A HSS must have the objectives of monitoring disease activity, achieving better healthcare outcomes and enhancing patient care. HSSs must be non-promotional, must not be designed as an inducement to prescribe and must not be designed or operated in a promotional manner. Decisions regarding provision of the HSS must be based upon objective criteria linked to the defined purpose and not linked to past or future prescription, supply, sale or consumption of a company's medicine. Proposals to provide a HSS must be reviewed, and the details approved in advance, by the appropriate non-promotional function within the company (e.g. Scientific Services, medical, legal etc.). The HSS must be provided under the supervision of this function. When company staff are involved in the provision of the HSS they must report to the aforementioned function within the company and their compensation must not relate to sales of the company's medicine.

A written agreement (or referral) between the company and the patient's HCP, including the nature of the support, project scope, timelines and HSS objective must be signed before commencement of the HSS. All patients involved in the HSS must be advised of the company's involvement and the patient's consent obtained, when required. The operation of the HSS must be monitored with reference to its objectives.

A HSS may be provided directly or indirectly (through a service provider) to patients. Contractual arrangements with service providers should clearly outline

the service, the requirements for safety reporting, adherence to data privacy requirements etc.

Information collected in the course of the provision of a HSS may not be used for promotional purposes or to plan promotional activity. Furthermore, it may not be used for clinical research purposes without the appropriate prior written consent of the HCP and the patient. In general, a HSS should only collect the minimum amount of personal information needed to ensure the HSS's management.

All HSS material used in the services must be non-promotional. Materials may be company branded. However, they may only include the brand name of the medicine, to support the safe use of the medicine, after the prescribing decision has been made. Companies must ensure that they have a process in place to ensure that all HSS materials are developed, reviewed, approved, released and removed from use, appropriately.

Companies must ensure that they have the resources to manage and monitor the HSS. The records relating to the HSSs must be retained according to the legislation and be made available for review by regulators and auditors.

Sales representatives may inform the relevant healthcare professional(s) about the availability of a HSS, but may not provide, deliver, demonstrate or have other involvement in a HSS.

16. HOSPITALITY, SPONSORSHIP AND MEETINGS

16.1 The pharmaceutical industry has a special obligation to ensure that healthcare professionals are kept in touch with continuing developments in the pharmaceutical field. With this in mind, the practice has arisen of meetings and events being organised between the industry and the professions for the further exchange of ideas and information. In addition, the custom has grown of the industry supporting independent meetings of healthcare professionals intended to update and expand the continuing education of the relevant healthcare professionals.

Many of these meetings could not take place without the support and assistance of the pharmaceutical industry. Companies may legitimately provide assistance that is directly related to the bona fide continuing education of the healthcare professionals and which genuinely facilitates attendance of the healthcare professional for the duration of the educational aspect of the event. Such support and assistance must however, always be such as to leave healthcare professionals' independence of judgement manifestly unimpaired.

16.2 Where appropriate and depending on the time, location and length of the meeting, support to healthcare professionals may cover actual travel expenses, meals, refreshments, accommodation and registration fees.

In this respect, if companies support HCPs to attend company-organised or third party international medical education events, congresses and symposia then the criteria for HCP selection must

be approved in advance by a non-promotional function of the company. Consideration and priority should be given to HCPs who are experts in their respective fields (e.g. are associated with university teaching hospitals, participate in training schemes or have academic and research interests in a relevant field). The decision to fund must be based on the potential of the attendee to acquire useful knowledge at the event, congress or symposium and ultimately improve patient management and patient outcomes.

- 16.3 (i) Companies shall not provide or offer any meals to healthcare professionals, unless, in each case (i.e. per meal and per HCP), the value of such meals (food and beverages) does not exceed €80 (including VAT and excluding any gratuity). This threshold is in addition to the existing restrictions on hospitality (reasonable, secondary to the main purpose etc) and only applies to events in Ireland.
- (ii) In the case of any virtual meeting (sponsored or other), hospitality cannot be provided to an individual HCP attending a virtual meeting. In the case of a group of HCPs attending a virtual meeting together, the provisions of clause 16.3(i) apply.

16.4 It should be the programme that attracts delegates and not the associated venue or hospitality.

Companies must not organise or sponsor meetings to coincide with sporting, entertainment or other leisure events or activities.

All Events must be held in appropriate locations and venues that are conducive to the main purpose of the Event.

Venues that are renowned for their entertainment or leisure facilities or are extravagant must not be used for such meetings.

16.5 In addition to the requirements of clause 16.3 any hospitality offered to healthcare professionals must:

- (i) Be reasonable in level and be likely to appear to be reasonable to independent third parties;
- (ii) Be secondary and strictly limited to the main purpose of the event at which it is offered;
- (iii) Not exceed the level that HCPs would normally be prepared to pay for themselves;
- (iv) Not be extended to spouses or other accompanying persons, unless they are healthcare professionals who qualify as participants in their own right. Travel expenses may not be paid for spouses or other accompanying persons, unless they are healthcare professionals who qualify as participants in their own right;
- (v) Not include sponsoring, securing, organising directly or indirectly any entertainment, sporting or leisure events.

16.6 Funding of healthcare professionals to compensate them for the time spent in attending the event is not permitted.

16.7 All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, for example, 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 must be held at an appropriate **location and venue** that is conducive to the main

purpose of the event. Clause 16.4 also applies to all such meetings.

16.8 A company may not organise or sponsor an event or a participant’s **attendance** at an event that takes place outside Ireland unless there is a valid reason to do so. All the previous relevant provisions must be applied together with the following additional principles:

- (i) Most of the invitees are from outside Ireland and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country or;
- (ii) Given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country;
- (iii) As with meetings held in Ireland, consideration must be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience and the hospitality to be provided, which must be secondary to the meeting and not out of proportion to the occasion;
- (iv) In addition to the requirements of Clause 16.5 any hospitality offered to healthcare professionals at international meetings must ensure that:
 - (a) it is the programme that attracts delegates and not the associated venue or hospitality;
 - (b) To avoid any confusion as to the primary purpose of the event, international events should not coincide with a major event of a sporting or social nature in a locality.
- (v) For flights that have a scheduled duration of five or less hours, only economy flights may be sponsored by companies for HCP attendance at conferences.

16.9 The following additional requirements shall apply in relation to the sponsorship of meetings convened by the healthcare professions:

No one company may undertake the sponsorship of any meeting or series of meetings to the exclusion of other available and willing sponsors. No payment must be made by a company to be included on a shortlist of possible sponsors.

(i) Smaller meetings

The sponsorship of local clinical meetings, initiated by an organising body of the healthcare professions, is frequently sought from companies. In such instances, companies must respond only to formal written requests for support from the organising committee. Any request for support should indicate the exact anticipated items of expenditure for which the support is sought.

Support must not extend beyond:

- cost of room hire
- cost of equipment hire
- actual travel expenses of speaker(s)
- honorarium to speaker(s) if appropriate
- modest meals and/or light refreshments

Promotional input from companies at an appropriate stage of the meeting must be with the agreement of the Chair or through a printed acknowledgement on the programme (if any).

(ii) Larger meetings

For larger meetings initiated by the healthcare professions, such as annual association meetings, support usually involves the rental of a stand or space for the purposes of exhibiting the company's

product range. This form of exhibition by companies is acceptable.

As far as possible, for reasons of security, medicine must not be brought to such meetings. In no circumstances should medicine be handed over to visitors to the stand or exhibition.

Other support for such meetings must not extend beyond a contribution to the general expenses of the meeting. An acknowledgement of this support, by way of a list of sponsors on the programme (if any) and/or by way of a similar list displayed on a notice board, is acceptable.

16.10 Corporate Hospitality

Aside from meetings and events as referred to in the preceding paragraphs, it is recognised that, on occasion, companies may provide what may be considered as "corporate hospitality" (e.g. opening a new office).

Corporate hospitality involving sporting, entertainment or social events or activities must not be extended to healthcare professionals.

The following principles shall apply to corporate hospitality:

- (i) There must be no element of product promotion at the event, either direct or implied;
- (ii) Companies should appreciate the need for moderation.

Corporate hospitality must never be such that, on a reasonable view, it might give rise to the inference that the scale and costs of such hospitality could adversely affect the cost of medicines to the patient or taxpayer;

- (iii) Corporate hospitality should be reasonable in level and likely to appear so to independent third parties. It should not exceed the level that HCPs would normally be prepared to pay for themselves.

17. MEDICAL EDUCATION

Medical education is aimed at increasing the scientific knowledge and competence of HCPs to enhance medical practice and improve patient outcomes.

- 17.1 Medical education activities / materials must not constitute promotion.
- 17.2 The level and type of a company's involvement must be clearly acknowledged and apparent from the outset. It must not mislead the HCP
- 17.3 Companies are responsible for the content of medical education activities / materials, if the arrangements are such that the companies have influenced or provided input into what is communicated during those activities. Such influence may include but is not limited to: the selection of topics, speakers and co-authorship of content.
- 17.4 The content of medical education materials or activities must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognised opinions.
- 17.5 The provisions of Clause 16 regarding hospitality and arrangements for meetings must be applied for all medical education events. Such requirements apply regardless of whether such activities are led, or supported by, the company.

18. USE OF CONSULTANTS

Healthcare professionals can be used as consultants and advisors, whether in groups or individually, for:

- Services (e.g. chairing or speaking at meetings, being involved in medical/scientific studies or in clinical trials)
- Training
- Participating in advisory board meetings (see Annex VI)
- Participating in market research where such participation involves remuneration and/or travel

With the exception of one-off phone interviews or mail/email/internet questionnaires, the arrangements that cover these genuine consultancy or other services must fulfil all of the following criteria:

- (i) A legitimate need must be clearly identified before the request for such services, and the arrangements with the prospective consultants, are made;
- (ii) A written contract or agreement, including details regarding the nature of the services to be provided and the basis for payment of those services, must be signed in advance of the commencement of the services;
- (iii) Criteria directly related to the identified need must drive the selection and evaluation of consultants;
- (iv) No greater number of healthcare professionals can be retained than is reasonably necessary to fulfil the identified need;
- (v) Records concerning the services provided by consultants must be maintained by the contracting company;

- (vi) The hiring of the healthcare professional to provide the relevant services must not be an inducement to prescribe, supply, sell or consume a particular medicinal product;
- (vii) The compensation for the services must be reasonable and reflect the fair market value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensating healthcare professionals.

Consultants who have entered contractual arrangements with companies or are employed on a part-time basis while still practising their profession, must be strongly encouraged to declare their arrangements with the company, whenever they write or speak in public about a matter that is the subject of the agreement or any other issue relating to that company. Additionally, companies are required to make public details of all Transfers of Value as per Annex V of this Code.

If a healthcare professional attends an event (an international event or otherwise) in a consultant or advisory capacity the provisions of Clause 16 covering hospitality shall apply.

Contracts between member companies, HCPs and HCOs under which they provide any type of services to member companies, not otherwise covered by the Code, are only allowed if

- (i) such services are provided for the purpose of supporting healthcare, research or education; and
- (ii) do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines.

19. MARKET RESEARCH, POST MARKETING SURVEILLANCE AND RELATED ACTIVITIES

19.1 Methods used for market research must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry. The following provisions set out in this clause apply whether the research is carried out directly by the company or by an organisation acting on its behalf.

19.2 Access to respondents must not be gained by subterfuge. Any incentives given must be kept to a minimum and be commensurate with the work involved.

19.3 Questions intended to solicit disparaging references to competing medicine or companies must be avoided.

19.4 Market research must not be used as a form of disguised sales promotion.

19.5 Post-marketing surveillance studies, pharmacoeconomic studies, non-interventional trials, clinical audit programmes and the like (including those that are retrospective in nature) commissioned, undertaken or provided by companies must never be promotional in nature and must be conducted primarily with a scientific or educational purpose. This clause does not preclude the use of the data generated from such studies to support claims in promotion.

20. NON-INTERVENTIONAL STUDIES

20.1 A “non-interventional study” (NIS) must not be disguised promotion and is defined as:

- (i) A study of one or more medicines which have a marketing authorisation where the medicine are prescribed in the usual manner in accordance with the terms of that authorisation and where;
 - (ii) The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and where;
 - (iii) The prescription of the medicine is clearly separated from the decision to include the patient in the study and where;
 - (iv) No diagnostic or monitoring procedures are applied to the patients included in the study, other than those which are ordinarily applied in the course of the particular therapeutic strategy in question and where epidemiological methods shall be used for the analysis of data arising from the study.
- 20.2 Non-interventional studies that are prospective in nature and that involve the collection of patient data specifically for the study from or on behalf of individual, or groups of, healthcare professionals must comply with all of the following criteria:
- (i) The study must be conducted with a scientific purpose;
 - (ii) There must be a written study plan;
 - (iii) The healthcare professionals and/or the site at which the study will take place, on the one hand, and the company sponsoring the study, on the other hand, must sign written contracts which specify the nature of the services to be provided and the basis for payment of those services;
 - (iv) Any remuneration provided must be reasonable and reflect the fair market value of the work performed;
 - (v) If applicable, the study protocol must be submitted to the Ethics Committee for review;
 - (vi) Laws, rules and regulations on personal data privacy (including the collection and use of personal data) must be respected;
 - (vii) The study must not constitute inducement to prescribe, supply, sell or consume a particular medicine;
 - (viii) The company's Scientific Service must approve the study protocol and supervise the conduct of non-interventional studies;
 - (ix) The study results must be analysed by or on behalf of the contracting company and summaries thereof must be made available within a reasonable period of time to the company's Scientific Service. This Scientific Service shall maintain records of such reports for a reasonable period of time. The company should send the summary report to all healthcare professionals that participated in the study and should make the summary report available to industry self-regulatory bodies and/or committees that are in charge of supervising or enforcing applicable Codes upon their request. If the study shows results that are important for the assessment of benefit-risk, the summary report should be immediately forwarded to the relevant competent authority;
 - (x) Medical sales representatives may only be involved in an administrative capacity and such involvement must be under the sole supervision of the company's Scientific Service that will also ensure that the representatives are adequately trained. Such involvement must not be linked to the promotion of any medicinal product.

To the extent applicable, companies are encouraged to comply with the above requirements for all other types of studies, including epidemiological studies and registries and other studies that are retrospective in nature.

21. RELATIONS WITH THE GENERAL PUBLIC AND LAY COMMUNICATION MEDIA

21.1 Subject to the provisions of the Medicine (Control of Advertising) Regulations 2007 (S.I. 541 of 2007), medicines may not be advertised or promoted to the general public if they are prescription-only medicines. This prohibition includes nonprescription medicines which by virtue of any applicable regulatory requirement, may not be advertised to the public.

21.2 Requests from individual members of the public for information or advice on personal medical matters must always be refused and the enquirer recommended to consult their own healthcare professional. This does not however obviate the regulatory obligation of the company to collect appropriate and comprehensive information from patients (with their consent) to support meaningful adverse reaction reporting as per the legislative requirements.

21.3 A press release is a statement about a newsworthy matter which is provided to the press by a company concerned with the matter. Companies are responsible for the content of any press release, including quotations and interviews, whose distribution is facilitated by them.

Press releases must be non-promotional communications both in content and purpose.

The content of press releases must apply the following principles unless they are mandated otherwise by the regulatory authority or in cases where patient safety is impacted e.g. urgent safety communications, quality defects, recalls, shortages etc. Furthermore, all companies undertaking this activity must have an approval process in place for press releases to ensure that they adhere to the following principles.

Press releases to the General (Lay) Media:

- (i) Must be in the public interest
- (ii) Notifications of corporate activities are acceptable if they do not involve any reference to medicines. This may include corporate investments, employments, reorganisation, mergers, acquisitions, partnership/sponsorship with Patient Organisations etc.
- (iii) Any reference to a company's medicine must reflect a bona fide significant medical/scientific development which warrants public notification and is communicated in the context of the relevant disease.
- (iv) Brand names must not be used unless the press release is a response to the publication of erroneous information or previous reference to the brand in the publication.
- (v) While comparisons to specific therapies must be avoided, terms like "standard of care" may be used where appropriate.
- (vi) Information must be accurate, fair, balanced and not create unrealistic expectations for the reader.
- (vii) Statements must not be made, or designed, for the purpose of encouraging members of the public to ask their prescriber to prescribe a medicine.
- (ix) Information about a new medicine must not be released to the public by the company until the medical profession

has been informed of its availability in so far as the circumstances allow.

Press Releases to the Medical Media:

The principles outlined for General (lay) media apply with the following exceptions;

- (x) The use of brand names may only be used if the product has a Marketing Authorisation, and then only to announce factual information, including but not limited to initial Marketing Authorisation, new approved presentations or indications, supply shortage and reimbursement status. Within such Press Releases, information relating specifically to the results of clinical trials should be scientific in tone and must not refer to the brand name.

21.4 Patient Organisations play a key role in representing, meeting the information needs of and offering support to people living with ill-health. To assist companies in their interactions with Patient Organisations, a “Guideline for companies on Working with Patient Organisations” is published in Annex III. The requirements of these guidelines have the same weight as the rest of the Code.

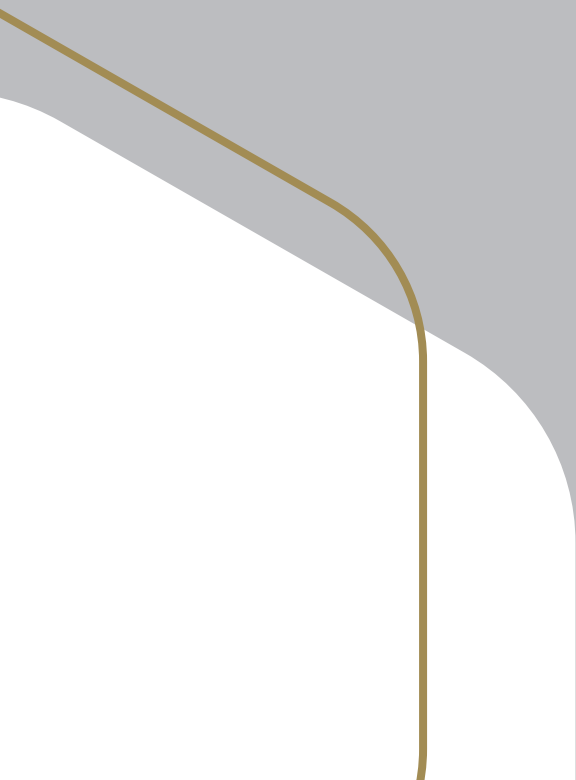
22. COMPANY PROCEDURES FOR CODE COMPLIANCE

22.1 Every company must establish a Scientific Service in charge of information about its medicine and the approval and supervision of non-interventional studies.

22.2 This Scientific Service must include a medical doctor or, where appropriate, a pharmacist or other suitably qualified person who will be responsible for:

- (i) Approving any promotional material before release. Such person must certify that he or she has examined the final version of all promotional material and that, in his or her belief, it is in accordance with the requirements of the Code and any applicable advertising laws and regulations, is consistent with the relevant SmPC and is a fair and truthful presentation of the facts about the medicinal product being promoted;
- (ii) Overseeing any non-interventional study. Such person must certify that he or she has examined the protocol relating to the non-interventional study and that in his or her belief it is in accordance with the requirements of the Code.

22.3 Each company must appoint at least one senior employee who shall be responsible for supervising the company and its subsidiaries to ensure that the standards of this Code are met.



Annex I

ADMINISTRATION OF THE CODE AND COMPLAINTS PROCEDURE

1. INTRODUCTION

The IPHA Code of Practice is a self-regulatory Code. All members of IPHA, as a condition of their membership of the Association, are signatories to the Code.

Non-IPHA member companies may also choose to become signatories to the Code. Where a person or body is concerned that the promotional activities of any signatory to the Code may be in breach of the Code, a complaint may be submitted to IPHA for consideration. Documents may be submitted to IPHA in either soft or hardcopy. The Code of Practice is administered by the Code Council (see Section 3 of this Annex) and complaints are heard in the first instance by the Code Council. Decisions of the Code Council may be appealed to the Appeals Board (see Section 5 of this Annex). Alleged breaches of the Code by a Code signatory which come to IPHA's attention other than by way of a formal written complaint are defined as "referrals" and are dealt with in accordance with the procedure set out in Section 7 of this Annex.

2. INTER-COMPANY RESOLUTION

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

Where a member company expresses concerns regarding the Code compliance of specific claims included in electronic promotional material belonging to another company it is highly recommended (in order to facilitate inter-company resolution) that a hard copy of the relevant part of the electronic material is shared by the other company with the company that has the concern.

3. CODE OF PRACTICE PANEL, CODE COUNCIL AND APPEALS BOARD

3.1 Composition of Panel

The Code Council is drawn from the Code of Practice Panel [the "Panel"] which is made up of the following:

- A minimum of 18 persons drawn from IPHA member companies;
- One person drawn from non-IPHA signatories to the Code ["the non-IPHA member"];
- A maximum of four persons who are financially and otherwise independent of the pharmaceutical industry;
- Two independent Chairs.

In the event of an appeal, the Appeals Board will be drawn from the Panel. Panel members who have considered a Complaint at Code Council level are not eligible to consider the same Complaint at Appeals Board level.

In the event that no non-IPHA signatory nominations have been received or such person is unavailable at the time of hearing a complaint, the Code Council/Appeals Board shall be constituted without a non-IPHA member. The same principle will apply independent persons.

3.2 Selection of the Panel

IPHA members:

Nomination papers are sent by the IPHA Executive to all member companies when a position(s) on the panel becomes available. The nominations are considered by the IPHA Prescription Medicines Division Strategy Board [the “Strategy Board”] which selects the appropriate person(s) to serve on the Panel. If insufficient nominations are received, the Strategy Board may fill any remaining vacancies as it deems appropriate.

Non-IPHA members:

The IPHA Executive invites nominations from all non-member Code signatories. The selection of the non-IPHA member is made by the Strategy Board.

Independent members:

The selection of the independent members is made by the Strategy Board.

3.3 Composition of the Panel

Most areas of management in the industry (e.g. general, regulatory, marketing, medical, sales, management) are considered to provide appropriate or relevant skills/expertise with regard to membership of the Panel. A mix of skills and expertise across the Panel is desirable and will be taken into account by the

Strategy Board in the selection process.

3.4 Term of Office

Selection to the Panel will be for a three-year term. All members are eligible for re-selection.

3.5 Chairs

Two independent Chairs, one for the Code Council [the “Code Council Chair”] and one for the Appeals Board [the “Appeals Board Chair”], will be appointed by the IPHA Board of Directors. These appointments will be reviewed every three years.

The Chairs have a casting vote only, except as provided for in Section 7.3 of this Annex, which stipulates that in referral cases the Code Council Chairmen shall not have any vote.

3.6 Consultation

The Chairmen shall have the right to consult external experts and/or obtain any assistance in any field. The Code Council and Appeals Board are encouraged to avail of this facility, should the need arise.

Individual members of the Code Council and the Appeals Board are encouraged to inform themselves by researching or consulting externally on issues in a general sense, whilst maintaining confidentiality.

3.7 Conflict of Interest

If a Panel member is employed by a company directly involved in a complaint, referral or appeal, either as Complainant or Respondent, such member cannot participate in the Code Council or Appeals Board established to consider that complaint, referral or appeal.

It is recognised that, on occasion, members of the Code Council or Appeals Board while not employed directly by a company involved in a complaint, referral or appeal, may have some degree of conflict of interest (e.g. direct competitor, same therapeutic area etc.).

However, it may not be feasible or practicable to require such a member to stand down for consideration of a given complaint, referral or appeal. A member of the Code Council or Appeals Board should declare his or her interest to enable the relevant Chair to make an appropriate decision. Confidentiality must be maintained.

3.8 Substitution

No substitution or replacement is allowed on the Code Council or Appeals Board or during the hearing of a particular complaint, referral or appeal.

3.9 Autonomy

Panel members must have autonomy vis-à-vis their company/employer in the context of their participation in the Code Council and/or the Appeals Board.

3.10 Confidentiality

Absolute confidentiality must be maintained by Panel members.

As a rule, parties to proceedings before the Code Council shall maintain confidentiality concerning any dealings with the Code Council until such time as the Code Council reaches a final decision. Parties in exceptional circumstances may discuss issues before the Code Council with third parties but only to the extent that they can show to the satisfaction of the Code Council that this was absolutely necessary because of the intimate involvement of the third party with the matter to be considered by the Code Council and only to the extent that such discussion was factual, fair and balanced.

3.11 Accountability

The Code Council and Appeals Board are accountable to the IPHA Board of Directors for their satisfactory performance.

The Code Council and the Appeals Board are responsible for their own conclusions and deliberations.

3.12 Procedures for Meetings

A member of the IPHA Executive must attend all meetings of the Code Council and Appeals Board in a non-voting capacity. For all other aspects, the Code Council and Appeals Board set their own rules of conduct and procedure. Proceedings before the Code Council and the Appeals Board are informal. The Appeals Board has recourse to all methods and operational procedures that apply to the Code Council.

3.13 Representation

No representation may be made by any party to the IPHA President; the IPHA Executive; members of the IPHA Board, Prescription Medicines Division Strategy Board, Code Council or Appeals Board; or to the Code Council or Appeals Board Chairs regarding a complaint, referral or appeal while it is being processed.

3.14

The time frames for Complaints, Appeals and referrals can be shortened or lengthened at the discretion of the Chairs depending on the complexity of the issues presented and having regard to the availability of the Chairs and members of the Code Panel.

4. CODE COMPLAINTS PROCEDURE

4.1 Who can make a complaint?

Complaints may be made by a company, healthcare professional or any other body or person, with the exception of the IPHA Board of Directors, the Strategy Boards and any other IPHA committee or any member of the IPHA Executive.

4.2 What constitutes a valid complaint?

Complaint made by Code Signatory:

When the Complainant is a Code signatory, 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 etc;
- (ii) It must specify those clauses of the Code which are alleged to have been breached;
- (iii) An electronic response is preferred, however, if submitted in hardcopy, ten bound copies of the complaint must be supplied (further copies will be requested in the event of an appeal).

The Complainant must also provide in writing:

- an unqualified undertaking that the company will comply with every reasonable request of the Code of Practice Council or Appeals Board, if relevant;
- confirmation that the company will accept the final decision of the Council, or Appeals Board, if relevant, (although it 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 Council or Appeals Board, if relevant, will result in the Complaint not being processed further.

Other Complainants:

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) the complaint must be submitted in writing. Anonymous complaints will not be accepted. The Complainant's identity will be disclosed to the Respondent, only in exceptional circumstances, where it may be necessary for the Respondent to know the identity of the Complainant so that the matter can be fully investigated, and only with permission from the Complainant.

The Code Council will examine the complaint in detail and determine which clauses of the Code have been breached.

4.3 Establishment of Code Council

On receipt of a complaint in the IPHA offices, the IPHA Executive will establish a Code Council (having due regard to conflicts of interest and other relevant matters) from amongst the members of the Code Panel, to consider the complaint.

A quorum of four (three IPHA members plus the Code Council Chair) is required to hear a complaint and arrive at a final decision.

One of the independent persons and the non-IPHA member will also be invited to participate in the Code Council. Papers regarding the case will only be circulated to those persons who have confirmed that they will be in a position to attend the meeting.

4.4 Code Council Procedure and Timelines

The deliberation of Code Council is performed on a case-by-case basis taking overall context, intent and the contents of the activity into account, and does not follow the principle of precedence.

The Code Council will endeavour to consider and deal with complaints in accordance with the following procedure and timelines:

The formal timeline 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 (i.e. the Respondent) who is requested to:
 - Provide a written response within 10 working days;
 - Provide an unqualified undertaking that the company will comply with every reasonable request of the Code of Practice Council or Appeals Board, if relevant;
 - Confirm that the company will accept the final decision of the Council, or Appeals Board, if relevant (although it may reserve the right to have recourse to law should it consider that route necessary).
 - An electronic response is preferred, however, if responding in hardcopy, supply ten bound copies of the response (further copies will be requested in the event of an appeal);

Failure by the Respondent to provide the required written undertaking of compliance and confirmation of acceptance of the Decision of the Code Council or Appeals Board, if relevant, will result in the matter being referred to the IPHA Board of Directors. The clock will stop until the Board has considered the matter and advised how the complaint is to be dealt with;

- Following receipt of the document(s) and prior to the first meeting of the Code Council, the Code Council Chair shall have the discretion to ask either party to supply any additional information considered necessary to establish the full facts of the alleged breach so as to enable the Code Council to reach a decision on the matters complained of;
- Prior to the meeting of the Code Council the IPHA Executive will issue a copy of the complaint (and the response, if received) to each member of the Code Council;
- A meeting of the Code Council will be arranged within 30 working days of the date of receipt of the complaint (i.e. whether or not the Respondent has replied).
- It is desirable but not always possible to reach a decision at that meeting. From time to time, subsequent meetings may be required;
- The Complainant and Respondent shall be kept informed of progress with the complaint. The names of the members of the Code Council hearing the complaint may only be made available to either party subsequent to the completion of a case and only then on request;
- Where the Code Council, having considered a complaint or referral, has found that the Code has been breached, it shall have the authority to consider whether the gravity of the breach upheld is such that Clause 2.1 of the Code has also been breached;
- The Code Council will issue a final decision within 10 working days of its last meeting and provide it to the Complainant and the Respondent;
- The Respondent will have 10 working

days from the date on which the decision is issued to either lodge an appeal or 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;

- If a breach of the Code is determined and an appeal is not lodged, the Prescription Medicine Division Strategy Board will be provided with a copy of the Code Council decision at that time.
- Except in exceptional circumstances, that must be notified in advance to the Code Council, or the lodging of an appeal, the respondent must execute the Code Council requirements in full within 20 working days of the issuing of the decision. Also within those 20 working days the respondent must provide written details of the precise actions that it took to the Code Council.

Any request for an extension of the 10 day timeline for submitting an appeal will be a matter for consideration by the Code Council Chair.

4.5 Withdrawal of complaints

The Complainant may withdraw the complaint at any time up until the response has been received by IPHA. If a complaint is withdrawn before it has been sent to the Respondent, the Respondent will not be informed about the complaint.

Where the Code Council Chair is of the view that the alleged breach is serious, he or she may choose to continue the investigation of the matter in the manner outlined under the referral system (see Section 7 of this Annex) regardless of the withdrawal of the complaint.

5. APPEALS BOARD PROCEDURE AND TIMELINES

5.1 What constitutes a valid Appeal?

The following requirements must be satisfied for an Appeal to be considered valid:

- (i) The Appeal must be in writing;
- (ii) It must specify which aspects of the Code Council's Decision are being appealed and also the grounds for the Appeal which must be one or more of the following:
 - (a) the finding(s) is(are) wrong
 - (b) the sanction(s) is(are) excessive
 - (c) finding(s) is(are) flawed because of a serious procedural or other irregularity;
- (iii) It may refer to documentation already submitted to the Code Council and include any further material, including new evidence;
- (v) An electronic response is preferred, however, if responding in hardcopy twelve bound copies of the appeal and twelve bound copies of the original complaint must be supplied.

5.2 Who can lodge an Appeal?

Only the Respondent to a Complaint may lodge an Appeal to the Appeals Board in respect of the Decision of the Code Council on the Complaint.

5.3 Establishment of Appeals Board

On receipt, in the IPHA offices, of a written Appeal from the Respondent in respect of a Decision of the Code Council, the IPHA Executive will establish an Appeals Board from amongst the members of the Panel having due regard to conflicts of interest and other

relevant matters.

A quorum of six (five IPHA members plus the Appeals Board Chair) is required to hear an Appeal and arrive at a final Decision. One of the independent persons and the non-IPHA member, if they have not participated in the Code Council hearing, will also be invited to participate in the Appeals Board.

5.4 Material Supplied to Members of Appeals Board

Appeals shall be conducted as follows:

- (i) In the case of an Appeal on the ground described in Section 5.1(ii)(a), the role of the Appeals Board is to reach a Decision based on the rehearing of those aspects of the Complaint under Appeal, conducted and heard as though at first instance, taking into account the original submissions to the Code Council and any additional evidence submitted by either party in the Appeal that the Appeals Board deems to be relevant.
- (ii) In the case of an Appeal on either of the grounds described in Section 5.1(ii)(b) and (c), the role of the Appeals Board is to reach a Decision taking into account the grounds of the Appeal, the original submissions to the Code Council, the Code Council Decision and any additional evidence submitted by either party in the Appeal that the Appeals Board deems to be relevant. The Appeals Board will not rehear the original Complaint.

A copy of the Complaint with the Response thereto, the Appeal with the Response thereto, and the Decision of the Code Council will be sent to each member of the Appeals Board.

5.5 Appeals Board Procedures & Timelines

The Appeals Board will endeavour to consider and deal with Complaints in accordance with

the following procedure and timelines:

- The formal timeline starts when a valid Appeal is received at the IPHA offices;
- A copy of the Appeal is sent to the other party involved in the Complaint, who is requested to provide a written Response, within 10 working days. Electronic is preferred, however, if the other party is a Code signatory and if the response is submitted in hardcopy, it must supply twelve bound copies of the Response and twelve bound copies of the original Code Council submission (complaint);
- Upon receipt of the Response to the Appeal, the Executive issues the documentation referred to at Section 5.4 above to each member of the Appeals Board.
- A meeting of the Appeals Board is arranged within 30 working days of the date of receipt of the Appeal (i.e. whether or not the other party has replied);
- It is desirable but not always possible to reach a Decision at the first meeting of the Appeals Board. From time to time, additional meetings may be required;
- The two parties involved in the Appeal shall be kept informed of progress with the Complaint;
- The Appeals Board may limit its deliberations to selected relevant additional evidence, at its discretion;
- The names of the members of the Appeals Board hearing the Appeal may only be made available to either party subsequent to the completion of a case and only then on request;
- The Appeals Board issues a final decision within 10 working days of its last meeting

which is provided to the Appellant, the Respondent and provided that a breach of the Code has occurred, also to the Prescription Medicine Division Strategy Board;

- Where a breach of the Code is confirmed by the Appeals Board, the company concerned has 10 working days to confirm in writing its intention to comply with the recommendations/sanctions imposed. Failure by the company concerned to do so will result in the matter being referred to the IPHA Board of Directors;
- Except in exceptional circumstances, that must be notified in advance to the Appeals Board, the respondent must execute the Appeals Board recommendations/sanctions in full within 20 working days of the issuing of the final decision. Also within those 20 working days the respondent must provide written details of the precise actions taken to the Appeals Board.

5.6 Decision of the Appeals Board

The Decision of the Appeals Board is final and binding.

Notwithstanding this, there may be occasions where resolution of a complaint regarding an EFPIA member is not achievable. In such circumstances EFPIA will be informed and EFPIA will decide what action should be taken as per the process outlined in Annex D of the consolidated EFPIA Code of Practice, July 2019.

5.7 Personal Representation during Appeals

Each party involved in an Appeal has the right to make an oral presentation to the Appeals Board. The following conditions will apply to all such personal representations:

- (i) The IPHA Executive must be notified in writing if the relevant party intends to exercise this right at least five working days before the date of the first meeting of the Appeals Board;
- (ii) Details of the company representatives who will be in attendance must also be provided in writing. External advisors (including barristers or representatives from firms of solicitors) are not permitted to attend on behalf of either party. Additionally, the Appeals Board Chair has the right to limit the number of representatives;
- (iii) A summary of each party's representations to the Appeals Board shall be submitted as soon as possible after the request for such representations and in any event, no later than five working days before the Appeals hearing. Each party to the Appeal will receive the summary of the other's representations in advance of the hearing;
- (iv) Each party's presentation shall be limited in duration (generally to a maximum of 20 minutes followed by 10 minutes for questions from the Appeals Board);
- (v) No new material or data may be introduced during the oral presentation that was not previously included in the written documentation provided to the Appeals Board.

5.8 Withdrawal of Appeals

The Appellant may withdraw the Appeal at any time up until the Response has been received by IPHA. If an Appeal is withdrawn before it has been sent to the Respondent, the Respondent will not be informed about the Appeal.

6. REQUIREMENT FOR COMPLAINTS TO HAVE SUBSTANCE

All complaints submitted for consideration must have substance. In the event of doubt about whether a complaint has substance, the Code Council Chair will be asked to adjudicate.

6.1 Complaints concerning promotional activities other than printed matter

The difficulty in particular of establishing evidence for the Code Council to consider in relation to complaints concerning promotional activities such as meetings, hospitality, samples etc. is recognised. The following requirements will therefore apply to such complaints:

- (i) Any complaint in relation to such activity must have substance;
- (ii) The complaint must be in writing and should contain enough detail about the activity alleged to be in breach of the Code, as to justify the Code Council's consideration;
- (iii) Any available material evidence must be included e.g. invitation or correspondence from the Respondent's company. The absence of such material evidence will not preclude the Code Council's consideration of the complaint.

If the Code Council considers that such a complaint justifies investigation, it will have the right to ask the Respondent's company to demonstrate that it was in compliance with the Code. These provisions shall also apply in the case of appeals concerning promotional activities other than printed matter.

7. REFERRALS (I.E. ALLEGED BREACHES OF CODE WHERE THERE IS NO FORMAL WRITTEN COMPLAINT)

Alleged breaches of the Code by a Code signatory which come to IPHA's attention other than by way of a formal written complaint are defined as "referrals". When the IPHA Chief Executive or other members of the executive become aware of any information relating to a potential breach of the Code, the Chief Executive is mandated to report it, without prejudice, to the Code Council Chair. Confidentiality regarding the source of the referral should be respected where possible. Referrals are dealt with in accordance with the following procedure:

7.1 Establishing if referral is appropriate and has substance

Where the Code Council Chair receives information, from whatever source, from which it appears that a Code signatory may have contravened the Code, the Code signatory concerned shall be requested to comment on the matter(s) of complaint.

The Code Council Chair shall decide, having taken into consideration any information received, if the referral has substance and in particular if there is enough detail about the alleged activity as to justify the Code Council's investigation. If the Code Council Chair decides that the matter does not warrant investigation by the Code Council, that decision will be final and the complainant shall be so advised.

7.2 Use of the referral mechanism by a Code signatory

Code signatories shall normally use the complaints mechanism to seek redress for alleged breaches of the Code. Where they use

the referral mechanism they must provide the Code Council Chair with a satisfactory explanation as to why it was not possible to utilise the normal complaints mechanism. The Code Council Chair shall then decide whether it is appropriate for the matter to be dealt with in this way or whether the Code signatory, should it wish to progress the matter further, should be required to use the complaints procedure outlined in Section 4 of this Annex.

Where the Chair decides it is appropriate for the matter to be dealt with by way of the referral mechanism, the Code signatory will be identified to the Code Council and the Respondent as the source of the referral.

7.3 Role of Code Council

The Code Council will be responsible for investigating the alleged breach and, in particular, for identifying any clauses of the Code which may have been breached. The referral will be handled using the standard procedures and timelines that apply to Code complaints, except that in such cases the Code Council Chair shall not have a vote. The Code Council will have the same powers to apply sanctions as in the case of a complaint.

7.4 Procedure for Consideration of Referrals by Code Council

The following procedure shall apply to the Code Council's investigation of a referral:

- In order to expedite matters, the Code Council Chair may write to the company that is alleged to have breached the Code before the first meeting of the Code Council seeking preliminary information for the Code Council to consider at its first meeting;
- In any case, the company will be required to provide the standard undertakings that apply to complaints, i.e. an unqualified undertaking that it will comply with every reasonable request of the Code Council and confirmation that it will accept the final decision of the Council (or Appeals Board if relevant);
- After its first meeting, the Code Council will issue a letter to the company setting out the alleged breaches of the Code and it will be required to submit a written response. The Code Council has the authority to seek any further additional information considered necessary from the company which is alleged to have breached the Code;
- All information requested by the Code Council Chair and Code Council must be provided within 10 working days, with extensions only possible at the discretion of the Code Council Chair. If submitted in hardcopy, ten bound copies of the information must be supplied (further copies will be requested in the event of an appeal). One electronic copy will suffice in lieu of 10 bound hardcopies.
- The company shall have a right of appeal to the Appeals Board in relation to the decision of the Code Council, including any sanctions applied. The procedures outlined in Section 5 of this Annex will apply to such appeals;
- In the case of a referral where the Code is found to have been breached, details of the case shall be reported in the usual manner in the Code of Practice Publication of Findings Report, with referrals being reported separately to complaints;
- It shall not be open to Code signatories to seek the views of the Code Council on any of their own activities.

8. SANCTIONS

Where the Code Council, having considered a complaint or referral, 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 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 with relevant healthcare professionals or by publication, in the medical and/or pharmaceutical press, of a corrective notice in terms approved by the Code Council/Appeals Board;
- (v) Order the immediate publication of the decision in whole or in part and specify how and to whom the decision is to be sent. This is additional to inclusion of details of the decision in the annual Code of Practice Publication of Findings report (see Section 11 of this Annex);
- (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.

This list is not exhaustive and other sanctions may be applied by the Code Council/Appeals Board as appropriate. Where a Code Council or an Appeals Board decision involves an

action to be taken by IPHA, the relevant Chair should inform the IPHA Chief Executive of this in writing and unless otherwise specified by the Chair, IPHA should wait until 10 days after the decision has been issued to the company before carrying out that action.

In the event that the decision of the Code Council is appealed, the Appeals Board shall assume responsibility for the application of any or all of the above sanctions. In addition, the Appeals Board may uphold the decision of the Code Council but vary the sanctions applied. As soon as a decision of the Code Council becomes the subject of an appeal, the decision and any sanctions imposed by the Code Council is deemed to be suspended.

9. ABUSE OF CODE

Abuse of the Code procedure shall in itself be a breach of the Code.

10. RECOURSE TO LEGAL SYSTEM

A company's right to have recourse to the legal system is not affected by participation in, and compliance with, the Code of Practice and the Code Council's and the Appeals Board's decisions.

However, it is envisaged that the transparency of procedures in this Code will ensure that the necessity for such action will not arise.

A Complainant/Respondent must advise the Code Council and the Appeals Board in the unlikely event of recourse to the legal system before or during a complaint. The Code Council or the Appeals Board, as appropriate, will have the right to take whatever action it sees fit under the circumstances.

11. CODE OF PRACTICE PUBLICATION OF FINDINGS

The Code of Practice Publication of Findings is published at least once a year by IPHA.

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

- All members of IPHA
- All non-IPHA member Code signatories and independent persons
- The Minister for Health/Department of Health
- The Health Products Regulatory Authority

The Publication of Findings will include the number and context of complaints and referrals, both those upheld and those not upheld, heard by the Code Council and Appeals Board each year. The full decision in respect of each complaint upheld in whole or part will be provided, including the names of companies found to have breached the Code. However, unless specifically requested by the respondent, the decision relating to a non-upheld complaint will not be added to the Publication of Findings.

12. ADMINISTRATION FEES

IPHA reserves the right to set fees for the operation of the IPHA Code Council and Appeals Board at any time in the future.

13. PROCEDURES FOR AMENDING PROVISIONS OF THE CODE

It is important that the Code and its associated guidelines should accurately reflect the highest standards and for this reason it is kept under constant review and amended from time to time where necessary, to clarify it and bring it up to date.

IPHA's Code of Practice Review Team will be convened as necessary to consider proposals to amend provisions of the Code and make appropriate recommendations. The Code Council, the Appeals Board, the general membership of IPHA, non-IPHA member signatories to the Code and any other external interested parties may refer items for discussion by the Review Team.

Annex II


GUIDELINE ON NURSING SERVICES PROVIDED BY COMPANIES

With the prior agreement of individual medical practitioners or healthcare organisations, some companies provide the services of specially trained nurses to educate patients about the medicines that they are prescribed and help them achieve treatment compliance with the aim of enhancing patient care.

Although these nurses may provide their services within a hospital, doctor's clinic or the patient's home etc. they are either directly in the employ of the companies or contracted from a third party agency by the companies. Owing to the special nature of such a service, it is important to set out guidance for sponsoring companies, the nurses and the medical professionals who benefit from these services. The guidance seeks to ensure standards of best practice and to enhance the understanding of the role and authority of these nurses in the provision of these services.

1. The provision of a nursing service must avoid any inference that it might be considered to be an inducement designed to promote the prescription, supply, sale or consumption of a medicine. The nursing service must be provided under the supervision of the Scientific Service of the company and the medical professional or the management of the practice/clinic receiving the nursing service, must be provided with written information describing the service.
2. The nurse has no authority to prescribe medicines or to change a prescription authorised by the medical practitioner.
3. Nurses may provide direct advice to a patient about a medicine upon receipt of a prescription by the patient. The advice must be consistent with the terms of the marketing authorisation.
4. A company must only offer the services of a nurse by prior arrangement.
5. Nurses must operate to detailed written instructions provided by the company. These instructions must clearly set out the role of the nurse. Nurses must be registered with Bord Altranais agus Cnáimhseachais na hÉireann. They must adhere to all requirements including the stipulation outlined in its Code of Professional Conduct that registration status should not be used in the promotion of commercial medicine. Nurses must transmit to their companies any safety information reported to them in relation to the company's medicine.
6. The remuneration of nurses must not be linked to sales or bonus scheme related to a product(s). Bonus schemes linked to a company's overall national performance or to the level of service provided may be considered.
7. Any material provided by the nurse to the patient must be non-promotional. Any material provided prior to the treatment

decision must not include medicine brand names. Any material provided after the independent prescribing decision has been made may be company branded, but may only include the medicine brand name if it is necessary for the safe use of the medicine.

8. Patient confidentiality is crucially important and any details taken and retained by the nurse, should be agreed with the healthcare professional and the patient, be based on informed patient consent and comply with data protection and all other legislation.
 9. Companies must ensure that nurses are adequately trained (including relevant product SmPC training where appropriate) and are fully conversant and compliant with the IPHA Code.
 10. The patient may at all times reserve the right to decline the support offered by nurses and such a decision must be respected.
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Annex III

WORKING WITH PATIENT ORGANISATIONS

1.

INTRODUCTION

Patient Organisations play a key role in representing, meeting the information needs of and offering support to people living with ill-health.

Increasingly, Patient Organisations (including patient and healthcare advocacy groups which are not disease specific) and companies are realising that they do share common interests and can benefit from working together towards achieving early diagnosis and appropriate treatment of an illness, improved compliance with treatment and better health outcomes. This type of collaboration is to be welcomed and encouraged.

The purpose of this document is to provide guidance to companies on how to ensure their relationship with Patient Organisations is positive, constructive, mutually beneficial and ethical.

2. GENERAL PRINCIPLES

The following general principles shall apply to the relationship between a company and a Patient Organisation:

- The independence of the Patient Organisation, in terms of their policies and their activities, must be guaranteed;
- The relationship between the Patient Organisation and the company shall be based on mutual respect and trust;
- In all matters where there is joint co-operation, there must be full transparency. In particular, public disclosure of direct and indirect support provided by companies to Patient Organisations is required;
- The company shall not request, and the Patient Organisation shall not undertake, the promotion of the company's medicine either directly or indirectly;
- The company and the Patient Organisation shall, on request, provide each other with annual reports, and any other information deemed appropriate by both parties so as to provide further background to the campaign, project, funding request, etc.

3. FUNDING OF PATIENT ORGANISATIONS

Despite the importance of Patient Organisations (POs) and the growing number of people who depend on their services, these groups are charities and must therefore raise money from a wide variety of sources such as legacies, foundations, Government and large corporations. It is also appropriate for companies to provide funding for Patient Organisations and many companies do so.

When Member Companies provide financial support, significant indirect support and/or significant non-financial support to POs, they must have in place a written agreement. This must state the amount of funding and also the purpose (e.g. core funding, specific meeting or publication, etc). It must also include a description of significant indirect support (e.g. the donation of public relations agency's time and the nature of its involvement) and significant non-financial support.

There are a number of ways in which it is acceptable for a company to provide funding for a Patient Organisation, for example:

- Companies may donate money without reference to the specific purpose for which it is to be used. This is sometimes referred to as a contribution to core funding;
- Funding may be provided for a Patient Organisation publication, meeting, project or piece of research in which the company has little or no involvement;
- A company may facilitate Patient Organisation meetings by providing or sponsoring speakers or providing a venue or making a contribution towards travel expenses for delegates;
- A company may undertake projects of joint interest with a Patient Organisation.

The following principles shall apply in relation to such funding:

Editorial control

- companies working with Patient Organisations should recognise the limits of their involvement (which should be set out in writing in all cases) and the independence of the Patient Organisation. In particular, companies must not seek to

influence the text of Patient Organisation materials they sponsor in a manner favourable to their own commercial interests. This does not preclude companies from correcting factual inaccuracies. In addition, at the request of Patient Organisations, companies may contribute to the drafting of the text from a fair and balanced scientific perspective.

Transparency

- Both parties should be transparent about funding arrangements, ensuring that partnership programmes and funding arrangements are not only proper, but also seen to be so. Each company must make publicly available a list of Patient Organisations to which it provides financial support and/or significant indirect/non-financial support. This should include a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the significance of the support. The description must include the monetary value of financial support and of invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value the description must describe clearly the non-monetary benefit

that the Patient Organisation receives.

This information may be provided on a national or European level and should be updated annually, by 30th June each year. Each reporting period shall cover a full calendar year (the “reporting period”). Companies must ensure that their sponsorship is always clearly acknowledged and apparent from the outset; Each company must make publicly available a list of Patient Organisations that it has engaged to provide significant contracted services. This should include a description of the nature of the services provided that is sufficiently complete to enable the average reader to form an understanding of the nature of the arrangement without the necessity to divulge confidential information. Companies must also make public the total amount paid per patient organisation over the reporting period.

Each Company must publish the methodologies used by it in preparing the disclosures and identifying supports and services provided.

The standardised PO Disclosure template is binding for member companies to use. A copy of the template can be downloaded from www.ipha.ie and is visible below.

Patient Organisation disclosure template

PO name	Country	Types of the support or services provided	Description of the support or services	Monetary value of financial support and of invoiced costs	Non-monetary benefit for PO	Fees for services paid
		Financial support		In euros		
		Financial support		In euros		
		Financial support		In euros		
		Financial support		In euros		
		Significant indirect support		In euros		
		Significant indirect support		In euros		
		Significant indirect support		In euros		
		Significant indirect support		In euros		
		Non-financial support			In euros	
		Non-financial support			In euros	
		Non-financial support			In euros	
		Non-financial support			In euros	
		Contracted services				In euros
		Contracted services				In euros
		Contracted services				In euros
		Contracted services				In euros

1: Add a clear description of the purpose of the support or services

2: For example, employee hours or companies facilities offered to support a Patient Organisation activity

Contracted services

- Contracts between companies and Patient Organisations under which they provide any type of services to companies are only allowed if such services are provided for the purpose of supporting healthcare or research. It is permitted to engage Patient Organisations as experts and advisors for services such as participation at advisory board meetings and speaker services. The arrangements that cover consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

- a) A written contract or agreement is agreed in advance which specifies the nature of the services to be provided and, subject to clause (g) below, the basis for payment of those services;
- b) A legitimate need for the services has been clearly identified and documented in advance of requesting the services and entering into the arrangements;
- c) The criteria for selecting services are directly related to the identified need and the persons responsible for selecting the service have the expertise necessary to evaluate whether the particular experts and advisors meet those criteria;
- d) The extent of the service is not greater than is reasonably necessary to achieve the identified need;
- e) The contracting company maintains records concerning, and makes appropriate use of, the services;
- f) The engaging of Patient Organisations is not an inducement to recommend a particular medicinal product;
- g) The compensation for the services is reasonable and does not exceed the fair

market value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensating Patient Organisations;

- h) In their written contracts with Patient Organisations, companies are strongly encouraged to include provisions regarding an obligation of the Patient Organisation to declare that they have provided paid services to the company whenever they write or speak in public about a matter that is the subject of the agreement or any other issue relating to that company;
- i) Each company must make publicly available a list of Patient Organisations that it has engaged to provide paid-for services (see last paragraph of the section titled 'Transparency' above).

Single company funding

- Companies welcome broad funding and support of Patient Organisations from multiple sources. Companies must ensure that their support is always acknowledged and apparent from the outset.
- No one company should fund a Patient Organisation to the exclusion of other available and willing sponsors. However a Patient Organisation's independence must be recognised insofar as whom they wish to work with exclusively. It would be reasonable for a willing sponsor to receive an explanation as to why they have not been included as a sponsor by the Patient Organisation;
- Where a Patient Organisation receives a significant part of its funding from one or more companies, the control of the association must be independent of the companies involved;

Use of logos and proprietary materials

- The public use of a patient organisation's logo and/or proprietary material by a company requires written permission from that organisation. In seeking such permission, the specific purpose and the way the logo and/or proprietary material will be used must be clearly stated.

Events and hospitality

- Any hospitality provided by a company to patient organisations and their members should be reasonable and secondary to the main purpose of the event at which it is offered and linked directly to the event in question, whether the event is organised by the Patient Organisation or the company. The same principles regarding hospitality apply if a company has provided sponsorship for hospitality at an event and has a significant say in how it is to be spent, although the Patient Organisation should always retain overall control of the event. Venues that are renowned for their entertainment or leisure facilities or are extravagant must not be used. Hospitality may only be extended to persons who qualify as participants in their own right. In exceptional cases, in case of clear health needs (e.g. disability), the travel, meals, accommodation and registration fees cost of an accompanying person considered to be a carer can be met.

Hospitality shall not include sponsoring or organising entertainment (e.g. sporting or leisure events).

If supporting members of patient organisations are to attend a conference, then member companies must have a clearly defined process in place for appropriate selection of the PO's representative considering factors such as relevant background and experience to be able to take full advantage of the conference. Compensation must not be

provided for time spent attending the event.

4. PROVISION OF INFORMATION BY COMPANIES

Many companies are engaged in comprehensive informational activities in conjunction with Patient Organisations focused on providing support material to patients who have been prescribed or use their medicine and in the publication of information about specific diseases. These activities play an important role in educating patients about their conditions and helping them to achieve good compliance with, and the best outcomes, from their medicines.

4.1 Prescription-only medicines

The advertising and promotion of prescription-only medicines to the public is prohibited by Irish and EU legislation, which is reflected in the IPHA Code of Practice. This prohibition extends to Patient Organisations as well as companies. Any informational activities by a company should not be undertaken in such a way as to give rise to the inference that their purpose is to encourage members of the public to ask their doctors to prescribe a specific medication. In particular:

- As a general rule, the brand name of a prescription-only medicine (including logos incorporating brand names) should not appear in any leaflet, brochure or other material, including a website, produced by a Patient Organisation that is sponsored in whole or in part by a company. This does not preclude a non-promotional reference to a named product in a Patient Organisation newsletter or website, provided that the sponsoring company has no editorial input and the reference to the product by the Patient Organisation is not in any way

linked with the sponsorship provided;

- No references by brand name to a prescription-only medicine should be included on any material displayed by a company at a Patient Organisation event or at an event organised for patients/the public by a company;
- The brand name of a prescription-only medicine may only appear in informational material produced by a company that is to be given to patients after the medicine is prescribed, to assist them in using it correctly;
- Speakers provided by a company for a Patient Organisation event must avoid any references to the company's medicine that could be regarded as promotion.

4.2 Disease awareness campaigns

In recent years, a number of companies have been associated with public advertising campaigns designed to raise awareness of specific diseases and encourage sufferers or at risk people to seek advice on treatment. Many of these campaigns have been run under the umbrella of Patient Organisations and have been funded wholly or in part by the industry. These campaigns are particularly useful for conditions or symptoms that might otherwise go untreated, including asymptomatic diseases like diabetes and hypertension, and embarrassing conditions like impotence and incontinence.

A disease awareness campaign should not in any way promote a brand of medicine, either directly by naming a product or indirectly, for example:

- If there are non-prescription as well as prescription-only medicines available to treat a particular condition, advising

patients to visit their doctor for treatment could be regarded as promoting the use of a prescription-only medicine. To avoid any such inference, consideration should be given to advising patients to talk to their doctor or pharmacist;

- In the case of a disease awareness campaign sponsored by a company which markets the only available medicine for that disease/condition, particular care is required to ensure that the campaign could not be regarded as promoting that product. Statements such as “Your doctor can prescribe a medicine to help you” should be avoided.

It is recommended that a company makes the medical profession and the relevant Patient Organisations (where appropriate) aware of its plans to run a disease awareness campaign before it is launched to the public.

4.3 Information about new scientific discoveries

A company may only provide information about a new scientific discovery of a prescription-only medicine to a Patient Organisation if the following conditions are satisfied:

- The information must be presented in a non-promotional way. Statements must not be made or designed for the purpose of encouraging members of the public to ask their doctors to prescribe a particular product;
- The information must be presented in a balanced way to avoid the risk of raising unfounded hopes in the public mind arising from the results of treatment.

A company can only incorporate a supportive statement about a new scientific discovery from a Patient Organisation in a press release,

with the written approval of the Patient Organisation.

4.4 OTC medicines

Unlike prescription-only medicines, most non-prescription or over-the-counter (OTC) medicines can be advertised to the public. The advertising and promotion of these medicines must comply with the IPHA Self-Care Advertising Code for the Consumer Healthcare Industry. In particular:

- Any reference to an OTC medicine (including its brand name and/or product specific logo) in promotional material produced by or paid for by a company (e.g. brochure, leaflet, website, company stand), is regarded as an advertisement. This includes advertisements in Patient Organisation newsletters, brochures, websites, etc.;
- Promotional material referring to OTC medicine by brand name/logo, including material prepared by a Patient Organisation but paid for by the manufacturer, must not be designed to disguise its real nature. In particular, such material must not resemble editorial matter;
- References to a company's product by active ingredient only in material prepared by a Patient Organisation are not regarded as advertising provided that the material is drafted independently of the company and any other relevant active ingredients are mentioned. Such material may carry advertising for OTC medicine, including those referred to by active ingredient in the editorial.

4.5 Requests for information from Patient Organisations

Companies should always refuse requests

from Patient Organisations and their members for advice on personal medical matters (e.g. is this medicine suitable for me?). In such cases, they should be advised to contact their own healthcare professional.

The intention of this is to ensure that companies do not intervene in the patient/healthcare professional relationship.

It is however permissible to answer general questions about medicines, for example, whether they are suitable for diabetics or coeliacs, whether the medicine should be taken before or after meals, etc.

Summaries of Product Characteristics (SmPCs), Package Leaflets (PLs) and European public assessment reports (EPARs) may also be provided to patients but must not be presented in a promotional way.

5. PROVISION OF SAMPLES

Free samples of medicine (i.e. both prescription-only and OTC medicines) may not be supplied to members of the public under Irish and EU legislation. Companies should not offer nor should Patient Organisations or their members seek, free samples. Packs containing medicine should not be displayed on company stands at Patient Organisation events.

6. SUMMARY

Co-operation between companies and Patient Organisations makes a valuable contribution to the nation's understanding of many conditions and improved compliance amongst the population being treated for these conditions. Adherence to this guideline will ensure that this collaboration is undertaken in a positive and ethical manner.

Annex IV

**GUIDELINE
ON DIGITAL
COMMUNICATION
IN THE
PHARMACEUTICAL
SECTOR**

1. INTRODUCTION

An important responsibility of the pharmaceutical industry is not only to ensure that it produces quality medicine and that these medicine are used in a rational manner, but also to facilitate the sharing of information on medicine and areas of research using current communication technologies, in compliance with the Code, to the benefit of patients and healthcare professionals.

The aim of this guidance is to provide advice on digital communication directed at HCPs and members of the public in Ireland. As a result, information placed on the internet outside Ireland, placed there by an Irish company or with the authority of such a company, that makes reference to the availability or use of the medicine in Ireland will also come within the scope of this document.

This guidance relates to prescription medicines only, is intended as a complement to the Code and while individual clauses from the body of the Code are not repeated here it is implicit that irrespective of the medium used all methods of promotion must conform to the Code in its entirety.

Digital communication describes communication through channels such as social networking sites (e.g. Facebook, Google Plus), Content communities (e.g. YouTube), Blogs (Tumblr, Micropress), 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.

2. OBLIGATIONS

- (i) Sources of the information provided at the digital platform, edition/publication dates and a description of persons or entities from which the information was obtained should be made available upon request.
- (ii) Every digital platform must have a homepage, discernibly linking to the following information:
 - Clear identity of the digital platform owner, with logo, physical and electronic address and contact telephone number(s).
 - Purpose and (unambiguous) target audience(s) of the digital platform (e.g. healthcare professionals, general public etc).
- (iii) Information related to medicine placed on the digital platform must have been reviewed and authorised to ensure Code compliance. Such information should be regularly reviewed with clear references to the last revision date for each section, page and/or article, as applicable.
- (iv) Information that could be construed as prescription medicine promotion must not be used on the landing page.

Particular attention must be paid to ensuring that the balance of safety and efficacy information is maintained on each microsite of a company's website, at all times. Under no circumstances may the safety information alone be missing from a site, even during website updates.

- (v) Company procedures should be in place to ensure that digital platforms are monitored for adverse events on a regular basis and in line with regulatory requirements. Companies should also

have procedures in place to monitor and deal with other complaints or inappropriate content.

When hosting recordings on digital platforms, companies must ensure that any product claims made by speakers within a recording are adequately substantiated and that references are available upon request.

- (vi) Reasonable care must be taken when referencing (linking to) other digital platforms and compliance with the Code is required in introducing such links. It should be clear to the platform visitor whether the link is to a company sponsored site or an independent site. Users should be given a clear indication when they are leaving digital platforms owned or funded by a company to be directed to an external platform.
- (vii) Linking to dynamic content (such as “blogs”, “chatrooms” or “forums”) on digital platforms wherein information constantly changes, and adherence to the Code is difficult, should be avoided.
- (viii) All email databases should be held in accordance with data privacy legislation and notices such as “unsubscribe” or similar wording should be included in all digital content.
- (ix) Content should be archived in a manner that allows future retrieval. Disputed portions of the content should be available in the event of objections being raised regarding non-compliance.

2.2 Information Aimed at the Public on Company Controlled/Sponsored Platforms

- (i) Nowhere in the digital platform pages should there be information which can be construed as promotion of prescription

medicines.

- (ii) Platforms intended for the public (e.g. medicine or disease information) should contain the expression “Information placed on this digital platform is not intended as a substitute for consultation with your healthcare professional” or words to similar effect, on the landing page and on other pages, where applicable. Additionally, the use of the phrase “Please consult your healthcare professional for further information” should be considered where appropriate.

2.3 Information aimed at Healthcare Professionals on Company Controlled/ Sponsored¹ Platforms

- (i) An effective process preventing access of others (e.g. a blocking warning, password or active declaration of status by users) should be used at the entry point of website sections aimed at healthcare professionals.
- (ii) Where a digital platform contains information aimed at both healthcare professionals and the general public it should be segregated into two sections, with the section aimed at healthcare professionals clearly marked with the expression “This section is intended for healthcare professionals only” or some similar phrase.
- (iii) If the platform contains a section where medical practitioners can exchange views, the moderation rules for this section should be clearly stated in the platform’s terms and conditions. Procedures should be in place to ensure that when a breach of these rules occurs (such as the discussion of off-label use) the material is immediately removed

and the contributor advised that such discussion is not permissible on a company sponsored/controlled forum.

- (iv) Where banner or banner like advertisements are in use, and if there is insufficient space on the electronic advertisement for all the information required (as set out in the Code), viewers must be either directed to click on the advertisement to bring them through to the required information, or a ‘button’ included on the advertisement containing the phrase “Abbreviated Prescribing Information” (or some such similar wording). The direction and / or button must be prominent and clearly legible. The hyperlink must be direct from the advertisement to the SmPC or abbreviated prescribing information etc which must be in a format that is prominent and clearly legible. Linking directly to the SmPC on www.medicines.ie is recommended.

2.4 Use of Social Media by Company Employees

Companies are advised to have a clear policy regarding social media use by company employees.

2.5 Information Sharing via Electronic Communication

No email HCP should be able to view the email addresses of other HCPs and all relevant data protection legislation should be adhered to.

2.6 Dynamic Content

- (i) Respect and transparency are essential in all communications and mechanisms should be in place to prevent unwanted or abusive messages.

¹ | Excluding platforms created by independent third parties (such as Patient Organisations) using grants received from companies.

- (ii) On message boards companies do not have full control of content and therefore should reserve the right to remove certain messages. This should be outlined in the rules for the digital platform.
- (iii) “Share,” “Like” or similar links may only be included in newsletters or e-zines aimed at the general public where they do not contain prescription medicine-related content to avoid prescription medicine promotion to non-healthcare professionals.

2.7 Third Party Digital Platforms Funded by Companies

- (i) Where a company engages in funding (by way of sponsorship, grant, donation, partnership or other such similar arrangement) of a digital platform with an independent third party, a written contract outlining both parties’ obligations is required. This should include pharmacovigilance responsibilities (if relevant) as well as control of the digital platform content to ensure compliance with the Code.
- (ii) Where a company engages in funding to an independent third party for a digital platform aimed at the public (as opposed to healthcare professionals) measures should be taken to ensure that the digital platform does not promote prescription medicines to the public. Such measures may include specific wording in an agreement relating to this area.

3. QUESTIONS AND ANSWERS

- 3.1 Question: What is the appropriate way to respond to inquiries from healthcare professionals via digital media?

Answer: Providing responses to inquiries

received from healthcare professionals through digital channels is acceptable if performed in accordance with the Code. The responsibility rests with the company to ensure that receipt of the response is restricted to the healthcare professional making the inquiry or their nominee.

- 3.2 Question: Is it appropriate for companies to contact healthcare professionals through social media channels?

Answer: The use of electronic data communications for promotion is prohibited except with the prior permission, or upon the request, of the HCP. Additionally, the responsibility rests with the company to ensure that receipt of the response is restricted to the healthcare professional making the inquiry or their nominee and that copyright is not infringed.

- 3.3 Question: Is it appropriate for companies to hold or sponsor virtual meetings and congresses etc?

Answer: Virtual congresses and meetings etc may be held or sponsored subject to compliance with the Code. In such meetings, the type and scope of sponsorship should be clearly disclosed. When compiling and/or releasing presentations or correspondence from the meeting, the sponsor should ensure that the material complies with the Code.

- 3.4 Question: Is it appropriate for companies to correct erroneous entries on Wikipedia, Facebook walls, etc?

Answer: This is a question of policy for a company. However, care needs to be exercised since if a company corrects certain information at a non-company mediated site but omits to correct other information that may be perceived

as related, such behaviour may be interpreted as a breach of the Code.

- 3.5 Question: Are companies responsible for collecting adverse events reported on the digital platforms that they own, support or sponsor?

Answer: Yes, companies' responsibilities encompass both collecting and reporting such information to relevant HCPs within the required timeframe(s) as set out in the legislation.

- 3.6 Question: Would it be an issue if prescription product branding elements were replicated without using the product name at a digital platform aimed at the public?

Answer: The promoting of prescription medicines to the public is prohibited. When branding elements (e.g. colour, logo, visual) are matched by the public with a prescription medicine brand, then it may be characterised as a violation of the prohibition to promote prescription medicines to the public.

- 3.7 Question: Is it possible to launch a digital platform using a prescription medicine product name?

Answer: Although there is no regulatory restriction, IPHA advises against launching digital platforms using prescription medicine names/ trademarks, unless specifically intended only for healthcare professionals (see Section 2.1(iv) of this guidance). On the other hand, owners of trademarks are recommended to acquire rights to digital platforms carrying their brand names, to prevent others from acquiring rights to such domains.

- 3.8 Question: Is it appropriate for companies to contact patients through social media channels?

Answer: Non-promotional contact may be acceptable in certain circumstances (e.g. reminding them to regularly take their prescribed medication) if documented approval from both the healthcare professional and the patient is received and, in the example above, the message carries no purpose other than supporting patient compliance with the medication schedule instructed by the patient's healthcare professional.

- 3.9 Question: Regarding Section 2.1(ii) of Annex IV of the IPHA Code must an Irish address be provided?

Answer: Section 2.1(ii) requires that every digital platform must have a homepage, discernibly linking to the following information:

- Clear identity of the digital platform owner, with company logo, street address, e-mail address and contact telephone number(s).
- Purpose and (unambiguous) target audience(s) of the digital platform (e.g. healthcare professionals, general public etc). However, if the platform owner is based outside of Ireland their relevant address is required and there is no requirement for an additional Irish address.



Annex V

**IPHA CODE ON
DISCLOSURE OF
TRANSFERS OF
VALUE FROM
COMPANIES TO
HEALTHCARE
PROFESSIONALS
AND HEALTHCARE
ORGANISATIONS**

1. INTRODUCTION

An important responsibility of the pharmaceutical industry is not only to ensure that it produces quality medicine and that these medicine are used in a rational manner, but also to facilitate the sharing of information on medicine and areas of research using current communication technologies, in compliance with the Code, to the benefit of patients and healthcare professionals.

This expertise makes an important contribution to the industry's efforts to improve the quality of patient care, with benefits for individuals and society at large. Healthcare professionals and healthcare organisations should be fairly compensated for the legitimate expertise and services they provide to the industry.

Prescription medicines developed by the industry are complex medicine designed to address the needs of patients. Thus educating healthcare professionals about the medicines and the diseases that they treat benefits patients. The pharmaceutical industry can provide a legitimate forum for the education of healthcare professionals and the exchange of knowledge among healthcare professionals and the industry.

Interactions between the pharmaceutical industry and healthcare professionals can have a profound and positive influence on the quality of patient treatment and the value of future research. At the same time, the integrity of the decision of a healthcare professional to prescribe a medicine is one of the key pillars of the integrity and effective functioning

of the healthcare system. IPHA recognises that interactions between the industry and healthcare professionals can create the potential for conflicts of interest. Consequently, professional and industry associations, including IPHA and other EU Associations, have adopted codes and guidelines to ensure that these interactions meet the high standards of integrity that patients, governments and other stakeholders expect.

This Annex provides for the disclosure of transfers of value to healthcare professionals, whether direct or indirect. When deciding how a transfer of value should be disclosed, companies should, wherever possible, identify and publish at the individual healthcare professional (rather than healthcare organisation) level, as long as this can be achieved with accuracy, consistency and compliance with applicable law.

Definition of terms used in the IPHA healthcare professional/healthcare organisation Disclosure Code

Donations and Grants

Collectively means those donations and grants (either cash or benefits in kind) within the scope of Clause 15 of the IPHA Code.

Events

All promotional, scientific or professional meetings, 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 (Clause 16 of the IPHA Code).

Research and Development Transfers of Value

Transfers of value to healthcare professionals or healthcare organisations related to the planning or conduct of (i) non-clinical studies (as defined in *OECD Principles on Good Laboratory Practice*²); (ii) clinical trials (as defined in Directive 2001/20/EC³); or (iii) noninterventional studies (NIS)⁴ that are prospective⁵ in nature and that involve the collection of patient data from or on behalf of individual, or groups of, healthcare professionals specifically for the study.

Transfers of Value

Direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only medicine exclusively for human use. Direct transfers of value are those made directly by a company for the benefit of a HCP. Indirect transfers of value are those made on behalf of a Member Company for the benefit of a HCP, or transfers of value made through an intermediate and where the Member Company knows or can identify the HCP/HCO that will benefit from the Transfer of Value.

2. DISCLOSURE OBLIGATION

2.1 General Obligation

Each company shall document and publicly disclose Transfers of Value it makes, directly or indirectly on the IPHA Central Report (www.transferofvalue.ie), subject to internal corporate compliance and feasibility, to enable a comprehensive report being made available from IPHA on ToVs within Ireland. Provided that they are unrestricted and publicly available, such disclosures may also be made on the relevant Company website.

- 2 | The OECD Principles on Good Laboratory Practice (as revised in 1997) define nonclinical studies as follows (Section I – 2. Definitions of Terms; section 2.3.1): Nonclinical health and environmental safety study, henceforth referred to simply as “study”, means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities. For complete reference, see www.oecd.org
- 3 | EU Directive 2001/20/EC (Article 2(a)) defines clinical trials as: any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy.

2.2 Excluded Disclosures

Without limitation, Transfers of Value that (i) are solely related to over-the-counter medicines; (ii) are not listed in Section 4 (below) of this Annex to the Code, such as items of medical utility, meals and drinks, samples or (iii) are part of ordinary course purchases and sales of medicine by and between a company and an healthcare professional or an healthcare organisation do not fall within the scope of the disclosure obligation.

3. FORM OF DISCLOSURE

3.1 Annual Disclosure Cycle

Disclosures must be made on an annual basis with each reporting period covering a full

calendar year (the “reporting period”). The first reporting period was 2015.

3.2 Time of Disclosure

Disclosure must be made by each company within six months after the end of the relevant reporting period. The information disclosed must remain in the public domain for a minimum of three years, unless there is a valid legal reason not to do so.

3.3 Geographical location for Disclosure

Disclosures shall be made pursuant to the national code of the country where the HCP has its physical address. The subsidiary or affiliate of each company in each Member State is responsible for disclosure in that jurisdiction. Therefore, to ensure compliance it is recommended that internal company

- 4 | EU Directive 2001/20/EC (Article 2(c)) defines non-interventional trials as: stud(ies) where the medicine is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data.
- 5 | Prospective versus retrospective NIS must be considered using the following table:
Transfers of Value relating to NISs that are retrospective (and thus not within the definition of R&D ToVs) must be reported on an individually named basis. Activities not falling within the definition of R&D ToVs, including NIS that are not conducted to maintain a Marketing Authorisation (in application of, and following, Clinical Trials Regulation 536/2014), must be disclosed under “consultancy/fee-for-services”. Companies must include a comment in the Methodological Note on this, where appropriate.

Prospective NIS	Retrospective NIS
Prospective cohort studies in which the prescription of the medicine is independent from the inclusion of the patient in the study A retrospective study to which a prospective element is subsequently introduced Long-term extension studies with patient follow up beyond trial protocol specified time for observation and active collection of additional data	Purely observational database review and/or research Retrospective review of records where all the events of interest have already happened – e.g. case-control, cross-sectional, and purely retrospective cohort studies Studies in which the prescriber later becomes an Investigator, prescribing has already occurred – e.g. retrospective data collection from individual medical records at the site of the investigator

procedure mandates the informing of the subsidiary or affiliate in each Member State regarding Transfers of Value related to, or in, their jurisdiction. If a company is not resident or does not have a subsidiary or an affiliate in the country where the HCP has its physical address, the company shall disclose such Transfer of Value in a manner consistent with the national code to which it is subject⁶.

3.4 Documentation and Retention of Records

Each company shall document all transfers of value required to be disclosed and maintain the relevant records of the disclosures made under this Code for a minimum of 5 years after the end of the relevant reporting period.

3.5 Legal Basis

The disclosure of ToVs for HCOs or HCPs, whether by the IPHA or by the company, may entail the processing of the personal data of HCPs, save for where the data provided is in aggregated form only and is not capable of identifying any individual HCP. A legal basis for processing personal data under data protection law may be required such as legitimate Interests, consent or any other appropriate legal basis. Companies that wish to use legitimate Interests as a basis for ToV reporting must follow the requirements set out in the “Minimum mandatory requirements for Privacy Policies (legitimate interest)” document, a copy of which can be downloaded from www.ipha.ie. Data protection legislation does not apply to institutions and companies must achieve 100% individual level disclosure for HCOs. The contract with the HCO must state that disclosure is a mandatory aspect of the provision of the contract.

4. INDIVIDUAL AND AGGREGATE DISCLOSURE

4.1 Individual Disclosure

Except as expressly provided by this Code, Transfers of Value shall be disclosed on an individual basis. Each company shall disclose, on an individual basis for each clearly identifiable HCP, the amounts attributable to Transfers of Value to such HCP in each reporting period which can be reasonably allocated to one of the categories set out below. Such Transfers of Value may be aggregated on a category-by-category basis, provided that itemised disclosure shall be made available upon request to (i) the relevant HCP, and/or (ii) the relevant authorities.

- (i) For Transfers of Value to a healthcare organisation, an amount related to any of the categories set forth below:
 - a) Donations and Grants. Donations and Grants to healthcare organisations that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organisations or associations that are comprised of healthcare professionals and/or that provide healthcare.
 - b) Contribution to costs related to Events. Contribution to costs related to Events, through healthcare organisations or third parties, including support to HCPs to attend Events, such as:
 - i. Registration fees;
 - ii. Sponsorship agreements with

⁶ | It should be noted that the EFPIA Code does not apply to Transfers of Value between an EFPIA member and a healthcare professional from a non-EFPIA country in a non-EFPIA country. Such activities are however subject to the national laws of the non-EFPIA country(ies). The EFPIA Disclosure Code relates to transparency of relationships with healthcare professionals and healthcare organisations in EFPIA member countries (primarily Europe; see www.efpia.eu).

healthcare organisations or with third parties appointed by an healthcare organisation to manage an Event;

and

iii. Travel and accommodation.

c) Fees for Service and Consultancy.

Transfers of Value resulting from or related to contracts between companies and institutions, organisations or associations of healthcare professionals under which such institutions, organisations or associations provide any type of services to a company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

(ii) For Transfers of Value to a healthcare professional:

a) Contribution to costs related to Events. Contribution to costs related to Events, such as:

i. Registration fees; and

ii. Travel and accommodation.

b) Transfers of Value resulting from or related to contracts between companies and healthcare professionals under which such healthcare professionals provide any type of services to a company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

4.2 Aggregate Disclosure

For Transfers of Value where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Section 4.1 above, cannot be disclosed on an individual basis for valid legal reasons, a company shall disclose the amounts attributable to such Transfers of Value in each reporting period on an aggregate basis. Such aggregate disclosure shall identify, for each category, (i) the number of HCPs covered by such disclosure, on an absolute basis and as a percentage of all HCPs, and (ii) the aggregate amount attributable to Transfers of Value to such HCPs.

4.3 Non Duplication

Where a Transfer of Value required to be disclosed pursuant to Articles 4.1 and 4.2 above is made to an individual healthcare professional indirectly via an healthcare organisation, such Transfer of Value shall only be required to be disclosed once. To the extent possible, such disclosure shall be made pursuant to Article 4.1(ii).

4.4 Research and Development Transfers of Value

Research and Development Transfers of Value in each reporting period shall be disclosed by each company on an aggregate basis. Costs related to events that are clearly related to activities covered in this section can be included in the aggregate amount under the “Research and Development Transfers of Value” category.

4.5 Reporting of Indirect ToVs to HCOs made through Professional Conference Organisers (PCOs)

When a Member Company contributes to the costs related to Events through PCOs⁷, the following reporting approach is considered compliant:

- When the payment is made to a PCO (i.e. the PCO is the HCP) and the HCO or HCP is known, this Indirect ToV is reported in the name of the benefitting HCO/HCP (through “include the name of the HCP PCO”), if not already included in the direct ToVs to the HCO.
- For other scenarios please see the table below:

HCP PCO receiving the ToVs	Beneficiary HCP/HCO benefitting	Disclosure
PCO on behalf of / in collaboration with an HCO	Where the Member Company knows the HCP/HCO benefitting	Individual disclosure
PCO on behalf of / in collaboration with an HCO	Where the member Company does not know the HCP/HCO benefitting	Whilst disclosure on an individual HCP/HCO names basis is standard, the Member Company may consider disclosing under the PCOs name with an indication of the speciality area and/or event name
PCO with HCO Scientific Committee	HCO known to the Member Company	Individual disclosure
PCO with HCP Scientific Committee	HCP known to the Member Company	Individual disclosure
PCO developing/organising an Event at its own initiative (independent event)	Where the Member Company knows the HCP/HCO participating in the event	Individual disclosure
PCO developing/organising an Event at its own initiative (independent event)	Where the Member Company does not know the HCP/HCO participating in the event	Whilst disclosure on an individual HCP/HCO names basis is encouraged, the Member Company may consider disclosing under the PCOs name and the name of the event, with indication of the speciality area.* *The PCO name, event name and speciality (if not already in the name) should must then be listed within the Indirect ToV HCO reporting category.

7 | A PCO is a company/individual specialised in the organisation and management of congresses, conferences, seminars and similar events (all “Events”). For the application of this guidance, commercial companies involved in organisation of travel (travel agencies) or accommodation (hotels, banqueting functions in hotels, etc.) are not considered PCOs.

This guidance applies whether the PCOs organise Events on their own initiative, or at the request of an HCO. The company's Methodological Note may state that the full value of ToVs to the PCO will not constitute a benefit (in cash or in kind) to the HCO since the PCO may retain a "service fee".

Contributions to costs related to Events paid through an intermediary to the benefit of an individual HCO (or HCP) that the Member Company can identify, must be reported at the level of the first-identifiable HCP which falls under the IPHA definition of an HCO (or HCP). For example, in the case of a benefit to an HCO, if that HCO is identified as a HCP, identification of any sub HCPs is not necessary.

A company's support and/or sponsorship to Events through PCOs must be confirmed in a written agreement with the PCO. The agreement must also require PCOs to advise the HCO that the company will disclose in line with the IPHA Code and that, therefore, the HCO may be publicly identified. It is also advised that the company must encourage the PCO to be transparent to the company about the amount of the support / sponsorship provided to the PCO that actually reaches the HCO.

4.6 Methodology

Each company must publish a note summarising the methodologies used by it in preparing the disclosures and identifying ToV for each category described above. The note, including a general summary shall describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Transfers of Value for the purposes of this Code.

4.7 Template for Disclosure

For consistency purposes, disclosures pursuant to this Code will be made using a structure set forth in Section 5 below, reflecting the requirements of this Code.

5. TEMPLATE FOR DISCLOSURE OF TOV

	Full Name	HCPs: City of Principal Practice HCOs: city where registered	Country of Principal Practice	Principal Practice Address	Unique country identifier (optional)*	Donations and Grants to HCOs
HCPs	INDIVIDUAL NAMED DISCLOSURE – one line per HCP (i.e. all transfers of value [ToVs]/annum for an individual HCP					
	Dr A					N/A
	etc					N/A
	OTHER, NOT INCLUDED ABOVE – where information cannot be disclosed on an individual basis for legal					
	Aggregate amount attributable to transfers of value to such HCPs					N/A
	Number of HCPs in aggregate disclosure					N/A
	Of the total number of HCPs whose ToV was disclosed % disclosed in aggregate					N/A
HCOs	INDIVIDUAL NAMED DISCLOSURE – one line per HCO (i.e. all ToVs /annum for an individual HCO will be summed					
	HCO 1				N/A	annual amount
	etc				N/A	annual amount
	OTHER, NOT INCLUDED ABOVE – where information cannot be disclosed on an individual basis for legal					
	Aggregate amount attributable to transfers of value to such HCPs					Aggregate HCOs
	Number of HCPs in aggregate disclosure					number
	Of the total number of HCPs whose ToV was disclosed % disclosed in aggregate					%
R&D	AGGREGATE					
	Research & Development Transfers of Value					

* To uniquely identify HCPs the use of the relevant Medical Council/Pharmaceutical Society of Ireland/Nursing and Midwifery Board of Ireland/Dental Council of Ireland registration numbers are strongly recommended.
N/A: not applicable, HCP: healthcare professional, HCO: healthcare organisation
Originally unique identifiers could only be supplied for HCPs but they are now also supported for HCOs.
Unique identifiers for HCOs should be included in the Unique Country Identifier field.
Unique identifiers for HCOs should be included in the UniqueID field in the dataset.

Contribution to costs of Events			Fee for service and consultancy		Total
Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accommodation	Fees	Related expenses agreed in the contract, including travel & accommodation relevant to the contract	
will be summed up: itemization should be available for the individual HCP or public authorities' consultation only)					
N/A	annual amount	annual amount	annual amount	annual amount	Optional
N/A	annual amount	annual amount	annual amount	annual amount	Optional
reasons					
N/A	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs	Optional
N/A	number	number	number	number	Optional
N/A	%	%	%	%	
up: itemization should be available for the individual HCP or public authorities' consultation only)					
annual amount	annual amount	annual amount	annual amount	annual amount	Optional
annual amount	annual amount	annual amount	annual amount	annual amount	Optional
reasons					
Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Optional
number	number	number	number	number	Optional
%	%	%	%	%	
DISCLOSURE					
					TOTAL AMOUNT

Annex VI

ORGANISATION AND CONDUCT OF ADVISORY BOARDS

1. INTRODUCTION

An Advisory Board is a group of external experts assembled by companies to obtain professional guidance, advice, insights or other information to further legitimate scientific or business needs, on a specific topic for which the expertise and knowledge are not available within the company. Advisors are selected on the basis that they have the necessary ability and qualifications to advise on specific scientific, commercial, and healthcare issues. Advisors may be registered healthcare professionals (HCP), scientists, payers, patients and representatives of Patient Organisations.

Advisory Boards provide an opportunity to collaborate with advisors to better understand the external environment, therapeutic areas, data and use of medicine approved or in development, the payer landscape or unmet medical or patient needs etc. Specifically, Patient Advisory Boards may be conducted to better understand the patient experience to better serve patients.

The organisation and conduct of Advisory Boards must be strictly non-promotional and Advisory Boards must not be conducted for any improper purposes such as to induce prescribing, convey information beyond what is required to meet the purpose of the meeting, solicit confidential competitive information or facilitate any other improper purpose.

1.1 Governance

Each company must have in place an appropriate governance process for approval of all aspects of planned Advisory Board meetings (e. g. defining a legitimate need, objectives, selection of appropriate advisors, selection of chairperson, internal attendees, invitations, contracts, agenda, data to be provided or presented, service honoraria, hospitality).

1.2 Legitimate Purpose

There must be a legitimate purpose documented for each Advisory Board with clearly defined objectives which detail the specific information/advice being sought that is currently unavailable within the company and why external expert advice is required. In the event that more than one Advisory Board is planned covering the same topic the necessity for this must be clearly demonstrated and described.

1.3 Attendance

There must be a legitimate need for internal and external Advisory Board attendees to ensure that only those individuals that are necessary for the company to gain scientific guidance, advice or information, attend the meeting. The number of external advisors required for each specific Advisory Board must be carefully considered and this justification documented. This number must not exceed the number required to meet the legitimate purpose of the Advisory Board. The internal attendees must be necessary and limited in number (not to exceed 50% of the number of external advisors). Sales representatives must never attend Advisory Board meetings.

1.4 Conduct

External advisors must be provided with an invitation which clearly outlines the purpose and objectives of the Advisory Board in addition to the basis on which they have been selected as an advisor for the meeting.

Once contracted the advisors must be provided with a meeting agenda, contract and necessary background materials as pre reading for the meeting. It is imperative that the focus of the meeting is to gain advice and that the meeting agenda reflects this and allows sufficient time for discussion.

The contract must clearly outline the advisor's obligations and/or deliverables. This will help minimise the amount of data presented during the meeting and maximise time for discussion and advice.

The Chairperson must ensure that all advisors have sufficient time to provide their opinions, advice and feedback during the meeting. Presentations must not exceed 40% of the agenda to facilitate provision of advice and discussion. Materials presented must be directly pertinent to the objective of the meeting. The material must be non-promotional in appearance and brand names must only be used if relevant and necessary to meet the objectives of the meeting.

Advisory Boards must be conducted in appropriate venues and not associated with any social or sporting events. Hospitality provided must be modest in nature and adhering to the limits outlined in the Code.

1.5 Payment

Advisors can be paid for their participation

and provision of their advice and guidance. Payment must represent the fair market value for the service provided and time involved. Reasonable travel expenses can be provided on provision of evidence of spend. The Chairperson may receive a greater honorarium based on increased workload, briefing etc.

1.6 Output

The Advisory Board must have as its output a written report which must include an executive summary of the meeting, the outcome of the discussions, advice received in response to questions posed, the extent to which the objectives of the meeting were met and specific recommendations emanating from the meeting. The meeting report must only be shared with internal stakeholders with a legitimate need for this information.

1.7 Documentation

It is important to maintain documentation relating to all aspects of the Advisory Board which must include the agenda, legitimate need, objectives, honoraria details, invitation letters, pre-read materials, meeting presentations, attendance list, contracts, meeting report, follow up actions, and evidence of approval of all aspects as per the governance process in place.



IPHA

© Irish Pharmaceutical Healthcare Association
7 Clanwilliam Terrace, Grand Canal Quay, D02 CC64
Tel: +353 (1) 6610018 Fax: +353 (1) 6610164
E-mail: info@ipha.ie
Websites: www.ipha.ie, www.transferofvalue.ie,
www.medicines.ie