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European Federation of Pharmaceutical Industries and Associations

EFPIA CODE OF PRACTICE

www.efpia.eu

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The EFPIA Code constitutes the collection of ethical rules agreed by EFPIA members for the Promotion of Medicinal Products to HCPs and the interactions with HCPs, HCOs and POs, with the intent of guaranteeing that these activities are conducted while respecting the most stringent ethical principles of professionalism and responsibility. This Code applies to all types of communication and interaction (traditional and digital).

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✱ DEFINITIONS

Definitions of capitalised terms are included to ensure their consistent understanding.

Applicable Codes:

- (i) in the case of Promotion or interaction that is undertaken, sponsored or organised by or on behalf of, or with, a Member Company located within Europe, the Member Association National Code of the country in which such Member Company is located; or (ii) in the case of Promotion or interaction that is undertaken, sponsored or organised by or on behalf of, or with, a Member Company located outside of Europe, the EFPIA Code; and
- the Member Association's National Code of the country in which the Promotion or the interaction takes place.

In case of international Event for which a Member Company sponsors the attendance of a HCP, if any funding is provided to such HCP in accordance with the provisions of Article 13, such funding is subject to the rules of the National Code where such HCP carries out his/her profession, as opposed to those in which the international Event takes place.

In the event of a conflict between the provisions of the Applicable Codes set forth above, the more restrictive of the conflicting provisions must apply, except for the application of Section 10.05, where the monetary threshold set in the country where the event takes place (i.e. the "host country") must prevail.

Contribution to Costs related to Events: is a support providing or covering the costs of meals, travel, accommodation and/or registration fees to support the attendance of an individual HCP or PO Representative to an Event organised or created by a Member Company and/or a Third Party.

Donations and Grants: collectively, mean providing funds, assets or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return.

European Federation of Pharmaceutical Industries and Associations (EFPIA): is the representative body of the pharmaceutical industry in Europe.

EFPIA Code: The EFPIA Code of Practice, including those Annexes which are expressly mentioned as binding and which form part of this Code.

Europe: includes those countries in which the EFPIA Member Associations' National Codes apply[1].

Events: All professional, promotional, scientific, educational 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) organised or sponsored by or on behalf of a Member Company.

1 - As of June 2019, these countries include: Austria, Belgium, Bosnia and Hezegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United Kingdom.

Healthcare Organisation (HCO): any legal person/entity (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for POs within the scope of article 21) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.

Healthcare Professional (HCP): any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his/her professional activities, may prescribe, purchase, supply, recommend or administer a Medicinal Product and whose primary practice, principal professional address or place of incorporation is in Europe. For the purpose of this Code, the definition of HCPs includes: (i) any official or employee of a government, agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply, recommend or administer Medicinal Products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of Medicinal Products.

Host Country Principle: refers to the primacy of the monetary threshold for a meal (food and beverages) set by the relevant Member Association in its National Code.
The monetary threshold set in the country where the Event takes place must prevail.

Informational or Educational Material: constitutes inexpensive material directly relevant to the practice of medicine or pharmacy and directly beneficial to the care of patients.

Item of Medical Utility: constitutes inexpensive item aimed directly at the education of HCPs enhancing the provision of medical services and patient care and that do not offset routine business practices of the HCPs.

Lifelong learning in healthcare: constitutes non-promotional education related to human health and diseases.

Location: refers to the geographic place where the Event is organized (e.g. the city, town).

Medical Sales Representative: personnel employed by a Member Company or retained by way of contract with Third Parties, who interact with HCPs and HCOs, in connection with the Promotion of Medicinal Products.

Medical Sample: has the meaning set forth in the Directive 2001/83/EC, namely sample of Medicinal Product free of charge to persons qualified to prescribe or supply them so that they can familiarize themselves with new products and acquire experience in dealing with them.

Medicinal Product: has the meaning set forth in Article 1 of the Directive 2001/83/EC, namely: (a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) 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.

Member Association: as defined in the EFPIA Statutes, means an organisation representing pharmaceutical manufacturers at national level whose members include, among others, research-based companies. Collectively, the national Member Associations or their constituent members, as the context may require, are bound by the EFPIA Code.

Member Company: as defined in the EFPIA Statutes, means research-based companies, developing and manufacturing Medicinal Products in Europe for human use.

Member Company Staff: personnel employed by a Member Company or retained by way of contract with Third Parties, who are concerned with any matter covered by this Code.

National Code: The code of practice of a Member Association.

Non-Interventional Study (NIS): is a study where the Medicinal Product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorization. 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 Medicinal Product is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures must be applied to the patients and epidemiological methods must be used for the analysis of collected data[2].

Patient Organisation (PO): non-for-profit legal person/entity (including the umbrella organisation to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in Europe.

Patient Organisation Representative: is a person who is mandated to represent and express the collective views of a PO on a specific issue or disease area[3].

Personal Health Data: is any information related to the physical, mental health or to the inherited or acquired genetic characteristics of an identified or identifiable natural person, including the provision of health care services, which reveal information about his or her physiology or health status[4].

Prescription-Only Medicines (POM): is a Medicinal Product that requires a medical prescription issued by a professional person qualified to prescribe.

Promotion: includes any activity undertaken, organised or sponsored by a Member Company, or with its authority, which promotes the prescription, supply, sale, administration, recommendation or consumption of its Medicinal Product(s).

Recipient: any HCP or HCO or PO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Europe.

Reporting Period: refers to the annual disclosure cycle and covers a full calendar year.

2 - Article 2 of the Directive 2001/20/EC
3 - EUPATI definition
4 - Definition based on the definitions of "personal data", "genetic data" and "data concerning health" in Article 4 of GDPR

Research and Development Transfers of Value: Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Regulation 536/2014); or (iii) NIS that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study.

Sponsorship: is a support provided by or on behalf of a Member Company, when permitted by law, as a contribution to support an activity (including an Event) performed, organised or created by a HCO, a PO or a Third Party.

Third Party: is a legal person/entity or individual that represents a Member Company or interacts with other Third Parties on behalf of a Member Company or relating to the Member Company's Medicinal Product, such as distributors, wholesalers, consultants, contract research organisations, professional congress organisers, contracted sales forces, market research companies, advertising agencies, providers of services related to events, public relations services, non-clinical, non-interventional studies management services.

Transfers of Value (ToV): Direct and indirect ToV, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of POM exclusively for human use. Direct ToVs are those made directly by a Member Company for the benefit of a Recipient. Indirect ToVs are those made on behalf of a Member Company for the benefit of a Recipient, or those made through a Third Party and where the Member Company knows or can identify the Recipient that will benefit from the Transfer of Value.

Venue: refers to the logistic place where the Event is organized (i.e. the hotel, the congress center).

PREAMBLE

This document replaces previous codes issued by EFPIA, namely:

- EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals *(Final Consolidated Version approved by the General Assembly of June 2014)*, which first came into effect in January 1992;

- EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations *(approved by the General Assembly of June 2011)*, which was first approved in September 2007; and

- EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations *(approved by the General Assembly of June 2014*), and which was first approved in June 2013.

ETHICAL PRINCIPLES

As pharmaceutical companies, we work in collaboration with various stakeholders including HCPs, HCOs, POs and their Representatives, regulatory authorities, governments and the public to improve health and quality of life.

We continuously invest in research and development to deliver new treatments for medical needs and improving the quality of treatment.
As commercial organisations, we encourage competition and economic development to sustain investment and foster innovation.

We believe in what we do and know that there is somewhere a patient whose health and wellbeing is, directly or indirectly, dependent on our work.
We aim at creating an environment where our stakeholders and the general public, consider pharmaceutical companies as trusted partners.

In addition to complying with extensive legal requirements (i.e. laws and regulations applicable to our industry such as pharmaceutical, competition, intellectual property and data protection laws as well as anti-bribery and anti-corruption legislation), the pharmaceutical industry has agreed to comply with additional standards in its self-regulatory codes and joint positions.

For EFPIA and its members, self-regulation means being fully committed to define, implement, comply with and enforce the highest ethical standards through EFPIA and National Codes, where breaches are not tolerated.
Self-regulation includes the concept of continuous challenge for us to exceed society's expectations and openness regarding suggestions from others on how we might further strengthen confidence in our industry and our behaviour.
Stakeholders who share the values and principles enshrined in this self-regulation are invited to adhere to these rules and guidance[5].

5 - EFPIA Leadership statement on ethical practices – June 2010

Our **Ethos** outlines the ethical principles that underpin the EFPIA Code and guide the industry's interactions with the healthcare and patient community

Our Ethos | Building a culture of trust

Care

Protect the safety of those who use our products – from the conduct of clinical trials and throughout the product lifecycle.

Innovation

Improve global health through innovative products and services, upholding the highest ethical, scientific, and medical standards.

Quality

Commit to providing high-quality products that have proven clinical efficacy and have a reliable safety profile.

Fairness

Support and respect fair trade practices and open competition.

Integrity

Act responsibly, ethically and professionally. Do not offer, promise, provide, or accept anything of value in order to inappropriately influence a decision, gain an unfair advantage.

Accountability

Be accountable for our actions and decisions, including the appropriate oversight of external third parties that act on our behalf.

Honesty

Ensure truthful and balanced communication with governmental authorities, healthcare professionals, patients and other stakeholders.

Speaking Up

Foster a culture in our respective organisations where concerns are shared openly and honestly so that we learn from mistakes and continuously improve.

Transparency

Advance science and patient care by sharing industry-sponsored clinical trial data in a responsible, accurate and appropriate manner. For EFPIA, disclosure of payments and other in-kind values provided to HCPs, HCOs, and POs.

Respect

Respect all people and embrace a culture of diversity and inclusion. Protect the environment. Treat animals under our care responsibly.

Privacy

Respect privacy rights and appropriately manage and protect personal information.

Education

Support the advancement of the scientific and medical education for the ultimate benefit of patients.

INTRODUCTION

The EFPIA's membership[6] is composed of:

- Full members, including: (i) research-based pharmaceutical companies, developing and manufacturing Medicinal Products in Europe for human use – called Member Companies; and (ii) those organisations representing pharmaceutical manufacturers at national level whose members include, among others, research-based companies – called Member Associations.
- Affiliate members, including: (i) companies specialising in particular fields of pharmaceutical research and/or development or in new technologies of particular interest to the pharmaceutical industry – called "affiliate Member Company"; and (ii) organisations representing research-based pharmaceutical companies at national level in Europe that have been granted the title of "affiliate Member Associations".
- Research-based pharmaceutical companies operating in a particular segment of the pharmaceutical market that joint a specialised group within EFPIA: Vaccines Europe (VE).

Separate entities belonging to the same multinational company – which could be the parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation – are deemed to constitute a single company, and are as such committed to comply with the EFPIA Code.

EFPIA and its members[7] are conscious of the importance of (i) providing accurate, fair and objective information about Medicinal Products so that rational decisions can be made as to their use, (ii) ensuring that interactions with HCPs, HCOs and POs, which are key to share knowledge aiming to improve the quality of patient care, take place in an ethical manner and (iii) introducing greater transparency around the pharmaceutical industry's interactions with HCPs, HCOs and POs.

Chapters 1, 2 and 3 reflect the requirements of Council Directive 2001/83/EC, as amended, relating to Medicinal Products, and fit into the general framework established by the Directive, which recognises the role of voluntary control of advertising of Medicinal Products by self-regulatory bodies and recourse to such bodies when complaints arise.

EFPIA encourages competition among pharmaceutical companies. The EFPIA Code is not intended to restrain the Promotion of Medicinal Products to HCPs, or limit interactions with HCPs, HCOs, and POs in a manner that is detrimental to fair competition. Instead, it seeks to ensure that pharmaceutical companies conduct such Promotion and interactions in a truthful manner, avoiding deceptive practices and potential conflicts of interest with stakeholders, and in compliance with applicable laws and regulations.

The EFPIA Code thereby aims to foster an environment where the general public can be confident that the choices regarding their Medicinal Products are being made on the basis of the merits of each product and the healthcare needs of patients.

6 - Article 4 of EFPIA Statutes

7 - The updated list of EFPIA membership can be found on www.efpia.eu

HCPs and HCOs provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and scientific experience. 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. HCPs and HCOs should be fairly remunerated for the legitimate expertise and services they provide to the industry.

EFPIA believes that interactions between Member Companies and HCPs 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 HCP to prescribe a Medicinal Product is one of the pillars of the healthcare system. EFPIA recognises that interactions between the industry and HCPs/HCOs can create the potential for conflicts of interest. Consequently, professional and industry associations, including EFPIA and its Member Associations, have adopted codes and guidelines to ensure that these interactions meet the high standards of integrity that patients, governments and other stakeholders expect.

In order, to continue to be successful, self-regulation needs to respond to the evolving demands of society. In particular, EFPIA recognises the growing expectation that interactions with society are not only conducted with integrity but are also transparent.

In the same way, the pharmaceutical industry works with POs to learn from their knowledge and experience of patient's condition that is able to provide a true picture of what it is like to live with a specific condition, how care is delivered, how that impacts on them, their careers and families and how medicines and other treatments can change their quality of life and meet their needs.
POs have a key role in helping to shape, develop and define the outcomes that make the most difference to patients. Member Companies disclose the amounts provided to POs in the framework of these interactions.

EFPIA strongly supports public scrutiny and the understanding of these relationships and disclosure contributes to the confidence of stakeholders in the pharmaceutical industry.

In relation to working with HCPs and HCOs, since the introduction of the EFPIA Disclosure Code, EFPIA has worked to encourage Member Companies to always look to disclose and to encourage HCPs (and HCOs where relevant) to agree to individual disclosure. Member Companies will not be criticized for over-disclosure.

SCOPE OF THE EFPIA CODE

The EFPIA Code covers:
- Promotion of POMs to HCPs,
- interactions between Member Companies and HCPs, HCOs and POs;
- disclosure of ToVs from Member Companies to HCPs, HCOs and POs; and
- procedural requirements of the EFPIA Code.

Member Companies are responsible for the obligations imposed under any relevant Applicable Code even if they commission a Third Party to design, implement or engage in activities covered by the Applicable Code on their behalf. In addition, Member Companies must take reasonable steps to ensure that any other parties that they commission to design, implement or engage in activities covered by the Applicable Code but that do not act on behalf of the Member Company (e.g. joint ventures, licensees) comply with Applicable Codes.

The EFPIA Code covers all methods of Promotion including, but not limited to, oral and written promotional activities and communications, journal and direct mail advertising, the activities of Medical Sales Representatives, the use of digital communications and channels, such as websites and social media, the use of audio-visual systems such as films, video recordings, data storage services and the like. It also covers the provision of Informational or Educational Materials, Items of Medical Utility, hospitality in relation to Events and Medical Samples.

The EFPIA Code also covers interactions between Member Companies and HCPs and HCOs including, but not limited to, those in the context of research or contractual arrangements (including certain aspects of clinical trials, non-interventional studies as well as consultancy and advisory board). It also covers the interactions between Member Companies and POs.

The EFPIA Code is not intended to restrain or regulate activities directed towards the general public which relate solely to non-prescription Medicinal Products. EFPIA, however, acknowledges that some Member Associations address these activities in their respective National Codes, and encourages other Member Associations to do so, where appropriate.

The EFPIA Code does not cover the following:
- the labelling of Medicinal Products and accompanying package leaflets, which are subject to the provisions of Title V of the Directive 2001/83/EC;
- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular Medicinal Product;
- factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general precautions, trade catalogues and price lists, provided they include no product claims;
- activities which relate solely to non-prescription Medicinal Products; or
- non-promotional, general information about Member Companies (such as information directed to investors or to current/prospective employees), including financial data, descriptions of research and development programmes, and regulatory developments affecting a Member Company and its Medicinal Products.

The following documents are attached to the EFPIA Code and are binding for EFPIA members:

- Annex A — Standardised Disclosure template;
- Annex B — EFPIA guidance;
- Annex C — Guidance obligations for Member Associations under the EFPIA Code; and
- Annex D — EFPIA Standard Operating Procedure related to processing of complaints and questions submitted to EFPIA;
- Annex E — EFPIA e4ethics rules and procedure.

Additional documents are developed to illustrate the provisions of the EFPIA Code and provide explanations for a consistent implementation, such as the following:

- EFPIA recommendation;
- Principles for the use of digital channels;
- EFPIA Guideline on a Quality Framework - Principles in Lifelong Learning in Healthcare.

APPLICABILITY OF THE EFPIA CODE

The EFPIA Code sets out the minimum standards which EFPIA considers must apply. In a manner compatible with their respective national laws and regulations, Member Associations must, at a minimum, adopt in their National Codes provisions no less rigorous than the provisions contained in the EFPIA Code. Member Associations are encouraged to tailor their National Codes to adapt to national conditions and to adopt additional provisions which might extend further than the minimum standards included in the EFPIA Code.

All Member Associations are required to implement the disclosure provisions into their National Codes in full, except where its provisions are in conflict with applicable national laws or regulations, in which case deviations are allowed, but only to the extent necessary to comply with such national law or regulation.

Promotion and interactions which take place within Europe must comply with applicable laws and regulations. In addition, Promotion and interactions which take place within Europe must also comply with Applicable Codes.

Member Companies must comply with any Applicable Codes and any laws and regulations to which they are subject. All Member Companies must either (i) be a member of the Member Association in each country where it conducts activities covered by the EFPIA Code (either directly or through the relevant subsidiary) or (ii) agree in writing with each such Member Association that it (or its relevant subsidiary) is bound by such Member Association's National Code (including any applicable sanctions that may be imposed there under).

Member Companies must be bound by the relevant National Code in each country in Europe in which they operate (whether directly or through its relevant subsidiary). If a Member Association where a Member Company operates fails to transpose the EFPIA Code into its National Code by the relevant deadline, such Member Company will be required to comply with the EFPIA Code itself.

Non-member associations and companies that decide to voluntarily implement the EFPIA Code must require that each of their respective members, affiliates and subsidiaries, as applicable, comply with all provisions of the EFPIA Code.

To facilitate compliance with the Applicable Codes, each Member Association must establish adequate procedures for ensuring that each of its member companies complies with the requirements of such National Code and any other National Code which may be applicable to its conduct, even if the member company does not belong to the other Member Association. In order to establish adequate procedures for ensuring compliance with the Applicable Codes, Member Associations will be required, among other things, to establish appropriate complaint procedures and sanctions for breaches of their respective codes. Additionally, all international Events and/or activities as relevant must be notified to any relevant local subsidiary or, alternatively, local advice must be taken.

The spirit, as well as the provisions of the EFPIA Code must be complied with. EFPIA also encourages compliance with the letter and spirit of the provisions of the International Federation of Pharmaceutical Manufacturers and Associations ("IFPMA") Code of Practice, where applicable.

CHAPTER 1.
PROMOTION OF POM TO HCPs

ARTICLE 1 MARKETING AUTHORIZATION

Section 1.01. A Medicinal Product must not be promoted prior to the grant of the marketing authorization allowing its sale or supply or outside of its approved indications.

Section 1.02. Promotion must be consistent with the particulars listed in the summary of product characteristics of the relevant Medicinal Product.

ARTICLE 2 INFORMATION TO BE MADE AVAILABLE

Section 2.01. Subject to applicable national laws and regulations, all promotional material must include the following information clearly and legibly:

- essential information consistent with the summary of product characteristics, specifying the date on which such essential information was generated or last revised;
- the supply classification of the Medicinal Product; and
- when appropriate, the selling price or indicative price of the various presentations and the conditions for reimbursement by social security bodies.

Section 2.02. Subject to applicable national laws and regulations, where an advertisement is intended only as a reminder, the requirements of Section 2.01 above need not be complied with, provided that the advertisement includes no more than the name of the Medicinal Product or its international non-proprietary name, where this exists, or the trademark.

ARTICLE 3 PROMOTION AND ITS SUBSTANTIATION

Section 3.01. Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the HCP to form his/her own opinion of the therapeutic value of the Medicinal Product concerned. It must be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.

Section 3.02. Promotion must be capable of substantiation which must be promptly provided in response to reasonable requests from HCPs. In particular, promotional claims about side-effects must reflect available evidence or be capable of substantiation by clinical experience. Substantiation need not be provided, however, in relation to the validity of elements approved in the marketing authorization.

Section 3.03. Promotion must encourage the rational use of Medicinal Products by presenting them objectively and without exaggerating their properties. Claims must not imply that a Medicinal Product, or an active ingredient, has some special merit, quality or property unless this can be substantiated.

Section 3.04. When Promotion refers to published studies, clear references must be given.

Section 3.05. Any comparison made between different Medicinal Products must be based on relevant and comparable aspects of the Medicinal Products. Comparative advertising must not be misleading or disparaging.

Section 3.06. All artwork, including graphs, illustrations, photographs and tables taken from published studies included in promotional material must: (a) clearly indicate the precise source(s) of the artwork; (b) be faithfully reproduced, except where adaptation or modification is required in order to comply with any Applicable Code(s), in which case it must be clearly stated that the artwork has been adapted and/or modified.
Particular care must be taken to ensure that artwork included in Promotion does not mislead about the nature of a Medicinal Product (for example, whether it is appropriate for use in children) or mislead about a claim or comparison (for example, by using incomplete or statistically irrelevant information or unusual scales).

Section 3.07. The word "**safe**" must never be used to describe a Medicinal Product without proper qualification.

Section 3.08. The word "**new**" must not be used to describe any Medicinal Product or presentation which has been generally available or any therapeutic indication which has been generally promoted, for more than one year.

Section 3.09. It must not be stated that a Medicinal Product has no side-effects, toxic hazards or risks of addiction or dependency.

ARTICLE 4 USE OF QUOTATIONS IN PROMOTION

Quotations from medical and scientific literature or from personal communications must be faithfully reproduced (except where adaptation or modification is required in order to comply with any Applicable Code(s), in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified.

ARTICLE 5 ACCEPTABILITY OF PROMOTION

Member Companies must maintain high ethical standards at all times. Promotion must: (a) never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry; (b) be of a nature which recognises the special nature of Medicinal Products and the professional standing of the intended audience; and (c) not be likely to cause offence.

ARTICLE 6 DISTRIBUTION OF PROMOTION

Section 6.01. Promotion must only be directed at those HCPs whose need for, or interest in, the particular information can reasonably be assumed.

Section 6.02. Mailing lists must be kept up-to-date. Requests to be removed from mailing lists must be complied with.

Section 6.03. Subject to applicable national laws and regulations, the use of faxes, e-mails, automated calling systems, text messages and other digital communications for Promotion is prohibited except with the prior permission, or upon the request, of those who receive it.

ARTICLE 7 TRANSPARENCY OF PROMOTION

Section 7.01. Promotion must not be disguised.

Section 7.02. Clinical assessments, post-marketing surveillance and experience programmes and post-authorization studies (including those that are retrospective in nature) must not be disguised Promotion. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose.

Section 7.03. Where a Member Company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial matter.

Section 7.04. Material relating to Medicinal Products and their uses, whether promotional in nature or not, which is sponsored by a Member Company must clearly indicate that it has been sponsored by that Member Company.

ARTICLE 8 PROMOTIONAL INFORMATION PROVIDED DURING INTERNATIONAL EVENTS

Promotional information which appears on exhibition stands or is communicated to participants at international Events may, unless prohibited or otherwise regulated by local laws and regulations, refer to Medicinal Products (or uses) which are not registered in the country where the Event takes place, or which are registered under different conditions, as long as: (i) any such promotional material is accompanied by a suitable statement indicating the countries in which the Medicinal Product is registered and makes clear that the Medicinal Product or indication is not registered locally, and (ii) any such promotional material which refers to the prescribing information (indications, warnings etc.) authorized in a country or countries where the Medicinal Product is registered must be accompanied by an explanatory statement indicating that registration conditions differ internationally.

ARTICLE 9 PERSONAL MEDICAL MATTERS

In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer must be advised to consult a HCP.

CHAPTER 2.
INTERACTIONS WITH HCPs, HCOs AND POs

ARTICLE 10 EVENTS AND HOSPITALITY

Section 10.01. All Events must be held in "appropriate" Locations and Venues that are conducive to the main purpose of the Event, avoiding those that are "renowned" for their entertainment facilities or are "extravagant".

Section 10.02. No Member Company may organise or sponsor an Event that takes place outside its home country unless:

- most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the Event in another country; or
- 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.

Section 10.03. Member Companies may only offer hospitality when such hospitality is "appropriate" and otherwise complies with the provisions of any Applicable Code(s).

Section 10.04. Hospitality extended in connection with Events must be limited to travel, meals, accommodation and genuine registration fees.

Section 10.05. Member Companies must not provide or offer any meal (food and beverages) to HCPs, HCOs' members or POs' Representatives, unless, in each case, the value of such meal does not exceed the monetary threshold set by the relevant Member Association in its National Code (following the "Host Country Principle").

Section 10.06. Hospitality may only be extended to persons who qualify as participants in their own right. In exceptional cases of established health needs (e.g. disability or injury), the travel, meals, accommodation and genuine registration fee costs of an accompanying person can be reimbursed within the same parameters.

Section 10.07. All forms of hospitality offered to HCPs, HCOs' members or POs' Representatives must be "reasonable" in level and strictly limited to the main purpose of the Event. As a general rule, the hospitality provided must not exceed what those individuals would normally be prepared to pay for themselves.

Section 10.08. Hospitality must not include sponsoring or organising entertainment events (e.g. sporting or leisure).

ARTICLE 11 PROHIBITION OF GIFTS

Section 11.01. Gifts for the personal benefit (such as sporting or entertainment tickets, social courtesy gifts) of HCPs, HCOs' members or POs' Representatives (either directly or indirectly) are prohibited.

Providing or offering cash, cash equivalents or personal services is also prohibited. For these purposes, personal services are any type of service unrelated to the profession and that confer a personal benefit to the Recipient.

Section 11.02. A promotional aid is a non-monetary item given for a promotional purpose (which does not include promotional materials as defined in Chapter 1). Providing or offering them to HCPs, HCOs'members or POs' Representatives in relation to the promotion of POM is prohibited.

ARTICLE 12 DONATIONS AND GRANTS TO HCOs AND POs

Section 12.01. Donations and Grants (in cash or in kind or otherwise) to HCOs and/or POs are only allowed if: (i) they are made for the purpose of supporting healthcare, research or education; (ii) they are documented and kept on record by the donor/grantor; and (iii) they do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.

Section 12.02. Donations and Grants to individuals are not permitted. The Contribution to Costs related to Events for HCPs to attend international Events is covered by Article 13.

ARTICLE 13 CONTRIBUTION TO COSTS RELATED TO EVENTS AND SPONSORSHIP

Section 13.01. Member Companies must comply with criteria governing the selection and support of HCPs or POs' Representatives to attend Events as provided in, or in connection with, any Applicable Code(s). No payment must be offered to compensate merely for the time spent by the HCP or PO's Representative in attending Events.

Section 13.02. The public use of an HCO or PO´s logo and/or proprietary material by a Member 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.

Section 13.03. Member Companies must ensure that their Sponsorship to HCOs and POs is always clearly acknowledged and apparent from the outset.

ARTICLE 14 MEMBER COMPANY FUNDING

No Member Company may require that it be the sole funder or sponsor of a PO or HCO or any of its programmes.
Member Companies welcome broad funding and sponsorship of POs and HCOs from multiple sources.

ARTICLE 15 CONTRACTED SERVICES

Section 15.01. Contracts between Member Companies and HCPs, HCOs, POs or POs' Representatives under which those provide any type of services to Member Companies (not otherwise covered by the Code) are only allowed if such services: (i) 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 Medicinal Products.

Section 15.02. It is permitted to contract HCPs or POs' Representatives as consultants, whether in groups or individually, for services such as speaking at and/or chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or hospitality. The arrangements that cover these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

a. a written contract is agreed in advance of the commencement of the services 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 arrangements;

c. the criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular consultant meets those criteria;

d. the number of consultants retained and the extent of the service are not greater than reasonably necessary to achieve the identified need;

e. the contracting Member Company maintains records concerning, and makes appropriate use of, the services provided by consultants;

f. the engagement of the consultant to provide the relevant service is not an inducement to recommend and/or prescribe, purchase, supply, sell or administer a particular Medicinal Product;

g. the remuneration for the services is reasonable and reflects the fair market value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensating the HCPs or PO Representatives.

Section 15.03. In their written contracts with consultants, Member Companies are strongly encouraged to include provisions regarding the obligation of the consultants to declare that they are consultants to the Member Company whenever they write or speak in public about a matter that is the subject of the agreement or any other matter relating to that Member Company.
Similarly, Member Companies that employ, on a part-time basis, HCPs that are still practising their profession are strongly encouraged to ensure that such persons have an obligation to declare their employment arrangements with the Member Company whenever they write or speak in public about a matter that is the subject of the employment or any other matter relating to that Member Company. The provisions of this Section 15.03 apply even though the EFPIA Code does not otherwise cover non-promotional, general information about Member Companies (as discussed in the "Scope of the EFPIA Code" section).[8]

8 - Companies are strongly encouraged to include such provisions in any contracts covered by this Section 15.03.

Section 15.04. Limited market research, such as one-off phone interviews or mail/e-mail/internet questionnaires are excluded from the scope of this Article 15, provided that the HCP, HCO's member or PO's Representative is not consulted in a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) and that the remuneration is minimal.

Section 15.05. If an HCP or a PO's Representative attends an Event (an international Event or otherwise) in a consultant capacity the relevant provisions of Article 10 must apply.

CHAPTER 3.
SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH HCPs AND HCOs

ARTICLE 16
LIFELONG LEARNING IN HEALTHCARE

Lifelong learning in healthcare (LLH) is aimed at increasing the scientific knowledge and competence of HCPs to enhance medical practice and improve patient outcome.
Member Companies can be engaged in or support different types of educational programs but such activities must not constitute Promotion. These activities can be one of three types: 1) Independent Medical Education i.e. conducted by an independent organisation and funded by the industry; 2) programs that are developed in collaboration with another stakeholder; or 3) pharmaceutical industry led LLH activities.
When funding Independent Medical Education or organizing LLH activities directly or in collaboration with third parties, Member Companies must ensure that their participation and role is clearly acknowledged and apparent from the outset.
LLH activities must have content that is fair, balanced and objective, designed to allow the expression of diverse evidence-based science and fulfill unmet educational needs in healthcare.
This Article is complemented by a Guideline on a Quality Framework for LLH (Annex 3).

ARTICLE 17
INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

Section 17.01. The provision of Informational or Educational Materials is permitted provided it is: (i) "inexpensive"; (ii) directly relevant to the practice of medicine or pharmacy; and (iii) directly beneficial to the care of patients.

Section 17.02. Items of Medical Utility aimed directly at the education of HCPs and patient care can be provided if they are "inexpensive" and do not offset routine business practices of those who receive them.

Section 17.03. The nature of Informational or Educational Materials and Items of Medical Utility considered may not constitute a circumvention of the prohibition on gifts defined under Article 11 of this Code. The transmission of such materials or items must not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer a Medicinal Product.

Section 17.04. Informational or Educational Materials and Items of Medical Utility can include the Member Company name, but must not be product branded, unless the Medicinal Product's name is essential for the correct use of the material or item by the patient.

ARTICLE 18 NON-INTERVENTIONAL STUDIES

Section 18.01. Non-Interventional Studies must be conducted with a primarily scientific purpose and must not be disguised Promotion.

Section 18.02. Non-Interventional Studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study must comply with all of the following criteria:

a. There is a written study plan (observational plan/protocol);

b. In countries where ethics committees are prepared to review such studies, the study plan must be submitted to the ethics committee for review;

c. The study plan must be approved by the Member Company's scientific service and the conduct of the study must be supervised by the Member Company's scientific service as described in Section 20.01.a;

d. The study results must be analysed by or on behalf of the contracting Member Company and summaries thereof must be made available within a reasonable period of time to the Member Company's scientific service (as described in Section 20.01.a), which service must maintain records of such reports for a reasonable period of time. The Member Company must send the summary report to all HCPs that participated in the study and must 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 must be immediately forwarded to the relevant competent authority;[9] and

e. Medical Sales Representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the Member Company's scientific service that will also ensure that the Medical Sales Representatives are adequately trained. Such involvement must not be linked to the Promotion of any Medicinal Product.

Section 18.03. To the extent applicable, Member Companies are encouraged to comply with Section 18.02 for all other types of NIS, including epidemiological studies and registries and other studies that are retrospective in nature. In any case, such studies are subject to Article 15.01.

ARTICLE 19 MEDICAL SAMPLES

Section 19.01. In principle, no Medical Samples should be given, except on an exceptional basis. Medical Samples must not be given as an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products, and must not be given for the sole purpose of treating patients.
Medical Samples are provided to HCPs so that they may familiarise themselves with the Medicinal Product and acquire experience in dealing with them.
In accordance with national and/or EU laws and regulations, a limited number of Medical Samples may be supplied on an exceptional basis and for a limited period. A reasonable interpretation of this provision is that each HCP should receive, per year, not more than 4 Medical Samples

9 - Member Companies are encouraged to publicly disclose the summary details and results of NIS in a manner that is consistent with the parallel obligations with respect to clinical trials.

of a particular Medicinal Product he/she is qualified to prescribe for 2 years after the HCP first requested samples of each particular Medicinal Product (i.e. the "4x2" standard).
In this context, a new Medicinal Product 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 Medicinal Product.
Without prejudice to the ban on medical sampling of Medicinal Product containing psychotropic and narcotic substances, Medical Samples can only be given in response to a written request from HCPs qualified to prescribe that particular Medicinal Product.
Written requests must be signed and dated by those who ask for the Medical Samples.
On an exceptional basis, Member Associations may allow, through additional guidance, a longer period than 2 years if required by local healthcare conditions.

Section 19.02. Member Companies must have adequate systems of control and accountability for Medical Samples which they distribute and for all Medicinal Products handled by theirs Medical Sales Representatives. This system must also clearly establish, for each HCP, the number of Medical Samples supplied in application of the provisions in Section 19.01.

Section 19.03. Each Medical Sample must be no larger than the smallest presentation of that particular Medicinal Product in the relevant country.
Each Medical Sample must be marked "free medical sample – not for sale" or words to that effect and must be accompanied by a copy of the summary of product characteristics.

ARTICLE 20 MEMBER COMPANY STAFF

Section 20.01. All Member Company staff must be fully conversant with the relevant requirements of the Applicable Code(s) and laws and regulations.

a. Each Member Company must establish a scientific service in charge of information about its Medicinal Products and the approval and supervision of NIS. Member Companies are free to decide how best to establish such service(s) in accordance with this Section 20.01 (i.e. whether there is one service in charge of both duties or separate services with clearly delineated duties), taking into account their own resources and organisation. The scientific service must include a medical doctor or, where appropriate, a pharmacist who will be responsible for approving any promotional material before release. Such person must certify that he or she has examined the final form of the promotional material and that in his or her belief it is in accordance with the requirements of the Applicable Code(s) and any relevant laws and regulations, is consistent with the summary of product characteristics and is a fair and truthful presentation of the facts about the Medicinal Product. In addition, the scientific service must include a medical doctor or, where appropriate, a pharmacist, who will be responsible for the oversight of any NIS (including the review of any responsibilities relating to such studies, particularly with respect to any responsibilities assumed by Medical Sales Representatives). Such person must certify that he or she has examined the protocol relating to the NIS and that in his or her belief it is in accordance with the requirements of the Applicable Code(s) and any relevant laws and regulations.

b. Each Member Company must appoint at least one senior employee who must be responsible for supervising the Member Company and its subsidiaries to ensure that the standards of the Applicable Code(s) are met.

Section 20.02. Each Member Company must ensure that its Medical Sales Representatives are familiar with the relevant requirements of the Applicable Code(s), and all applicable laws and regulations, and are adequately trained and have sufficient scientific knowledge to be able to provide precise and complete information about the Medicinal Products they promote.

a. Medical Sales Representatives must comply with all relevant requirements of the Applicable Code(s), and all applicable laws and regulations, and Member Companies are responsible for ensuring their compliance.

b. Medical Sales Representatives must approach their duties responsibly and ethically.

c. During each visit, and subject to applicable laws and regulations, Medical Sales Representatives must give the persons visited, or have available for them, a summary of the product characteristics for each Medicinal Product they present.

d. Medical Sales Representatives must transmit to the scientific service of their companies forthwith any information they receive in relation to the use of their company's Medicinal Products, particularly reports of side effects.

e. Medical Sales Representatives must ensure that the frequency, timing and duration of visits to HCPs, pharmacies, hospitals or other healthcare facilities, together with the manner in which they are made, do not cause inconvenience.

f. Medical Sales Representatives must not use any inducement or subterfuge to gain an interview. In an interview, or when seeking an appointment for an interview, 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.

CHAPTER 4.
SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH POs

ARTICLE 21 INTERACTIONS WITH POs

Section 21.01. Member Companies must comply with the following principles that EFPIA, together with pan-European POs, have subscribed to:

- The independence of POs, in terms of their political judgement, policies and activities, must be assured.
- All interactions between POs and Member Companies must be based on mutual respect, with the views and decisions of each partner having equal value.
- Member Companies must not request, nor shall POs undertake, the Promotion of a particular POM.
- The objectives and scope of any collaboration must be transparent. Financial and non-financial support provided by Member Companies must always be clearly acknowledged.
- Member Companies welcome broad funding of POs from multiple sources.

Section 21.02. EU and national laws and regulations prohibit the advertising of POM to the general public.

Section 21.03. 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. unrestricted grant, 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.

Section 21.04. Member Companies must not influence the text of PO's material they sponsor in a manner favourable to their own commercial interests. This does not preclude Member Companies from correcting factual inaccuracies. In addition, at the request of POs, Member Companies may contribute to the drafting of the text from a fair and balanced scientific perspective.

CHAPTER 5.
DISCLOSURE OF ToVs FROM MEMBER COMPANIES

ARTICLE 22. DISCLOSURE OF ToVs TO HCPs, HCOs, AND POs

Section 22.01. Time of Disclosure
Disclosures must be made by each Member Company within 6 months after the end of the relevant Reporting Period and the information disclosed must be required to remain in the public domain for a minimum of 3 years after the time such information is first disclosed unless, in each case, (i) a shorter period is required under applicable national laws or regulations, or (ii) the relevant data protection legal basis (e.g. the legitimate interest grounds, a legal duty or the Recipient's consent relating to a specific disclosure) is no longer applicable.
The common reporting period for publication of ToVs to Recipients is set during the time interval from 20th to 30th June each year at the latest. Where a National Code provides a different time interval for its country, this must consistently apply to all disclosure obligations to Recipients.

ARTICLE 23. DISCLOSURE OF ToVs TO HCPs AND HCOs

Section 23.01. Rationale
The following article provides for disclosures of ToVs to HCPs and HCOs, whether directly or indirectly. When deciding how a ToV must be disclosed, Member Companies should, wherever possible, identify and publish at the individual HCP (rather than HCO) level, as long as this can be achieved with accuracy, consistency and in compliance with applicable laws and regulations.

Section 23.02. Implementation and deviations
This Article sets out the minimum standards which EFPIA considers must apply to all Member Associations. All Member Associations must transpose this article into their National Codes in full, except where its provisions are in conflict with applicable national laws or regulations, in which case deviations are allowed, but only to the extent necessary to comply with such national law or regulation.
Where a Member Association has determined that this article cannot be implemented in full due to national law or regulation, such Member Association will not be in breach of its obligations under this article if such deviation is no broader than necessary to comply with such national law or regulation and if it clearly documents the legal issues limiting the full implementation. It is understood that if there is an inconsistency between this article and the applicable law or regulation to which a Member Company is subject which would make adherence to this article not reasonably possible, the Member Company must comply with such law or regulation and such lack of adherence will not constitute a breach of this article.

Section 23.03. Disclosure Obligation
General Obligation. Subject to the terms of this article, each Member Company must document and disclose ToVs it makes, directly or indirectly, to or for the benefit of a Recipient, as described in more detail in Article 23.05.

Excluded Disclosures. Without limitation, ToVs that (i) are solely related to over-the-counter medicines; (ii) are not listed in Section 23.05 of this article, such as Items of Medical Utility

(governed by Article 17), meals (governed by Article 10, especially Section 10.05), Medical Samples (governed by Article 19); or (iii) are part of ordinary course purchases and sales of Medicinal Products by and between a Member Company and a HCP (such as a pharmacist) or a HCO do not fall within the scope of the disclosure obligation described above in *"General Obligation"*.

Section 23.04. Form of Disclosure

Annual Disclosure Cycle. Disclosures must be made on an annual basis and each Reporting Period must cover a full calendar year.

Template. Subject to "Platform of Disclosure", for consistency purposes, disclosures pursuant to this article will be made using a structure set forth in Annex A for reference, reflecting the requirements of this article. Deviations from this template are only acceptable where legal requirements justify that this article is not transposed in full – therefore, within a given country, only one template must apply.

Platform of Disclosure. Disclosures can be made in either of the following ways, provided that they are unrestricted and publicly available:

- on the relevant Member Company's website in accordance with the section "Applicable National Code"; or
- on a central platform, such as one provided by the relevant government, regulatory or professional authority or body or a Member Association, provided that disclosures made on a central platform developed at the initiative of Member Associations must be made, so far as possible, using a structure set forth in Annex A for reference.

Applicable National Code. Disclosures must be made pursuant to the National Code of the country where the Recipient has its professional address. If a Member Company is not resident or does not have a subsidiary or an affiliate in the country where the Recipient has its physical address, the Member Company must disclose such ToV in a manner consistent with the relevant National Code.

Language of Disclosure. Disclosures must be made in the language(s) prescribed in the National Code by the relevant Member Association. Member Companies are encouraged to make disclosures in English in addition to the mandatory disclosures in the local language (if other than English).

Documentation and Retention of Records. Each Member Company must document all ToVs required to be disclosed pursuant to Section 23.03 and maintain the relevant records of the disclosures made under this article for a minimum of 5 years after the end of the relevant Reporting Period, unless a shorter period is required under applicable national laws or regulations.

Section 23.05. Individual and Aggregate Disclosure

Individual Disclosure. Except as expressly provided by this article, ToVs must be disclosed on an individual basis. Each Member Company must disclose, on an individual basis for each clearly identifiable Recipient, the amounts attributable to ToVs to such Recipient in each Reporting Period which can be reasonably allocated to one of the categories set out below. Such ToVs

may be aggregated on a category-by-category basis, provided that itemised disclosure must be made available upon request to (i) the relevant Recipient, and/or (ii) the relevant authorities.

p For ToVs to a HCO, an amount related to any of the categories set forth below:

Donations and Grants. Donations and Grants to HCOs that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare (governed by Article 12).

Contribution to costs related to Events. Contribution to costs related to Events, through HCOs or Third Parties[10], including support to HCPs to attend Events, such as:

- Registration fees;
- Sponsorship agreements with HCOs or with Third Parties appointed by an HCO to manage an Event; and
- Travel and accommodation (to the extent governed by Article 10).

Fees for Service and Consultancy. ToVs resulting from or related to contracts between Member Companies and HCOs under which such HCOs provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

p For ToVs to a HCP:

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

- Registration fees; and
- Travel and accommodation (to the extent governed by Article 10).

Fees for Service and Consultancy. ToVs resulting from or related to contracts between Member Companies and HCPs under which such HCPs provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

Aggregate Disclosure. For ToVs where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Section 23.05, cannot be disclosed on an individual basis for legal reasons, a Member Company must disclose the amounts attributable to such ToVs in each Reporting Period on an aggregate basis. Such aggregate disclosure must identify, for each category, (i) the number of Recipients covered by such disclosure, on an absolute basis and as a percentage of all Recipients, and (ii) the aggregate amount attributable to ToVs to such Recipients.

Non duplication. Where a ToV required to be disclosed pursuant to Section 23.05 is made to an individual HCP indirectly via a HCO, such ToV must only be required to be disclosed once. To the extent possible, such disclosure must be made on an individual HCP named basis pursuant to Section 23.05.

10 - cf. Guidance of indirect ToVs through Third Parties – Support to/Sponsorship to Events through Professional Conference Organisers in Annex B

Research and Development ToV. Research and Development ToVs in each Reporting Period must be disclosed by each Member 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.

Methodology. Each Member Company must publish a note summarising the methodologies used by it in preparing the disclosures and identifying ToVs for each category described in Section 23.05. The note, including a general summary and/or country specific considerations, must 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 amounts of ToVs for purposes of this article, as applicable.

ARTICLE 24. DISCLOSURE OF SUPPORT AND SERVICES PROVIDED TO POs

Each Member Company must disclose a list of POs to which it provides financial support and/or significant indirect/non-financial support or with whom it has engaged to provide contracted services for that Member Company.

This disclosure must include a description of the nature of the support or services provided that is sufficiently complete to enable the average reader to form an understanding of the nature of the support or the arrangement without the necessity to divulge confidential information. In addition to the name of the PO, the following elements must be included:

p For support:
- the monetary value of financial support and of invoiced costs.
- the non-monetary benefit that the PO receives when the non-financial support cannot be assigned to a meaningful monetary value.

p For contracted services: the total amount paid per PO over the Reporting Period.

This information must be disclosed on the Member Company website either on a national or European level on an annual basis and each Reporting Period shall cover a full calendar year.

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

CHAPTER 6.
PROCEDURAL REQUIREMENTS

ARTICLE 25. ENFORCEMENT

Section 25.01. Enforcement through Member Associations
Member Associations must, within current applicable laws and regulations enforce the provisions of the EFPIA Code. In the event that a breach is established pursuant to the procedures of its National Code, each Member Association shall require from the offending company an immediate cessation of the offending activity and a signed undertaking by the company to prevent recurrence.

Each Member Association shall adopt Implementation and Procedure Rules (as set forth in more detail in Article 28), which will be binding upon its members, and set forth the framework for the implementation of this Code, the processing of complaints and the enforcement of sanctions in a manner consistent with applicable data protection, competition and other laws and regulations.

Section 25.02. Disclosure Requirements Different from those established in Article 23
This article sets out the minimum standards applicable to Member Associations, except where it is in conflict with applicable national law or regulation, in which case deviations are allowed, but only to the extent necessary to comply with such national law or regulation. Any provisions contained in National Codes that embody higher standards than those of this article shall not be deemed to constitute deviations from this article.

Any proposal to transpose Article 23 into a National Code, or to amend any provision transposing that article, that requires disclosures different from those required under this article, shall be clearly and conspicuously so identified in the relevant Member Association's consultative process and any materials relating to such proposal. In such case, the EFPIA Board shall be asked to confirm consistency with this article, following an EFPIA Board's decision after consultation with the EFPIA Codes Committee. Member Companies abiding by such National Codes as confirmed by the EFPIA Board shall not be considered to have failed to meet their obligations under this article.

If the applicable national law or regulation, the relevant national code or other industry self-regulation prescribes equivalent or more stringent disclosure requirements, the relevant Member Company shall comply with such equivalent or more stringent requirements in a manner as consistent as possible with the substantive disclosure requirements of Article 23.

ARTICLE 26. AMENDMENTS TO, AND GUIDANCE REGARDING COMPLIANCE WITH, THE EFPIA CODE

Section 26.01. Code Compliance
The EFPIA Codes Committee shall assist Member Associations to comply with their obligations under this Code. The key tasks of the Committee are set forth in Article 28.

Section 26.02. Amendments to the EFPIA Code
The EFPIA Codes Committee shall regularly review this Code and any guidance issued regarding compliance with this Code.
Any proposed amendments to the EFPIA Code will be submitted to the EFPIA Board for a decision and to the EFPIA General Assembly for ratification. Proposed amendments to this EFPIA Code shall be reviewed by the Codes Committee following consultation with EFPIA members and the relevant EFPIA committees.

ARTICLE 27. AWARENESS AND EDUCATION

Member Associations must, within current applicable laws and regulations facilitate companies' awareness of and education about the EFPIA Code, including by providing guidance to companies in order to prevent breaches of the National Codes. Member Associations are encouraged to share their respective interpretations of the EFPIA Code through the regular meetings organised by EFPIA (see Section 28.02) and through IFPMA.

ARTICLE 28. IMPLEMENTATION AND PROCEDURE RULES

The Implementation and Procedure Rules set forth herein establish the framework for the implementation of the EFPIA Code, the processing of complaints and the initiation or administration of sanctions by Member Associations.

Section 28.01. Member Association Implementation
Each Member Association is required to:

a. Establish national procedures and structures to receive and process complaints, to determine sanctions and to publish appropriate details regarding the same including, at a minimum, a national body of the Member Association that is designated to handle complaints and consists of a non-industry chair and, besides any industry members, membership from other stakeholders;

b. Ensure that its National Code, together with its administrative procedures and other relevant information, are easily accessible through, at a minimum, publication of its National Code on its website; and

c. Prepare, and provide to the EFPIA Codes Committee (defined below), an annual report summarizing the work undertaken by it in connection with the implementation, development and enforcement of its National Code during the year.

Section 28.02. EFPIA Codes Committee Implementation and Key Tasks
The EFPIA Codes Committee must assist Member Associations to comply with their obligations under Section 28.01 above.

a. The EFPIA Codes Committee is composed of all the national body secretaries, who will elect a chair person among their peers, assisted by one person from the EFPIA staff.

b. As a key part of its role of assisting Member Associations in their National Code compliance activities, the EFPIA Codes Committee must monitor the adoption of compliant National Codes. The EFPIA Codes Committee will not participate in the adjudication of any individual complaint under any National Code.

c. In order to promote the EFPIA Code and to share best practice, the EFPIA Codes Committee must, at least annually, invite Member Associations and Member Companies representatives to participate in a meeting at which the participants are encouraged to share their respective relevant experiences relating to the EFPIA Code. Any conclusions from the meeting must be summarised in the annual code report (referred to under (e) below) and, if appropriate, be presented to the EFPIA Board.

d. The EFPIA Codes Committee must publish an annual code report which summarizes the work and operations which have taken place in connection with the implementation, development and enforcement of the various National Codes during the applicable year, based on the country reports provided by the Member Associations pursuant to (c) above (such report shall be produced by 31 March, which date is prior to the General Assembly so as to allow sufficient time to remedy inadequate or incomplete transposition by any Member Association).

e. On an annual basis, the EFPIA Codes Committee must: (i) advise the EFPIA Board of its work and operations and the work and operations of the Member Associations, as summarized in the Member Association annual reports; and (ii) review with the EFPIA Board any additional recommendations to improve the EFPIA Code with a view towards increasing transparency and openness within the pharmaceutical industry and among Member Associations and Member Companies.

Section 28.03. Reception of Complaints

Complaints may be lodged either with a Member Association or with EFPIA. Adjudication of complaints must be a matter solely for the Member Associations.

Complaints received by EFPIA must be processed as follows:

a. EFPIA must forward any complaints it receives (without considering their admissibility or commenting upon them) to the relevant Member Association(s).

b. EFPIA must send an acknowledgement of receipt to the complainant, indicating the relevant Member Association(s) to which the complaint has been sent for processing and decision.

c. In addition, upon receipt by EFPIA of multiple external complaints (i.e. several complaints on the same or similar subjects lodged from outside the industry against several subsidiaries of a single company), EFPIA must communicate these complaints to the Member Association either of the parent company or of the EU subsidiary designated by the parent company.

Section 28.04. Processing of Complaints and Sanctions by Member Associations

a. Member Associations must ensure that all complaints, whether originating from within the industry or not, are processed in the same manner, without regard to the origin of the complaint.

b. Complaints must be processed at national level through the procedures and structures established by the Member Associations pursuant to Section 28.01. Each Member Association's national body must take decisions and pronounce any sanctions on the basis of the National Code in force in its country.

c. Each Member Association must include in its National Code provisions governing the imposition of sanctions for violations of its National Code. Sanctions must be proportionate to the nature of the infringement, have a deterrent effect and take account of repeated offences of a similar nature or patterns of different offences. A combination of publication and fines is

generally considered to be the most effective sanction; however, each Member Association may use any other appropriate sanction to enforce its National Code. Each Member Association should consider any applicable legal, regulatory or fiscal requirements which would affect the nature or extent of sanctions which may be imposed. Where publication or fines are not permitted due to applicable legal, regulatory or fiscal requirements, Member Associations should impose the most effective alternative sanction.

d. Where a complaint fails to establish a prima facie case for a violation of an Applicable Code, such complaint shall be dismissed with respect to that National Code. Member Associations may also provide that any complaint which pursues an entirely or predominantly commercial interest shall be dismissed.

e. Each Member Association should establish effective procedures for appeals against the initial decisions made by its national body. Such procedures and appeals should also take place at national level.

f. National bodies shall ensure that any final decision taken in an individual case shall be published in its entirety or, where only selected details are published, in a level of detail that reflects the seriousness and/or recurrence of the breach as follows:
   - in cases of a serious/repeated breach, the company name(s) should be published together with details of the case;
   - in cases of a minor breach, or where there is no breach, publication of the details of the case may exclude the company name(s).

g. Member Associations or national bodies are encouraged to publish summaries in English of cases that have precedential value and are of international interest (keeping in mind that cases resulting in the finding of a breach as well as those where no breach is found to have occurred may each have such value and/or interest).

The process used by EFPIA is set out in a standard operating procedure (Annex D).

ANNEX A (binding)
Standardised disclosure template

ANNEX A - STANDARDISED DISCLOSURE TEMPLATE

Date of publication: .....

	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	Contribution to costs of Events			Fee for service and consultancy			**TOTAL** *OPTIONAL*
							Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accommodation	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract		
HCPs	*INDIVIDUAL NAMED DISCLOSURE - one line per HCP (i.e. all transfers of value during a year for an individual HCP will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)*												
	Dr A					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		
	Dr B					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		
	etc.					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
	Aggregate amount attributable to transfers of value to such Recipients					N/A	N/A	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*		*Optional*
	Number of Recipients in aggregate disclosure					N/A	N/A	*number*	*number*	*number*	*number*		*Optional*
	% of the number of Recipients included in the aggreate disclosure in the total number, by category, of Recipients disclosed					N/A	N/A	%	%	%	%		N/A
HCOs	*INDIVIDUAL NAMED DISCLOSURE - one line per HCO (i.e. all transfers of value during a year for an individual HCO will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)*												
	HCO 1					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	HCO 2					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	etc.					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
	Aggregate amount attributable to transfers of value to such Recipients					*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*		*Optional*
	Number of Recipients in aggregate disclosure					*number*	*number*	*number*	*number*	*number*	*number*		*Optional*
	% of the number of Recipients included in the aggreate disclosure in the total number, by category, of Recipients disclosed					%	%	%	%	%	%		N/A

R&D	*AGGREGATE DISCLOSURE*		
	Transfers of Value re Research & Development as defined in the EFPIA Code of Practice	*TOTAL AMOUNT*	*OPTIONAL*

latest update: 27 June 2019

ANNEX B (binding)
EFPIA guidance

GUIDANCE ON DISCLOSURE OF NON-INTERVENTIONAL STUDIES

Background

In application of the EFPIA HCP/HCO Disclosure Code to exemption on individual reporting of ToVs relating to non-interventional studies (NIS) is limited to **NIS that are prospective in nature**. The Code prescribes that **retrospective NIS** must be reported on an individual names basis, in line with applicable codes.

Member Companies informed EFPIA that it was not always possible to distinguish ToVs relating to prospective (included in the aggregated reporting of R&D ToVs) and retrospective (to be reported on an individual basis) NIS.

The Ethics & Compliance Committee (E&CC) had considered that definitions in the new EU Clinical Trials Regulation 536/2014[11] could be used for reference when implementing the Disclosure requirements, thus anticipating and align with the regulatory change that will eventually take place.

On 13th June 2017, EFPIA Board approved the Guidance on disclosure of all NIS on an individual basis in case ToVs relating prospective and retrospective non-interventional studies cannot be distinguished.

This Guidance provides a basis for distinguishing between prospective versus retrospective NIS and aims at ensuring consistency in reporting of ToVs relating to NIS

Relevant EFPIA Disclosure Code provision

Schedule 1: Definition of Terms
Research and Development Transfers of Value – Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Regulation N° 536/2014[12]); or (iii) **non-interventional studies that are prospective in nature** and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (Section 15.01 of the HCP Code).

11 - Application date of the new Clinical Trials Regulation 536/2014 is dependent on the development of the IT system " EU Clinical Trial Portal and Database". At the moment, the "go-live date" is expected in second half of 2019. The effective implementation date of the Regulation will not change definitions, these definitions are considered as an appropriate reference for consistent implementation of provisions relating to the disclosure of ToVs relating to NIS.

12 - In the EFPIA HCP/HCO Disclosure Code, the definition of R&D ToVs refers to EU Directive 2001/20/EC on Clinical Trials. This legal instrument is replaced by EU Regulation N°536/2014. The definition under the EFPIA HCP/HCO Disclosure will refer to the update regulatory provisions.

Guidance

Transfers of Value relating to non-interventional studies (NIS) that are not within the definition of R&D ToVs under the EFPIA Disclosure Code must be reported on an individually named basis. In this regard, prospective versus retrospective NIS will be considered following classification in the table below:

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** p e.g. case-control, cross-sectional, and purely retrospective cohort studies **Studies in which the prescriber later becomes an Investigator, but prescribing has already occurred** p e.g. retrospective data collection from individual medical records at the site of the investigator

For sake of clarity, activities not falling within the definition of R&D ToVs, including NIS that are not conducted to maintain a marketing authorisation (in application and following definitions of the "Clinical Trials" Regulation 536/2014), will be disclosed under "consultancy/fee-for-services".

Member Companies are encouraged to include a comment in the Methodological Note, where appropriate.

This Guidance will apply at the latest to 2018's ToVs (reported in 2019).

DISCLOSURE OF INDIRECT TRANSFERS OF VALUES (ToVs) THROUGH THIRD PARTIES
SUPPORTTO/SPONSORSHIPTOEVENTSTHROUGHPROFESSIONALCONFERENCEORGANISERS(PCOS)

Background

Third parties[13] provide support to Member Companies in a variety of capacities, impacting more or less on the conduct of activities regulated by the EFPIA Codes. Such activities would be reported as **indirect Transfers of Values** (ToVs) following provisions of the EFPIA Disclosure Code. When Member Companies provide support / sponsorship to PCOs involved in the organisation of scientific Events, it is understood that the Member Companies' intention is to provide support to HCPs/HCOs *at arm's length*.

Indirect ToVs are those made on behalf of a Member Company for the benefit of a Recipient, or ToVs through an intermediate and where the Member Company knows or can identify the HCP/HCO that will benefit from the ToV[14].

In consideration of the multiple ways collaboration with third parties can be contracted, it may not be straightforward to report in application of the EFPIA Disclosure Code *in full*. As this may lead to underreporting of ToVs through third parties, further Guidance aims at providing a consistent approach towards improved reporting wherever possible in compliance with applicable law and regulations.

This Guidance clarifies reporting of Indirect ToVs to HCOs made through Professional Congress Organiser (PCOs[15]).

In consideration of legal issues that may arise in the reporting of ToVs through Distributors on behalf of a Member Company, reporting of such ToVs are not within scope of this Guidance. Where appropriate, EFPIA may consider further Guidance for this category of (and other categories of third parties involved in) ToVs.

Relevant EFPIA Disclosure Code provision

Section 3.01.1.b

Contribution to costs related to Events, through HCOs or third parties, including sponsorship to HCPs to attend Events, must be disclosed individually under the name of the Recipient; such costs may relate to:

- Registration fees;
- Sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event; and
- Travel and accommodation (to the extent governed by Article 10 of the EFPIA HCP Code).

13 - Third parties are entities or individuals that represent a company in the market place or interact with other third parties on behalf of a company or relating to the company's product. Among others, these thirds parties can be distributors, travel agents, consultants, contract research organisations. **This Guidance applies to PCOs as third parties involved in Events involving HCOs**.

14 - Definition of an indirect ToV in EFPIA's HCP/HCO Disclosure Code Schedule 1

15 - 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.

Schedule 1: Definitions

Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient, 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.

Guidance

Contributions provided to Events through PCOs – that would therefore be the Recipient of the ToVs – must be considered as indirect ToVs.

When a Member Company contributes to the costs related to Events through PCOs, the following reporting approaches are considered compliant with EFPIA reporting requirements:

- All ToVs to an HCO (either as Recipient or as Beneficiary) are reported in the relevant category under the name of the HCO
- ToVs through PCOs are reported:
  - either in the name of benefitting HCO (through *include the name of Recipient PCO*), if not included in direct ToVs to the HCO;
  - or in the name of Recipient PCO (to the benefit of *include the name of benefitting HCO*)

This Guidance applies whether PCOs organise Events on their own initiative, or at the request of an HCO.

For further clarification, the attached table reviews scenarios of support / sponsorship to Events through PCOs that may help in preparation of reporting according to this Guidance.

For good order, it is reminded that contribution to costs related to Events paid through third parties to the benefit of individual HCPs that the Member Company knows, must be reported on an individually named basis, as Indirect ToVs to HCPs.

Further recommendation

EFPIA recommend that Member Companies confirm support / sponsorship to Events through PCOs in written agreements, and encourage them to include provisions relating to information that the PCOs must communicate to the Member Company to allow appropriate reporting of ToVs following the EFPIA Disclosure Code.

The Member Companies are encouraged to describe the process followed to collect the information in their Methodological Note, where it must also be stated that the full value ToVs to the PCO will not constitute a benefit (in cash or in kind) to the HCO as the PCO may retain a "service fee".

Additional Guidance adopted at national level or requested by national legal requirements may complement this EFPIA Guidance (for such cases, Article 4.03 of EFPIA Disclosure Code applies).

This Guidance will apply at the latest to 2018's ToVs (reported in 2019).

Additional Guidance on ToVs through PCOs
SUPPORTTO/SPONSORSHIPTOEVENTSTHROUGHPROFESSIONALCONFERENCEORGANISERS(PCOS)

For further clarification, the table below reviews scenarios of support / sponsorship to Events through PCOs, which may help in preparation of reporting according to this EFPIA Guidance.

Examples of possible scenarios in support of Events
These examples are offered to help Member Companies when preparing their disclosure reports in the perspective of optimal reporting of Events which they sponsor / support

RECIPIENT PCO RECEIVING THE TOVS	BENEFICIARY HCP/HCO BENEFITTING	DISCLOSURE
PCO on behalf of / in collaboration with a HCO	**where the Member Company knows the HCP/ HCO benefitting**	**Individual disclosure following guidance**
PCO on behalf of / in collaboration with HCO	where the Member Company does not known the HCP/ HCO benefitting	Whilst disclosure on an individual HCP/HCO named basis, the Member Company may consider disclosing under the PCOs name with indication of the specialty area
PCO with HCO Scientific Committee	**HCO(s) is (are) known to the Member Company**	**Individual disclosure following guidance**
PCO with HCP Scientific Committee	**HCP(s) is (are) known to the Member Company**	**Individual disclosure following relevant EFPIA HCP/HCO Disclosure Code provisions**
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 following guidance**
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 named basis, the Member Company may consider disclosing under the PCOs name with indication of the specialty area

Disclosures on an individual names basis are subject to appropriate consent; where such consent cannot be secured, related ToVs will be disclosure in aggregate.

ANNEX C (binding)
Guidance obligations for Member Associations under the EFPIA Code

Member Companies must comply with any relevant guidance provided under this Annex or in connection with any Applicable Code(s).

Article 10 Events and hospitality
Member Association must set a monetary threshold in its National Code, failing which EFPIA will set such threshold in lieu of such Member Association.

Member Associations must provide guidance on the meaning of the term "reasonable", as used in the Article 10. Member Associations must also provide guidance on "appropriate", "renowned" and "extravagant" Venues, as used in the Article 10.

Article 17 Informational or Educational Materials and Items of Medical Utility
Member Associations must provide guidance on the meaning of the term "inexpensive", as used in Article 17.

ANNEX D (binding)
EFPIA standard operating procedure related to processing of complaints and questions submitted to EFPIA

IMPLEMENTATION & ENFORCEMENT OF CODES

Background

Organisations that are members of EFPIA – be it full or affiliate member, or member of a specialised group, sign-off on Principles laid out in the EFPIA Charter. The Board may consider that non-compliance with the EFPIA Principles jeopardises the attainment of the aims pursued by EFPIA, and may therefore decide to exclude organisations that impede EFPIA's general policy following the provisions laid down in the Statutes.

Under Principle 4, EFPIA members are required to implement high and transparent standards of conduct in dealings with external stakeholders, including abiding by the rules of EFPIA including rules laid down in the EFPIA Codes.

In line with applicable codes, implementation and enforcement (including handling of complaints) is entrusted to national disciplinary bodies. **EFPIA's role – with the support of the Codes Committee – is to ensure consistent implementation of the Codes.**

The EFPIA Codes provide for implementation and procedural rules for the processing of complaints submitted under applicable codes in line with the EFPIA requirements, including:

- the EFPIA's "Code of Practice on the Promotion of Medicines and Relationships with Healthcare Professionals" (HCP Code);
- the "EFPIA Code on Relationships between the Pharmaceutical Industry and Patient Organisations" (PO Code); and
- the "EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations" (Disclosure Code).

Under these Rules each member association is required to:

- **Establish national procedures and structures to receive and process complaints**, to determine sanctions and to publish appropriate details regarding the same including, at a minimum, a national body of the member association that is designated to handle complaints and consists of a non-industry chair and, besides any industry members, membership from other stakeholders;
- Ensure that its national code, together with its **administrative procedures and other relevant information, are easily accessible** through, at a minimum, publication of its national code on its website; and
- Prepare, and provide to the EFPIA Codes Committee, an **annual report** summarizing the work undertaken by it in connection with the **implementation, development and enforcement** of its national code during the year.

This Standard Operating Procedure (SOP) clarifies processes for the follow-up of complaints / questions submitted to EFPIA.

This SOP does not cover the process that should ensure that EFPIA Codes are transposed into national codes, in line with national laws and regulations. This task is entrusted to the Codes Committee that reports yearly to the Board on issues arising from the transposition, implementation and enforcement of applicable codes.

Relevant EFPIA Code Provision

The "Implementation and Procedure Rules" set forth in each of the EFPIA Codes establish the framework for the implementation of Codes, the processing of complaints and the initiation or administration of sanctions by member associations.

ANNEX A to the EFPIA Codes is attached for reference.

STANDARD OPERATING PROCEDURES (SOP)

Enforcement and adjudication of complaints is been entrusted to Member Associations, EFPIA's role is to ensure consistent implementation of the EFPIA Codes.

Complaints may be lodged either with a Member Association or with EFPIA. Adjudication of complaints shall be a matter solely for the national associations.

The EFPIA Director General will appoint a Compliance Officer within the EFPIA Staff, who will be mandated to ensure processes are followed and prepare responses to questions submitted to EFPIA. In line with the EFPIA Codes, the Compliance Officer will prepare recommendations to the Board in collaboration with the Codes Committee.

The following sections establish **procedural steps** for matters that may arise when EFPIA is involved in enforcement of codes. These procedural steps are to be read in conjunction with the EFPIA Codes, particularly the "Applicability of Codes" section and the responsibilities on Member Associations for the "Implementation and Procedure Rules".

Common procedure rules

Each attendee of an EFPIA meeting where matters covered by this SOP are to be considered, should ensure that relevant interests are disclosed to EFPIA before such a meeting.

A. COMPLAINTS[16] RECEIVED BY EFPIA

Section 3 of the "Implementation & Procedural Rules" further provides that **complaints received by EFPIA shall be processed as follows**:

- EFPIA will forward any complaints it receives (without considering their admissibility or commenting upon them) to the relevant member association(s).
- EFPIA will send an acknowledgement of receipt to the complainant, indicating the relevant national association(s) to which the complaint has been sent for processing and decision.
- In addition, upon receipt by EFPIA of multiple external complaints (i.e. several complaints onthe same or similar subjects lodged from outside the industry against several subsidiaries of a single company), EFPIA will communicate these complaints to the national association either of the parent company or of the EU subsidiary designated by the parent company.

Procedural Steps

- When a complaint is received by EFPIA, the Compliance Officer forwards it, within 10 working days, to the relevant Member Association(s) for action under the Member Association(s)'s procedure for dealing with complaints, and the complainant will be informed of which Member Association(s) are responsible for dealing with the complaint
- Simultaneously, the Compliance Officer will inform, in writing, the responsible senior employee[17] of the company(ies) against which the complaint is made. If the complaint involves a number of countries, EFPIA will forward the complaint to the Member Association of the parent company and to the relevant company's subsidiary(ies)
- The Member Association(s) must acknowledge receipt of the complaint from EFPIA within 30 days following EFPIA's communication
- The Member Association(s) should consider the complaint under its usual procedure, including timelines. During the adjudication period, EFPIA will not intervene, neither will it answer questions neither from the complainant nor from the Member Company(ies) involved in the case
- When the Member Association(s) has(ve) completed its(their) consideration of the matter, EFPIA must be so informed of the decision(s) made by the adjudication bodies, including, where appropriate, the sanction imposed. The Member Association(s) should provide updates to EFPIA as the matter proceeds no later than 6 months after it receipt of the complaint, and subsequently within each following quarter until a final decision is made on the compliant (within a reasonable timeframe)
- A summary of decisions made on cases submitted to EFPIA will be published in EFPIA's Codes Activity Report – once the complaint has been concluded, the learnings might lead to further discussion by the Codes Committee including enhancing code consistent implementation, where relevant.

16 - EFPIA will consider as a complaint any concerns raised about an EFPIA Member Company for materials or activities related to EFPIA Codes' implementation and/or enforcement.

17 - Each Member 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 the Applicable Code(s) are met. *See EFPIA Charter and Section 18.02 of the EFPIA HCP Code*

Throughout the complaint procedure (from receipt of the complaint at EFPIA to decision of the competent adjudication bodies), EFPIA will not communicate with parties involved in the complaint within the limits of its involvement set out in the EFPIA Codes and following the procedural steps described in this SOP. In this context, communications within EFPIA will be limited to General Counsel and Compliance Officer; the Director General will be involved to the extent justified by the complaint.

B. MEMBER COMPANY REFUSING TO SUBMIT TO DECISIONS OF A NATIONAL CODE AUTHORITY

The "Applicability of Codes" section in each of the EFPIA Codes makes it clear that Member Companies must comply with any applicable codes and any laws and regulations to which they are subject. EFPIA member companies must:

- Either be a member of the Member Association in each country where it conducts activities covered by the EFPIA Codes (either directly or through the relevant subsidiary);
- Or agree in writing with each such Member Association that it (or its relevant subsidiary) is bound by such Member Association's code (including any applicable sanctions that may be imposed thereafter).

There may be occasions where a Member Association is not able to achieve resolution of a complaint concerning an EFPIA Member Company, for example, if that Member Company does not accept a ruling or follow the agreed process. In such circumstances, EFPIA will need to be informed and to decide what action should be taken bearing in mind the obligations of EFPIA membership.

EFPIA will not consider the merits of the case – this is the role of the Member Associations. The role of EFPIA is in relation to whether the Member Company is meeting its membership obligations, and – where appropriate – to provide further clarification on interpretation of the EFPIA Codes, which will always need to be considered in conjunction with national laws, regulation and codes.

Procedural Steps

- When a Member Association, following completion of the adjudication of a complaint is unable to achieve resolution of a complaint concerning a EFPIA Member Company, the Association will inform EFPIA, indicating the reasons[18] why it cannot achieve resolution of the complaint;
- Within 10 working days of notification of the issue, EFPIA's Compliance Officer will inform, in writing, the responsible senior employee[19] of the Member Company concerned with the Member Association's request for EFPIA's intervention;

18 - For example: the Member Company concerned might not be a member of the Member Association in that country; or it might not accept a decision of that Member Association.

19 - Each Member 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 the Applicable Code(s) are met. *See EFPIA Charter and Section 18.02 of the EFPIA HCP Code*

- Based on the respondent Member Company's comments (that should be provided to EFPIA within 30 days of EFPIA's request), EFPIA's Compliance Officer will consult with the Codes Committee Chairs to agree on follow-up actions that could be recommended. These actions could be to report to the Codes Committee and/or to EFPIA Board. The Codes Committee Chairs should agree on these actions within 60 days;
- No later than 120 days following the Member Association's initial information, EFPIA will inform the Member Company of steps that it is expected to take in accordance with its EFPIA membership obligations;
- Within 30 days, the Member Company should inform EFPIA of follow-up actions put in place, and the Member Association will confirm with EFPIA that the issue has been settled;
- If no response is received from the Member Company or the response is not adequate, EFPIA will take the opinion of the Codes Committee on next steps to be taken. The Codes Committee could decide on further action, such as reporting the matter to the EFPIA Board that will decide on the recommended action that should be agreed.

C. MEMBER COMPANY NOT SUBMITTED TO APPLICABLE CODES

Member Companies that are not within the membership of EFPIA's Member Associations in countries where they operate are expected to formalise their submission to applicable national codes, including the sanction system.

Member Associations must ensure that the arrangements for application of national codes cover any EFPIA Member Company when such company is not a member of the national Member Association. Each Member Association must have a process to allow non-members of that Member Association to agree to comply with their national code and to accept the jurisdiction of that Member Association's adjudication body. However, Member Associations must not oblige the EFPIA Member Company becoming a member of the Member Association. The arrangements and conditions should be clear and transparent.

Scope and Applicability of EFPIA Codes

The EFPIA Codes apply to activities relating to **prescription-only medicines (POM)** (whether patented or off-patent, branded or generics). *This is similar to the scope of the EU Pharma Regulation*[20]. The Codes are **applicable to all activities relating to POM and relationships with Healthcare Professionals, Healthcare Organisations and Patient Organisations** (as defined in the Codes, and excluding commercial activities).

When joining EFPIA's membership, a corporation commits to obligations described in the EFPIA Charter, including *inter alia:*

- **Implement high and transparent standards of conduct in dealings with external stakeholders**, including:
  - Abiding by the rules of EFPIA including **rules laid down in the EFPIA Codes**

20 - DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use.

- **Signing-off the national self-regulatory codes in all the countries where the Member Company operates**, and confirm that it is bound by such member association's code (including any applicable sanctions that may be imposed there under);
- Each Member 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 the Applicable Code(s) are met;

For application of the EFPIA Codes, the **term "company"** shall mean any legal entity that organises or sponsors promotion, or engages in interactions with healthcare professionals covered by an Applicable Code, which takes place within Europe, whether such entity be a parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation.[21]

To ensure EFPIA Codes' applicability, implementation and enforcement is conducted in a consistent manner, EFPIA – with the support of Member Associations – will continue to regularly monitor Member Companies' commitments to applicable national codes.

Procedural Steps

- When actions undertaken by a Member Association aiming at ensuring that an EFPIA Member Company is subject to that Member Association's national code are unsuccessful, the Member Association will inform EFPIA, in writing, providing details of its actions and the Member Company's response;
- EFPIA will intervene directly when an EFPIA Member Company does not submit to the national applicable codes and require that the Member Company formalises its adherence to national applicable codes including their adjudication arrangements within 2 months of EFPIA's request;
- If the EFPIA Member Company still does not agree to respond to EFPIA's request to confirm its adherence to applicable national codes (including submission to the national sanction system), the Board will be informed;
- As part of its yearly review of code activities, the Codes Committee will provide an update on the status of EFPIA Member Companies and their obligations under the EFPIA Codes. Where the Codes Committee establishes a **pattern of non-adherence** – i.e. a Member Company has not agreed to be subject to national applicable codes in more than one country, or countries where a majority of EFPIA Member Companies are not subject to the Member Association's code – the Codes Committee will make proposals to address the situation and is likely to request the Board's intervention.

D. MEMBER ASSOCIATIONS IN DEFAULT OF ADOPTING ADEQUATE IMPLEMENTATION AND PROCEDURAL RULES

Under the EFPIA Codes, each Member Association is required to establish national procedures and structures to receive and process complaints. The national body that is designated to handle complaints must consist of a non-industry chairperson and, besides any industry members, membership from other stakeholders.

21 - See Section "Applicability of the Code" in the EFPIA Codes

Procedural steps

- When EFPIA establishes that a Member Association does not have the required national procedures and body in place to receive and process complaints, it shared the elements on which its assessment is based with the Member Association, with a request to provide a written explanation within 30 days.
- If EFPIA maintains its view that the Member Association's arrangements for implementation of its code are inconsistent with those required by the EFPIA Codes, EFPIA will refer to the Codes Committee that will hear the Member Association at its next upcoming meeting.
- Within 30 days of the Codes Committee meeting, the Compliance Officer will submit a remediation plan (approved by the Codes Committee Chairs) to the Member Association with the deadline for implementation of proposed measures (which should not exceed 3 months).
- Where the Member Association fails to confirm the establishment of appropriate implementation and procedure rules within the 3-month deadline, the Codes Committee will escalate the case to the Board with a request for intervention.

E. QUESTIONS SUBMITTED TO EFPIA FOR CLARIFICATION OF CODE PROVISIONS

The EFPIA Codes set out the minimum standards which EFPIA considers must apply to all EFPIA Member Companies in the countries where they operate. Member Associations will transpose the EFPIA Codes' provisions into their national codes, in line with applicable law or regulation. Member Associations may adopt stricter standards.

Member Companies shall be **bound by the relevant EFPIA Member Association's code** in each country in Europe in which they operate (whether directly or through its relevant operation in that country).

Deviations and Variations

Where provisions are in conflict with applicable national laws or regulations, **deviations** are allowed, but only to the extent necessary to comply with such national law or regulation.

Variations to the EFPIA Codes include provisions that are stricter than the EFPIA Codes. These are often the consequence of code development over time and the value attached to self-regulation within the national context.

Clarification and interpretation of Code provisions

When questions are submitted to EFPIA, the Compliance Officer will provide clarification of the EFPIA Codes provisions, which are minimum standards that must apply in all countries where EFPIA has a Member Association. However, such clarification / interpretation will often need to be complemented by relevant Member Associations that would further clarify specific rules applicable.

It should be noted that any clarification / interpretation provided cannot constitute a judgment of compliance with applicable codes. Decisions regarding compliance / breaches are the sole responsibility of national adjudications bodies.
When questions are submitted about the EFPIA Codes, EFPIA will provide clarification, and – where applicable – may revert to the Member Association(s) concerned.

Procedural steps

- EFPIA will acknowledge receipt of a question submitted by a Member (either a company or an association) within 10 days;
- When an EFPIA Member submits a question that goes beyond factual clarification of an EFPIA Code provision, EFPIA's Compliance Officer will draft an answer for review by the Codes Committee Chairs and the Member Association of the country(ies) involved, who may want to complement. It is expected that input from Codes Committee Chairs and Member Associations will not delay EFPIA's response beyond 1 month following the date of the question;
- Where the Codes Committee Chairs would consider that the question must be submitted to the full Codes Committee, EFPIA's Compliance Officer will inform the author of the question. In such case, the final response should however be sent no later than 3 months following the date of the question;
- Answers that pertain to Codes interpretation with a broader scope will be summarized in the yearly Codes Activities Report, and may be submitted as a Recommendation for Guidance to the Board approval, enhancing consistent implementation of the EFPIA Codes.

EFPIA will treat questions submitted with due confidentiality in regard of sensitivity of information shared, considering that the Compliance Officer will keep General Counsel informed of follow-up to any question relating to Codes submitted to EFPIA.

ANNEX E (binding)

EFPIA e4ethics rules and procedure

1. Background

Article 10 of the EFPIA Code defines the requirements applicable to pharmaceutical companies when organising events (professional, promotional, scientific, educational meetings, congresses, conferences) and/or providing hospitality during these events (paying for travel, meals, accommodation and genuine registration fees).

In 2011, EFPIA coordinated the monitoring of European third-party organised events (with more than 500 HCPs coming from 5 different countries in the scope of the EFPIA Code) by setting up an on-line platform to pre-assess events (named e4ethics).

Through e4ethics, EFPIA helps ensure a consistent implementation of the EFPIA Code provisions, enhances compliance with the Code and allows collaboration with our stakeholders (e.g. learned societies, congress organisers). While an EFPIA member company needed to take its individual decision to sponsor, participate or collaborate to an event, e4ethics provided an independent reference to inform such a decision.

2. e4ethics decisions binding and mandatory assessments

Based on a recommendation of the EFPIA Codes Committee (CodCom) and Ethics & Compliance Committee (E&CC), the EFPIA Board decided, in March 2020, to make the e4ethics platform binding, meaning that sponsoring, participation or collaboration in an event that has not been approved or has been qualified as non-compliant by e4ethics is considered as a potential breach to the EFPIA Code which could be enforced by the competent national Code authorities. **In summary, this means that e4ethics decisions are binding for EFPIA Member Companies and that Member Companies must verify that an e4ethics positive assessment is available.**

3. Collaboration with MedTech Europe

In 2012, MedTech Europe, the European Association for Medical Devices, set up the Conference Vetting System (CVS) as an independently managed system that checks the compliance of third-party educational events with MedTech Europe's Code of Ethical Business Practice and Mecomed's Code of Business Practice. The outcome of the assessment determines the appropriateness for MedTech Europe and Mecomed member companies to provide financial support to the events. The decisions rendered by the Compliance Officer are binding on MedTech Europe and Mecomed members. This means that these members cannot provide support to an event which is found to be non-compliant.

In March 2020, the EFPIA Board approved the collaboration with MedTech Europe in the field of congresses' assessments. Therefore, e4ethics assessments will be integrated in CVS even if the assessments will be directed to two different websites: e4ethics and CVS. Based on the EFPIA Board recommendation, a testing period of 6 months will be implemented and will start on 1st January 2021. During this testing period, the binding effect of decisions and the mandatory nature of assessments will be in force.

A. KEY ELEMENTS

Each platform keeps its identity and branding, meaning that each one would have its own page with relevant information, including specific user-friendly routing to the submission form, but both pages will be hosted on www.ethicalmedtech.eu. An e4ethics banner will be added on MedTech Europe website but decisions rendered by CVS Compliance Officers shall be posted on what will become the joint online calendar. Technical adjustment will have to be made within the CVS software to allow profile separation, while keeping a shared history of knowledge and an optimisation of service level.

Common back end[22]: In the back end, all assessment requests will be received by MedTech Europe Compliance Officers, which will become the Compliance Officers also for Pharma Events.

The scope of e4ethics will remain the same: European congresses, organised by a third party, with 5 different countries in the scope of the EFPIA Code and more than 500 HCPs. Virtual congresses are out-of-scope.

B. ALIGNMENT OF CRITERIA

The criteria applying to e4ethics will be aligned to those of CVS:

- The submission for events assessment must be done proactively and online by the EFPIA member companies or the congress organisers.
- The travel arrangements and meals & drinks threshold will no longer be part of the criteria assessed. Therefore, the EFPIA Member Associations will not be consulted.
- Submission in e4ethics will be mandatory**,** i.e. EFPIA Member Companies need to verify that an e4ethics positive assessment is available for the Event prior to being able to provide any kind of support, from the first day of the pilot phase. The submission for such assessment can be made by the Member Company or the Congress Organiser (HCO/PCO).
- Binding nature of all decisions rendered by e4ethics on the EFPIA members during and after the pilot phase, meaning that an Event assessed as non-compliant cannot receive any form of support from EFPIA members.
- Full MedTech Europe/EFPIA alignment on the approach and interpretation of the six assessment criteria[23], which means that there will not be a difference on how Pharma and MedTech Events will be assessed.

C. IMPORTANT CONSIDERATIONS

The following considerations are important:

- Decisions are rendered on the basis of the documents and information provided to the CVS Compliance Officer via the online submission form. The CVS Compliance Officer does not independently verify whether the information or documents are up to date.
- Decisions do not consider, nor supplant national and local laws, regulations or professional and company codes that may impose more stringent requirements upon members, HCPs, HCOs or PCOs.

22 - For the IT project, were underlined the importance to build-in data analytics tools as well as necessity to transfer historic data of e4ethics, to be used for later data analytics purposes.

23 - Event Programme - Geographic Location - Event Venue Facility – Hospitality - Event Registration Packages - Communication Support

- The schedule and relevance of scientific programme sessions of an Event are reviewed, but not their value or quality.
- The sole purpose of the vetting system is to assist corporate members in determining the appropriateness for member companies to provide support to an Event.

4. Procedure applicable to e4ethics

A. APPEAL

The assessments for e4ethics will follow the CVS process: the MedTech compliance panel will be in charge of the appeal procedure for the assessments. An appeal of the CVS Compliance Officer's assessment is possible. The body responsible for reviewing such appeals is the MedTech Europe Compliance Panel, given the value of having one single authority overseeing the decision processes respectively pertaining to MedTech and Pharma Events.

An appeal may be filed by the Member Company or the Congress Organiser (HCO/PCO) with the Compliance Panel provided that the following requirements are respected:

- Appeals must be filed within a deadline of 10 days for Pre-Clearance and Regular Submissions after the Compliance Officer's assessment decision has been published on the joint online calendar.
- A formal appeal needs to be addressed to the Chair of the Compliance Panel at cvs@ethicalmedtech.eu

The Compliance Panel will endeavour to respond to appeals within 72 hours of receipt.

B. COMPLAINT RELATED TO AN EVENT

In case of a complaint related to a European congress (and not related to an assessment), the EFPIA SOP is applicable (Annex D part A of the EFPIA Code). EFPIA will forward the complaint to the relevant national Code authority. The final decision of the national Code authority will be shared with the MedTech compliance panel for information.

A. COMPLAINTS[24] RECEIVED BY EFPIA

Section 3 of the "Implementation & Procedural Rules" further provides that ***complaints received by EFPIA shall be processed as follows****:*

i. EFPIA will forward any complaints it receives (without considering their admissibility or commenting upon them) to the relevant member association(s).
ii. EFPIA will send an acknowledgement of receipt to the complainant, indicating the relevant national association(s) to which the complaint has been sent for processing and decision.
iii. In addition, upon receipt by EFPIA of multiple external complaints (i.e. several complaints on the same or similar subjects lodged from outside the industry against several subsidiaries of a single company), EFPIA will communicate these complaints to the national association either of the parent company or of the EU subsidiary designated by the parent company.

24 - EFPIA will consider as a complaint any concerns raised about an EFPIA Member Company for materials or activities related to EFPIA Codes' implementation and/or enforcement.

Procedural Steps

4. When a complaint is received by EFPIA, the EFPIA Compliance Officer forwards it, within 10 working days, to the relevant Member Association(s) for action under the Member Association(s)'s procedure for dealing with complaints, and the complainant will be informed of which Member Association(s) are responsible for dealing with the complaint;
5. Simultaneously, the EFPIA Compliance Officer will inform, in writing, the responsible senior employee[25] of the company(ies) against which the complaint is made. If the complaint involves a number of countries, EFPIA will forward the complaint to the Member Association of the parent company and to the relevant company's subsidiary(ies);
6. The Member Association(s) must acknowledge receipt of the complaint from EFPIA within 30 days following EFPIA's communication;
7. The Member Association(s) should consider the complaint under its usual procedure, including timelines. During the adjudication period, EFPIA will not intervene, neither will it answer questions neither from the complainant nor from the Member Company(ies) involved in the case;
8. When the Member Association(s) has(ve) completed its(their) consideration of the matter, EFPIA must be so informed of the decision(s) made by the adjudication bodies, including, where appropriate, the sanction imposed. The Member Association(s) should provide updates to EFPIA as the matter proceeds no later than 6 months after it receipt of the complaint, and subsequently within each following quarter until a final decision is made on the compliant (within a reasonable timeframe);
9. A summary of decisions made on cases submitted to EFPIA will be published in EFPIA's Codes Activity Report – once the complaint has been concluded, the learnings might lead to further discussion by the Codes Committee including enhancing code consistent implementation, where relevant.

Throughout the complaint procedure (from receipt of the complaint at EFPIA to decision of the competent adjudication bodies), EFPIA will not communicate with parties involved in the complaint within the limits of its involvement set out in the EFPIA Codes and following the procedural steps described in this SOP. In this context, communications within EFPIA will be limited to General Counsel and EFPIA Compliance Officer; the Director General will be involved to the extent justified by the complaint."

25 - Each Member 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 the Applicable Code(s) are met. See EFPIA Charter and Section 18.02 of the EFPIA HCP Code

ANNEX 1
EFPIA recommendation
DISCLOSURE "GATEWAY" ON MEMBER ASSOCIATIONS WEBSITES

Background

In application of the EFPIA Disclosure Code, ToVs to HCPs / HCOs are published (in line with applicable laws and regulations) in one of the following forms:

- on individual Member Companies websites;
- through an Associations platform operating as a "gateway" to individual companies websites;
- on a multi-stakeholder platform;
- on a government platform.

Following disclosure in 2016, media have criticised poor access to the data, denouncing lack of transparency. On 14th July 2016 (i.e. only 2 weeks following public disclosure), Der Spiegel provided access to all data disclosure by Member Companies in Germany, re-organising the data in a full transparent way, using the searchable database constructed by Correctiv (a Research Centre of Public Interest). In the months following, Correctiv provide access to a similar database for Switzerland and Austria.

Similar platforms have been developed in Sweden and had been announced in Finland.

Against this trend, the Board supported the Codes Committee suggestion to take steps leading from disclosure to transparency, as the pharma industry should take credit for its disclosure initiative.

Relevant EFPIA Disclosure Code provision

Section 2.04. Platform of Disclosure.
Disclosures can be made in either of the following ways, provided that they are unrestricted and publicly available:

- on the relevant Member Company's website in accordance with Section 2.05; or
- on a central platform, such as one provided by the relevant government, regulatory or professional authority or body or a Member Association, provided that disclosures made on a central platform developed at the initiative of Member Associations shall be made, so far as possible, using a structure set forth in Schedule 2 for reference.

Recommendation

In countries where there is no central platform in place, Member Associations are encouraged to provide access to individual Member Companies reporting in their country through a "Gateway" on the Association's website as a way to improve access to information disclosed.

Each Member Association will frame the "Gateway" in consideration of the national context and in line with application law and regulations, and in consideration of the EFPIA HCP Code "Guidelines for Internet Websites Available to Healthcare Professionals, Patients and the Public in Europe". In this context, it is recommended to include a pop-up on the relevant Member Association webpage indicating that the visitor is being redirected to a webpage that is not under the Member Association's responsibility.

Each Member Association is expected to ask its member companies to provide the links to their disclosure reports.

It is expected that Member Associations take steps to operationalise the "Gateways" in time for the upcoming disclosure period (June 2018).

Follow-up

The Codes Committee will check the follow-up that Member Associations will have given to this recommendation – a status report will be included in the 2018 Codes Report.

Based on learning, the Codes Committee may issue recommendation aiming at improving transparency.

ANNEX 2

Principles for the use of digital channels

1. Principles applicable to all types of communication

COMPLIANCE WITH LAWS, REGULATIONS AND CODES OF PRACTICE

A digital channel is only a platform for communicating. Laws and regulations applicable to other platforms and media also apply to digital media. The content, target group and use of the platform are relevant factors to determine applicable rules, not the media as such.

Therefore, the provisions of the Directive 2001/83/EC related to the Medicinal Products' advertising and of the EFPIA Code of Practice apply to digital communication.
The processing of personal data must comply with applicable data protection regulations.

RESPONSIBILITY

Member Companies are responsible for all material disseminated via any digital channel that is initiated, branded and/or sponsored by Member Companies, or any Third Party acting on their behalf, including promotion of Medicinal Products.

A Member Company owning the social media page or site is responsible for the content. E.g. any mention of a Prescription-Only Medicine is likely to be considered promotion of that medicine to the public and prohibited. Another example might be the use of social media directed to the public to alert HCPs about the publication of a study on a Medicinal Product which is also likely to be considered promotion of that Medicinal Product and therefore prohibited.
Member Companies may also have responsibilities when interacting on digital channels owned by other companies or organisations.

Member Companies are also responsible for information disseminated by Member Company staff who do so via their private social media channel including, a) when they can reasonably be perceived as representing the Member Company, or b) if they are instructed, approved or facilitated by the Member Company to do so. The Member Company should have internal guidelines in place on how its staff should behave on digital channels including their own personal account activities.

For digital channels owned by the Member Company, processes should be established to monitor, moderate and/or delete any inappropriate comments in a timely manner to the extent permitted by the data protection regulations and applicable laws and codes. Member Companies may need to have similar processes when using digital channels owned by other companies or organisations.

PHARMACOVIGILANCE

Member Companies should consider developing specific guidance for digital channels and contacting their pharmacovigilance experts for specific projects in order to meet their pharmacovigilance responsibilities including the obligation to record and report any adverse effects that are discussed about their Medicinal Products.

TRANSPARENCY

Section 7.04 of the EFPIA Code of Practice requires Member Companies to clearly indicate when they have sponsored a communication. Whenever a Member Company or an individual or entity acting on behalf of a Member Company provides information on a digital channel, it should clearly state the involvement of the Member Company, including but not limited to defining content, funding in part or in totality.

In addition, the transfers of values to HCPs, HCOs and POs are reportable under the disclosure obligations as described in the EFPIA Code of Practice (Chapter 5).

When possible, the target audience of the channel should be clearly identified (e.g., HCPs and the public, or a combination thereof).

2. How to identify the allowed information for the different digital channels

It is important that the Member Company understands what content is appropriate for the different digital channels and the respective audience. All laws and regulations in this regard must be complied with in the same way as for other media.

Information included on a digital channel should be regularly updated and should clearly display, for each page and/or item, as applicable, the most recent date as of which such information was updated.

The following questions can be useful to assess risks associated with digital communication and appropriateness of digital channel content, access, set-up and maintenance:

p What is the objective of the communication (promote, inform, exchange)?

p What content will be made available on the digital channel?

- ◊ Is the content related to Medicinal Products?
- ◊ Is the content promotional or non-promotional?
- ◊ Is the content related to disease awareness?
- ◊ Is the content related to healthcare information e.g. in connection with diagnosis, treatment education, dietary support
- ◊ Is the role of the Member Company providing/developing the content clear?

p Who is the intended audience? e.g. public, HCPs or both

- ◊ Is verification of audience required?
- ◊ If yes, how?

p What is the channel standard set-up?

- ◊ Is the digital channel open to audience reaction such as sharing, commenting, exchanging?
- ◊ How is the information cascaded across the digital channels?
- ◊ Is the digital channel an open platform or for a closed audience?
- ◊ Are there limitations in content size? e.g. Twitter
- ◊ Are there any community guidelines applicable? e.g. Facebook, YouTube
- ◊ How is the information about the channel audience processed?

p How is the content reviewed, approved and maintained including by the Member Company?

3. EFPIA guidance for members for various digital channels

Below is a short description of the general use of different types of digital channels. When deciding which digital channel to use and how to develop it, the principles set out above should be taken into account.
The content published by a Member Company on each channel must be appropriate and aligned with relevant regulations, laws and codes including the EFPIA Code of Practice.

WEBSITES

Websites are classified as a channel that reaches the public, unless verification (e.g. pop-up for identification, or password) is required to access the website e.g. to HCPs. Some websites may include forums where the public can exchange or discuss topics.

Since many website visits are a result of using a search engine, keyword optimization has become an important tool. Member Companies can use appropriate search optimization to ensure that their websites are displayed high on the list of search results for relevant key words.
However, Member Companies need to ensure that the use of keyword optimization is appropriate for the intended audience. For example, optimized search through use of key words directed to websites with therapy-oriented information for the public or websites aimed at HCPs, where such websites can only be accessed by the authorized individuals.

Member Companies may sponsor website material to be produced by a Third Party in which the role of the Member Company must be made clear. If the Member Company i) is initiating the material, or the concept for it; ii) is influencing the content of the material in any way; iii) is selecting or directly paying the authors; then the Member Company is very likely to be liable for the contents of the website. If the reverse is true, and there is a strictly arm's length arrangement with the Member Company just providing a grant, then the Member Company may not be liable.

Member Companies should be confident about the choice of linked websites and that these do not promote Prescription-Only Medicines to the public. If a Member Company includes website addresses in an advertisement of a Prescription-Only Medicines to HCPs, the core

principles apply, of ensuring the content of those websites is appropriate.

SOCIAL MEDIA

In general, social media are digital channels that are considered to be aimed at the public. Social media are websites or applications on which people can interact in social networks (e.g. Facebook, Twitter, Snapchat, LinkedIn, YouTube, Instagram). In most cases social media are used to reach or interact with the public. A social media platform can be an open channel for the public or a closed channel for a targeted audience where verification of the audience is required before providing access.

BLOGS

The difference between a text on a website and on a blog is that a blog is usually owned and updated by a person or a group of people who posts on the blog regularly.

A blog can be owned by the Member Company or the Member Company may engage (either through sponsorship or consultancy fees) the owner to write on a blog (such as "social influencers"). In both cases, the blog should clearly state the involvement of the Member Company.

Given that, by its very nature, a blog is for contributors to freely and spontaneously express their personal views on a subject, Member Companies should not sponsor such blogs if they were intended, or could reasonably be expected, to promote Prescription-Only Medicines and their uses.

PODCASTS

A Member Company can have its own podcast which should follow the same rules as for websites.

A podcast can be downloaded from any podcast distributor. Core principles apply, of ensuring the recipient is well defined and targeted and that content is appropriate. E.g. a podcast promoting Prescription-Only Medicines should only be accessed by HCPs.

APPLICATIONS (APPS)

An application, usually referred to as an "app", is to be downloaded on an electronic device (e.g. smartphone, computer or tablet).

A Member Company can develop apps for the use of external stakeholders (e.g. HCPs, HCOs, patients, payers), provided that they follow the same rules as for websites. Also, they should consider potential regulatory requirements if the app fulfils the requirements for a medical device. Core principles apply, including ensuring the audience is well defined and targeted.

An app can also be developed to improve compliance with a treatment method. If an app targets a specific group (e.g. HCPs, patients, caregivers), it is important that only this group is offered access to the app content.

WEBINARS

A webinar is an on-line event conducted via the internet and it can be either performed as a live streaming event or as an on-demand service.

A Member Company can be the direct organiser of a webinar and/or use a Third Party facilitator to run the event. The Member Company is responsible for these webinars including the content and ensuring that the audience is well defined and targeted. Similar arrangements apply to Third Party webinars sponsored by Member Companies

Such webinars can be for the communication with external stakeholders (e.g. HCPs, HCOs, patients, payers) provided, that they follow the same rules as for websites.

DIRECT CHANNELS

These are one-to-one or one-to-many channels, which are targeting selected recipients; these are most commonly private, not visible to non-selected recipients; they could be replies on social media channels to an individual.

Member Companies should ensure they have the consent of the recipients to be in contact with them, and the recipients should be able to stop receiving messages easily. Appropriateness of the frequency of contact should be borne in mind.

DISCUSSION FORUMS

If a Member Company facilitates a discussion forum on either a Third Party platform, or hosts a forum on its own platform, the Member Company must be confident that they can moderate the site such that the content complies with relevant regulations, laws and codes including the EFPIA Code of Practice. The intended audience should be identified so that relevant requirements are complied with. If discussion forums are used for market research, Member Companies should ensure these are compliant with relevant legal and ethical guidelines.

ANNEX 3
EFPIA Guideline on a Quality Framework - Principles in Lifelong Learning in Healthcare

EXECUTIVE SUMMARY

Lifelong Learning is defined by the European Commission as 'all learning activity undertaken throughout life, with the aim of improving knowledge, skills, competences within a personal, civic, social and/or employment related perspective '. The pharmaceutical industry has a longstanding commitment to engaging and innovating in Lifelong Learning in Healthcare (LLH). This non-binding guideline for EFPIA Members Companies provides definition and standards for quality, transparency and ethics in medical learning.
Adhering to the principles in this guideline, will assist the pharmaceutical industry to ensure a disciplined approach to the funding and organisation of LLH and its continued contribution to improved patient outcomes. Adherence to laws and regulations, and organizing up-to-date, fair and balanced learning programmes remains essential to the development of quality educational programmes. By implementing and/or maintaining this approach to LLH, the pharmaceutical industry agrees to formally incorporate educational principles of LLH, provide transparency and facilitate working effectively with other stakeholders in healthcare.

Preamble

The purpose of this document is to provide a guideline for the implementation of EFPIA Code Article 16. The guideline must be read with the requirements and spirit of the Code in mind and in accordance with applicable laws and regulations, in particular, the EU Directive 2001/83/EC Titles VIII and VIIIa on information and advertising.
The intention of this guideline is to ensure that LLH by the pharmaceutical industry adheres to high ethical standards and robust educational principles with the ultimate common goal to benefit patients.
LLH must not constitute promotion.

High scientific standards and the process of quality assurance for medical learning programmes are required to maximize transparency, ensure quality, fair and balanced content, and mitigate bias. The pharmaceutical industry strives to use educational principles which are based on, learner-centric engagement to advance the value and impact of learning.

The Value of the Pharmaceutical Industry in LLH

The pharmaceutical industry has a legitimate role among other stakeholders in providing evidence to ensure innovations are used safely and in the appropriate patient populations.

To keep up with the speed and breadth of scientific and medical progress, different LLH providers are needed for rapid diffusion of new evidence and innovations in healthcare. Given that the pharmaceutical industry must ensure its medicines are used safely and in the right populations, it provides important high quality and a complementary channel for LLH.

To facilitate a robust and practical learning experience with a fair and balanced presentation of evidence, the pharmaceutical industry often partners with leading and recognised experts.

The pharmaceutical industry is in constant dialogue with healthcare professionals at the global, regional and local levels and may be in a position to identify and address learning needs that may not be covered by other providers of LLH.

With its large geographic footprint, the pharmaceutical industry can provide opportunities for education to HCPs in countries with limited access to LLH offerings.

With innovation in therapeutic areas, the pharmaceutical industry is frequently at the forefront of the provision of LLH to assist and accelerate the translation of clinical research and other advancements into clinical practice.

Introduction

Multiple terms are used to describe learning and Continuous Professional Development (CPD). These vary across regions and countries and may or may not be associated with formal accreditation. In the EFPIA Code Article 16 as well as in this document the term Lifelong Learning in Healthcare (LLH) is used to describe non promotional educational activities led and/or funded by the pharmaceutical industry and that fulfil unmet educational needs in healthcare.

LLH must not be to promote company products, devices or healthcare solutions, but to translate evidence relevant for enhancing patient care into respective learning interventions in disease areas. Company-driven, product only specific educational activities which promote medicinal products are out of scope for this document. Such activities must comply with laws and regulations for the promotion of medicines.

The following types of educational activities are covered by this guideline and have common objectives, but differ as to the level of pharmaceutical industry involvement, ownership and funding:

1. Independent Medical Education (IME), with or without Continuous Medical Education (CME) or Continuous Professional Development (CPD) accreditation. IME is conducted by an independent organisation without industry involvement or influence and can be funded by the pharmaceutical industry.
2. LLH programmes developed through collaboration or partnership of one or more pharmaceutical company(ies) with professional societies, healthcare organizations, education providers, or other key stakeholders. The collaboration/partnership includes a commitment to a definition of mutual relationships and goals; a jointly developed structure and shared responsibility; mutual authority and accountability for success.
3. Pharmaceutical industry led LLH activities, which may address human health, and diseases -specific learning needs. These activities are organized by individual pharmaceutical companies and may involve scientific committees, and/or independent scientific and professional organisations. Ownership, accountability and funding for these programmes remains that of the pharmaceutical company.

Whatever the type of LLH, the pharmaceutical industry is committed to delivering and supporting high-quality learning. The pharmaceutical industry expects other stakeholders,

such as IME providers, scientific committees, scientific organizations or professional associations to adhere to the following principles when receiving pharmaceutical industry support/funding for LLH.

Quality Framework

This document describes the following 3 elements:

1. Ethical, transparent and responsible engagement;
2. Quality content: programmes and activities must not be promotional, either in content or intent; and
3. Robust processes: educational needs assessment, learning design and outcomes measurement.

Ethical, transparent and responsible engagement is mandatory for any LLH activity. Quality content and robust processes are strongly recommended to meet the highest quality learning standards and educational impact.

1. MANDATORY REQUIREMENTS: ETHICAL, TRANSPARENT, AND RESPONSIBLE ENGAGEMENT

Ethical, transparent and responsible engagement is the overarching and basic principle of the quality framework and is mandatory. It is supported by robust educational processes and quality content. It is the responsibility of the funding pharmaceutical company to ensure the scientific integrity of LLH activity.

The purpose of ethical, transparent and responsible engagement is to address the following major considerations:

- **Funding**: Transparency regarding the reporting of funding and other value provided to those delivering or receiving the education as per EFPIA Code Chapter 2 and 5
- **Disclosure**: Disclosure of interests and potential conflicts of interest for any activity type of LLH by all party(ies) involved
- **Intent:** Transparency regarding intent, involvement, roles and responsibilities and nature of potential collaboration with external stakeholders (clinicians, medical associations/ organizations)
- **Data privacy**: respect regulations (such as per GDPR)
- **Compliance** with pharmaceutical industry codes of practice [such as IFPMA, EFPIA], EU regulations and local applicable laws and regulations

2. RECOMMENDED PRACTICES

2.1 Quality content

The objective of LLH is to increase the scientific knowledge and competence of HCPs to enhance medical practice and improve the overall patient and healthcare outcomes. Quality content is the foundation of LLH.

To ensure high quality content is provided by pharmaceutical industry led and/or funded LLH activities, the programmes must not be promotional, either in content or intent. They must not include product branding (trade name, logo, brand colours etc.), nor product claims.

It is recommended that a scientific committee formed of experts in the specific disease areas is responsible for developing the agenda/programme, selecting the faculty and guaranteeing the scientific integrity of the programme. With the exception of IME, members of pharmaceutical industry scientific/medical functions and therapeutic area specialists can be members of scientific committees.

Companies should consider the following principles in order to ensure high quality content for LLH programmes:

- Needs-based: needs may be identified through scientific literature review, by a scientific committee and/or a dedicated educational needs assessment - see Section 3.1
- Up to date, factual and of high scientific standard capable of substantiation: use of the most appropriate, current and evidence-based content relevant to current clinical practice and standards
- Balanced and objective: provision of scientifically balanced perspectives on the subject matter with involvement of independent scientific input when appropriate and allowing time for scientific peer to peer exchange
- Incorporates multiple sources of scientific data
- Referenced: all content should be referenced so learners can assess the level of statistical and clinical relevance of the content

Different learning styles, the cultural differences of the audience and modes of delivery should be considered to best meet the learning objectives. All components of the programme, regardless of method, design or channel (digital, visual and practical) must give a clear, fair and balanced view of the information/data they aim to convey and allow the expression of diverse theories and recognised opinions.

2.2 Robust processes

To ensure high educational quality; a robust and standardized process is strongly recommended, including:

- Educational needs assessment
- Learning design
- Outcomes assessment

Each pharmaceutical company will individualise their own educational processes. Examples below are intended to assist companies in the design of their processes

2.2.1. Educational needs assessment

A disciplined and accurate assessment of programme participants´ learning needs is a recommended initial step in planning educational activities and should ensure clarity on the selection criteria. Selection of delegates should be based on educational needs.

Needs can be classified as:

- Perceived needs; expressed and perceived by learners– e.g. a survey among HCPs attending a specific LLH activity
- Expressed needs; expressed in action – e.g. a clinical centre's need to understand new guidelines in clinical practice
- Normative needs; stated by experts
- Comparative needs; expressed in group comparison for instance between clinical institutions and their clinical practice.

An educational needs assessment should include input from multiple stakeholders in healthcare. Methods for assessing learner´s needs can include reviewing literature, qualitative exploratory research, surveys, input from experts and other stakeholders in healthcare, advisory boards and multiple other data collection methods.

2.2.2. Learning design

The current healthcare ecosystem is undergoing a major transformation. This is driven by a more patient centric approach towards healthcare and vast improvements in technology. This transformation requires all stakeholders in the healthcare ecosystem to collaborate for LLH processes to meet high educational standards.

A quality assurance framework[1] may include a standardized process for learning design and should be part of a developed higher-level strategy that aims at increasing the scientific knowledge and competence of HCPs to enhance medical practice and improve patient and healthcare outcomes.

Such processes could include an outcomes-based planning approach and should communicate what LLH should achieve. The following steps may be used in education:

1. Identify the intended outcomes based on educational needs (see needs assessment)
2. Agree on acceptable evidence e.g. discuss programme and faculty with scientific committee based on identified learning outcomes
3. Plan the learning experience

2.2.3. Outcomes measurement

To ensure continuous improvement in LLH, different approaches for measurement should be used and outcomes used to improve future programmes. Measurements may apply to different learning or instructional design and delivery channels. Although objective measures are preferred, subjective measures are used where the opinion of learners is sought, (e.g. 'satisfaction' or 'relevance').

1 Anderson et al, Moore et all, Michie et all

Recommended bibliography

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