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SIFFA and LPMA Code of Good Practice and Ethics

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DEFINITIONS

Definitions of capitalised terms are provided hereinafter to ensure consistent understanding.

Support in Relation to Event Costs: registration fees, training materials, travel and accommodation expenses, including catering costs for an event, covering expenses for the participation of a Healthcare Professional (HCP) or a representative of a Patient Organisation (PO) in an Event organised by a Member Company and/or a Third Party.

Location: the geographic area (e.g., city) where the Event is being organised.

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

Member Company: according to the EFPIA Statutes, a Member Company is a scientific research company based in Europe that develops and manufactures Medicinal Products for human use.

Member Company Employees: employees of the Member Company or persons employed by the Member Company on the basis of an agreement with Third Parties covered by this Code.

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

Europe: countries which are bound by the National codes adopted by EFPIA Member Associations¹.

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

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

Transfers of Value (ToV): direct or indirect financial or non-financial support in the form of monetary funds or otherwise, which is provided, whether for promotional purposes or otherwise, in connection with the development and sale of Prescription Medicines for human use. Direct ToV are those made directly by a Member Company for the benefit of a Recipient. Indirect ToV 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.

Research and Development Transfers of Value: ToV to a Healthcare Professional or Healthcare Organisation (HCO) involved in the planning or conducting of the following activities: (i) non-clinical trials (as defined in the OECD Guidelines for Good Laboratory Practice); (ii) clinical trials (as defined in Regulation No. 536/2014); or (iii) non-interventional studies related to the collection of patient data from individual Healthcare Professionals or Healthcare Professional groups or on behalf of Healthcare Professionals specifically for research purposes.

Informational or Educational Materials: relatively inexpensive materials directly related to the practice of medicine or pharmacy and beneficial to patient care quality.

Medical Education: education related to human health and diseases and specific non-promotional training related to Medicinal Products.

Items of Medical Utility: relatively inexpensive items that are aimed directly at the education of Healthcare Professionals, enhancing the provision of medical services and patient care, and that do not replace items necessary for routine business practices of Healthcare Professionals.

Medical Representatives: employees of the Member Company or persons employed by the Member Company on the basis of an agreement with Third Parties, that are cooperating with Healthcare Professionals or Healthcare Organisations in relation to the promotion of Medicinal Products.

National Code: the Code adopted by a Member Association.

Venue: the premises (i.e., hotel, congress centre) where an Event is being organised.

Patient Organisation (PO): a non-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, its legal address, place of incorporation or primary place of operation is located in Europe.

Patient Organisation Representative: a person who is authorised to represent and express the collective views of a PO regarding a specific issue or disease².

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

Events: all professional, educational, scientific or promotional events, meetings, congresses, conferences, symposiums, and other similar events (including advisory board meetings, visits

² EUPATI definition.

to research or manufacturing facilities and planning conferences, training events or meetings with experts in connection to clinical trials and non-interventional studies) organised or sponsored by or on behalf of a Member Company.

Applicable Codes:

- (a) (i) if the Promotion or Collaboration in question is carried out, sponsored or organised by, or on behalf of or in association with a Member Company located in Europe, then the applicable National Code shall be the code adopted by the Member Association which the Member Company belongs to; (ii) if the Promotion or Collaboration in question is carried out, sponsored or organised by, or on behalf of or in association with a Member Company that is not located in Europe, the applicable code shall be the EFPIA Code and
- (b) the National Code adopted by the Member Association of the country in which the Promotion or Cooperation in question takes place.

If a Member Company sponsors the participation of a Healthcare Professional in an international Event and if such a Healthcare Professional is granted funding in accordance with the provisions of Section 13 of this Code, such funding is subject to the requirements of the National Code of the country where such a Healthcare Professional carries out his/her business, as opposed to the requirements of the National Code of the country 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.

Prescription Medicines: a Medicinal Product that requires a medical prescription issued by a specialist appropriately qualified to prescribe the Medicinal Product in question.

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

Recipient: any Healthcare Specialist, Healthcare Organisation or Patient Organisation, as applicable, whose primary place of practice, principal professional address or place of incorporation is located in Europe.

Sponsorship: support provided by or on behalf of a Member Company, when permitted by law, with the intention to support an activity (including an Event as defined by this Code) organised by a Healthcare Organisation, Patient Organisation or Third Party.

Third Party: a private person or legal entity that represents a Member Company or collaborates with other Third Parties on behalf of a Member Company or in relation 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, non-clinical, non-interventional study management.

Host Country Principle: the principle refers to the primacy of the monetary threshold for one 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 shall prevail.

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

Healthcare Specialist (HCS): any individual that is a member of the medical, dental, pharmaceutical or nursing profession 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 located in Europe. For the purposes of this Code, the definition of HCS includes (i) officials or employees of public administration institutions, agencies or other public or private organisations that may prescribe, purchase, supply, recommend or administer a Medicinal Product, and (ii) any employee of a Member Company whose primary occupation is that of a Healthcare Specialist. This definition does not include (x) any other Member Company employees, and (y) wholesalers of Medicinal Products.

Health Data: any information related to the physical or mental health or to the inherited or acquired genetic characteristics of an identified or identifiable individual, including information regarding the provision of healthcare services revealing details about his or her physiology or health status³.

Medicinal Product: medicines according to the definition set forth in Article 1 of Directive 2001/83/EC, namely: (a) any substance or combination of substances characterised 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 making a medical diagnosis or with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic effect.

Non-Interventional Studies⁴: trials during which a Medicinal Product is prescribed as usual under the conditions of the Registrational Procedure for the Medicinal Product concerned. The assignment of a patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice, and the prescription of any Medicinal Product is clearly separated from the decision to include the patient in the medical trial. No additional diagnostic or monitoring procedures must be applied to the patients and epidemiological methods must be used for the analysis of collected data⁵.

Medical Sample: a sample according to the definition set forth in Directive 2001/83/EC, namely a sample of a Medicinal Product issued free of charge to persons qualified to prescribe or supply it in order to allow such persons to familiarise themselves with the new product and acquire experience in dealing with it.

Donations and Grants (Targeted Support): the voluntary provision of funds, material goods or services in support of healthcare, research or education, provided that the donor or grantor is not remunerated in the form of goods or services.

³ This definition is based on the definitions of “personal data”, “genetic data” and “data concerning health” in Article 4 of the GDPR.

⁴ (*non-interventional studies*), including epidemiological studies.

⁵ See Article 2 of Directive 2001/20/EC.

PREAMBLE

The **Code of Good Practice and Ethics** (hereinafter Code) of the Association of International Innovative Pharmaceuticals Producers (hereinafter SIFFA) and the Latvian Generic Medicines Association (hereinafter LPMA) is a set of ethical norms established on the basis of the Code of Practice of the European Federation of Pharmaceutical Industries and Associations (EFPIA), adopted by the EFPIA Board on 22 March 2019 and approved by the EFPIA General Assembly on 27 June 2019, concerning the Promotion of Medicinal Products to Healthcare Specialists and cooperation with Healthcare Specialists, Healthcare Organisations and Patient Organisations, to which SIFFA and LPMA members have agreed so as to ensure that such activities comply with the highest standards of ethics, professionalism and accountability. This Code applies to all types of communication and cooperation (traditional and digital).

This document replaces previous codes issued by the SIFFA and LPMA, namely:

- The SIFFA and LPMA Code of Ethics for the Promotion of Medicinal Products, which came into force on 1 April 2016, as amended on 15 April 2019, and formed the basis of the EFPIA Code on the Promotion of Prescription Medicines and Cooperation with Healthcare Professionals (*first entered into force in January 1992 and the final consolidated version of the Code was approved by the EFPIA General Assembly in June 2014*);
- The SIFFA and LPMA Memorandum of Cooperation between the Ministry of Health, Patient Organisations and non-governmental organisations in the pharmaceutical industry, signed on 5 November 2007 and based on the EFPIA Code of Practice for Relations between the Pharmaceutical Industry and Patient Organisations (*first approved in September 2007, the latest version approved by the EFPIA General Assembly in June 2011*);

The SIFFA and LPMA Code of Transparency, which entered into force on 1 January 2015 and is based on the EFPIA Code on the Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (*first approved in June 2013, the final version of the Code approved by the EFPIA General Assembly in June 2014*).

ETHICAL PRINCIPLES

As pharmaceutical companies, we work in collaboration with various stakeholders including HCPs, HCOs, POs and their representatives, regulatory authorities, government agencies 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 improve 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 a patient somewhere out there whose health and wellbeing is, directly or indirectly, dependent on our work.

We aim at creating an environment where our stakeholders and the public at large 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, fair 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 the EFPIA and its members, self-regulation means being fully committed to define, implement, comply with and enforce the highest ethical standards through the EFPIA and National Codes, where breaches are not tolerated.

Self-regulation includes the concept of a 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 guidance⁶.

This demonstrates our commitment to the following ethical principles:

First and foremost, the **PATIENTS ARE AT THE HEART OF WHAT WE DO**. We aspire to ensure that everything we do is ultimately for the benefit of patients. Our main contribution to society is the production of quality Medicinal Products and the promotion of the correct and rational use of these Medicinal Products in healthcare.

We act with **INTEGRITY**. In cooperation with stakeholders, we act responsibly and do our best to ensure that our communication is accurate, well-considered and factual. We are accountable for our decisions, actions and interactions and we encourage others to follow the same high ethical standards.

We treat all stakeholders with **RESPECT**. We commit to approach our stakeholders in an open and responsive manner, maintaining a constructive attitude, mutual respect and the desire to learn more. We value the importance of an independent decision-making process by stakeholders, based on evidence and the interests of patients. With respect to society at large, we listen to what is expected from us and adapt our style of work accordingly. We follow applicable laws and make ethical judgements when processing Personal Health Data.

We are committed to the **PRINCIPLE OF TRANSPARENCY**. We are open about our activities and interactions and encourage stakeholders to act with the same transparency.

INTRODUCTION

The EFPIA's membership⁷ is composed of:

- Full members, including: (i) pharmaceutical companies researching, developing and manufacturing Medicinal Products in Europe for human use (Member Companies); and (ii) organisations representing pharmaceutical manufacturers at a national level whose members include, among others, research companies (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 (affiliate Member Companies); and (ii)

⁶ EFPIA Leadership Statement on Ethical Practices – June 2010.

⁷ See Article 4 of EFPIA Statutes.

organisations that represent pharmaceutical research companies in Europe at a national level and that have been granted the title of “affiliate Member Association”;

- Pharmaceutical research companies operating in a particular segment of the pharmaceutical market that are part of a specialised group within EFPIA: (i) European Bio-pharmaceutical Enterprises (EBE); and (ii) Vaccines Europe (VE).

Separate entities belonging to the same multinational company – which could be the parent company (e.g. the headquarters, main 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 members⁸ 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 take place in an ethical manner, which is key for sharing knowledge and improving the quality of patient care, and (iii) introducing greater transparency regarding 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 importance of the voluntary regulation of Medicinal Product Promotion by self-regulatory bodies and the possibility of involving such bodies when complaints arise.

EFPIA encourages fair competition among pharmaceutical companies. The EFPIA Code is not intended to limit the Promotion of Medicinal Products to HCPs, or limit cooperation with HCPs, HCOs, and POs in a manner that is detrimental to fair competition. Instead, the EFPIA Code seeks to ensure that pharmaceutical companies conduct such Promotion and cooperation in good faith, avoiding deceptive practices and potential conflicts of interest with stakeholders and observing 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.

HCPs and HCOs provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and scientific experience. This knowledge and experience is an important contribution to the pharmaceutical industry's efforts to improve the quality of patient care. Thus, the beneficiaries are both individuals and society as a whole. HCPs and HCOs should be fairly compensated for the legitimate expertise and services they provide to the industry.

EFPIA believes that cooperation between Member Companies and HCPs has 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 an HCP to prescribe a Medicinal Product is one of the pillars of the healthcare system. EFPIA recognises that cooperation 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.

⁸ The updated EFPIA membership list can be found at www.efpia.eu.

For the continued success of self-regulation, the self-regulation mechanisms need to correspond to the evolving demands of society. In particular, EFPIA recognises the growing expectation for interactions between companies and society to be not only conducted with integrity but also in a transparent manner.

In the same way, the pharmaceutical industry works with POs to learn from their experience and knowledge regarding medical conditions of patients, acquire a true understanding of what it is like to live with a specific condition, how patient care is provided, how it impacts the patients, their careers and families and how medicines and other treatments can meet their needs and impact their quality of life.

POs have a key role in helping to formulate, create and develop solutions that will make the most difference to patients. Member Companies disclose the amount of financial support provided to POs during their collaboration.

EFPIA believes that it is vitally important for the public to understand and control these relationships, and the disclosure of such information contributes to increased stakeholder confidence in the pharmaceutical industry.

In relation to working with HCPs and HCOs, since the introduction of the EFPIA Disclosure Code, the EFPIA has worked hard to encourage Member Companies to always disclose relevant information and to encourage HCPs (and HCOs where relevant) to agree to individual disclosure. Under no circumstances will Member Companies be criticised for disclosing too much information.

SCOPE OF THE CODE

The Code covers:

- Promotion of Prescription Medicines to HCPs,
- Cooperation of Member Companies with HCPs, HCOs and POs (applies to prescription and non-prescription medicines),
- Disclosure of information related to Transfers of Value by Member Companies to HCPs, HCOs and POs (applies to prescription and non-prescription medicines), and
- Provisions for the application of the Code.

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

The Code covers all methods of Promotion including, but not limited to, oral and written promotional activities and communications, journal and direct mail promotions, 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 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 activities). It also covers cooperation between Member Companies and POs.

The Code is not intended to limit or regulate activities aimed at the general public and only affecting non-prescription Medicinal Products.

The 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 Directive 2001/83/EC;
- Correspondence, if it is not of a promotional nature and is necessary for answering a specific question regarding a particular Medicinal Product;
- Factual, informative statements and reference materials relating, for example, to a change of packaging, a warning of possible adverse reactions as one of the general precautions for the use of medicinal products, product catalogues and price lists, if they do not include promotion of the medicinal product;
- Activities involving only 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 all 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 the processing of complaints and questions submitted to the EFPIA.

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

- EFPIA recommendations; and
- Examples of ethical principles.

APPLICABILITY OF THE CODE

The EFPIA Code sets out the minimum standards that the EFPIA considers to be mandatory. In a manner compatible with their respective national laws and regulations, Member Associations must, at a minimum, adopt provisions in their National Codes that are 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 must incorporate the rules on the disclosure of information into the National Codes, in full, unless these rules conflict with applicable national law. In this case, derogations shall be permitted to the extent necessary to comply with the requirements of the relevant national laws and regulations.

Promotion and cooperation which takes place within Europe must comply with applicable laws and regulations. In addition, Promotion and cooperation which takes 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 thereunder).

Member Companies are bound by the relevant National Code in each European country in which they operate (whether directly or through its relevant subsidiary). If a Member Association governing a territory within which 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 the 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 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 (hereinafter IFPMA) Code of Practice, where applicable.

CHAPTER 1. PROMOTION OF PRESCRIPTION MEDICINES TO HEALTHCARE PROFESSIONALS

SECTION 1. REGISTRATION OF MEDICINES

1.01. A Medicinal Product may not be promoted until a registration certificate has been received authorising the sale or supply of the Medicinal Product concerned. Also, unapproved indications (off-label use) may not be promoted.

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

SECTION 2. INFORMATION TO BE MADE AVAILABLE

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

- a. essential information consistent with the summary of product characteristics, specifying the date on which such essential information was generated or last revised;
- b. the procedure for dispensing the Medicinal Product.

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

SECTION 3. PROMOTION AND ITS SUBSTANTIATION

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 clearly reflect that evidence. It must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.

3.02. The Promotion must be justifiable, and a substantiation must be promptly provided in response to reasonable requests from HCPs. In particular, promotional claims about side-effects must reflect available evidence or be based on clinical experience. No justification is required for facts that are confirmed by the Medicinal Product registration rules.

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.

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

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

3.06. Graphic materials, including diagrams, illustrations, photographs and tables, obtained from published research and used in promotional materials must: (a) clearly indicate the source(s) of the graphic materials concerned; (b) be accurately reproduced, except for where the graphic materials need to be adapted or modified to ensure compliance with the requirements of the Code. In this case, it must be made clear that the work in question has been adapted and/or modified.

Particular care must be taken to ensure that artwork included in the Promotion is not misleading in regard to the nature of a Medicinal Product (for example, whether it is appropriate for children) or in regard to a claim or comparison (for example, by using incomplete or statistically irrelevant information or unusual scaling).

3.07. The word “safe” must never be used to describe a Medicinal Product without proper qualification.

3.08. The word “new” must not be used to describe any Medicinal Product or presentation which has been generally available for more than one year or any therapeutic indications which have been generally promoted for more than one year.

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

SECTION 4. USE OF QUOTATIONS IN PROMOTION

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

SECTION 5. ETHICS 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) never ignore the special nature of the Medicinal Product and the professional standing of the intended audience; and (c) not be likely to cause offence.

SECTION 6. PROMOTION DISSEMINATION

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

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

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 the purposes of Promotion is prohibited except with the prior permission or upon the request of the recipient.

SECTION 7. PROMOTION TRANSPARENCY

7.01. Promotion must not be disguised.

7.02. Clinical trials, post-registrational observations and experience programmes, as well as post-registrational trials (including retrospective studies) may not be used as surreptitious Promotion. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose.

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 content.

7.04. Materials sponsored by a Member Company relating to Medicinal Products and their uses, whether promotional in nature or not, must clearly indicate that they have been sponsored by that Member Company.

SECTION 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.) authorised in a country or countries where the Medicinal Product is registered must be accompanied by an explanatory statement indicating that registration conditions differ internationally.

SECTION 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. COOPERATION WITH HEALTHCARE PROFESSIONALS, HEALTHCARE ORGANISATIONS AND PATIENT ORGANISATIONS

SECTION 10. EVENTS AND HOSPITALITY

10.01. All Events must take place in an appropriate location and Venue that is consistent with the main purpose of the Event. Events that are “extravagant” or “famous” for their entertainment should be avoided.

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.

10.03. Hospitality Services may only be offered by Member Companies if they are appropriate and otherwise in accordance with the Code.

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

10.05. Member Companies must not provide or offer any meal (food and beverages) to HCP, HCO or PO representatives, unless, in each case, the value of such a meal does not exceed the monetary threshold set by the Code (following the “Host Country Principle”).

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) where a participant requires assistance, the travel, catering, accommodation and registration fee costs of an accompanying person can be reimbursed within the same parameters.

10.07. All forms of hospitality offered to HCP, HCO or PO representatives must be “reasonable” and strictly limited to the main purpose of the Event. As a general rule, the monetary value of the hospitality provided must not exceed the amount that the recipients of such hospitality would normally be prepared to pay for themselves.

10.08. Hospitality must not cover sponsorship or the organisation of any entertainment events (e.g., sports or recreational events).

SECTION 11. PROHIBITION OF GIFTS

11.01. It is prohibited to directly or indirectly offer, promise or present gifts intended for the personal use of HCP, HCO or PO representatives (such as tickets to sports or entertainment events, social courtesy gifts).

Offering or gifting cash, cash equivalents or personal services is also prohibited. In this context, personal services are any type of service unrelated to the profession of the recipient and that confer a personal benefit to the recipient.

11.02. A promotional aid is a non-monetary item given for promotional purposes (which does not include promotional materials as defined in Chapter 1). Providing or offering promotional aids to HCP, HCO or PO representatives in relation to the promotion of Prescription Medicines is prohibited.

SECTION 12. DONATIONS AND GRANTS (TARGETED SUPPORT) TO HEALTHCARE ORGANISATIONS AND PATIENT ORGANISATIONS

12.01. Donations and grants (targeted support) to HCOs and/or POs (in cash or otherwise) 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 incentive to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.

12.02. Donations and grants (targeted support) to individuals are not allowed. Company support conditions for HCP participation in international Events are set out in Section 13 of the Code.

SECTION 13. SUPPORT IN RELATION TO EVENT COSTS AND SPONSORSHIP

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

13.02. The public use of an HCO or PO 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.

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

SECTION 14. FINANCING OF MEMBER COMPANIES

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.

SECTION 15. CONTRACTED SERVICES

15.01. Contracts between Member Companies and HCPs, HCOs, POs or PO representatives under which the aforementioned persons or organisations provide any type of service to Member Companies not covered by other provisions of this 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 incentive to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.

15.02. It is permitted to contract HCP or PO representatives as consultants, whether in groups or individually, for services such as performing in and/or conducting events, participating in medical/scientific studies, clinical trials, training, participating at advisory board meetings, and participating in market research even if such participation involves remuneration and/or hospitality services. To the extent possible, the provision of the relevant consultations or other services must comply with all of 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 is not greater than reasonably necessary to achieve the identified necessity;
- e. the contracting Member Company maintains records concerning, and makes appropriate use of, the services provided by consultants;
- f. the contracting of the consultant to provide the relevant service is not an incentive 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.

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.

It is also highly recommended that Member Companies employing part-time HCPs who are still working in their profession ensure that they indicate their employment in the Member Company in situations where they publicly comment in writing or orally on the subject of their employment contract or other matters related to the Member Company. The provisions of Section 15.03. also apply to general, non-promotional information about Member Companies (as stated in the Section titled "Scope of the EFPIA Code").⁹

15.04. Limited market research, such as one-off phone interviews or mail/e-mail/internet questionnaires are excluded from the scope of Section 15, provided that the HCP, HCO or PO representative is not consulted in a recurring manner (either with respect to the frequency of

⁹ Companies are strongly encouraged to include such provisions in any contracts covered by Section 15.03. of the Code.

calls made in general or calls relating to the same research) and that the remuneration is minimal.

15.05. If an HCP or PO representative attends an Event (an international Event or otherwise) in a consultant capacity, the relevant provisions of Section 10 shall apply.

CHAPTER 3. SPECIFIC REQUIREMENTS FOR COOPERATION WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

SECTION 16. MEDICAL EDUCATION

The aim of Medical Education is to increase the scientific knowledge and competence of HCPs so as to enhance treatment quality and results.

Member Companies may engage in various Medical Education programmes and events, but only if such activities do not constitute Promotion in the interpretation of this Code.

When funding independent Medical Education or organising Medical Education 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. When Member Companies are engaged in organising Medical Education events and creating the content of such events, they are responsible for what is communicated during such events. Such content must be fair, balanced and objective, and designed to allow the expression of diverse theories and opinions.

SECTION 17. INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

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 patients¹⁰.

17.02. Items of Medical Utility aimed directly at the education of HCPs and improvement of patient care can be provided if they are “inexpensive” and do not replace items that are necessary for the daily operations of the recipient of the Item of Medical Utility. Medical devices or equivalent Items of Medical Utility that are necessary for the use of a particular Medicinal Product and that are placed at the disposal of an HCP for the purpose of educating patients or for the care of patients for whom the specific Medicinal Product is prescribed do not constitute such devices.

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

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

¹⁰ Paragraph 23 of Cabinet Regulation No. 378 “Procedures for Advertising Medicinal Products and Procedures by Which a Medicinal Product Manufacturer is Entitled to Give Free Samples of Medicinal Products to Physicians”.

SECTION 18. NON-INTERVENTIONAL STUDIES

18.01. Non-interventional studies must be conducted primarily for scientific purposes and must not be used for surreptitious Promotion.

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 purposes of the study, must comply with all of the following criteria:

- a. a written study plan/protocol has been prepared;
- b. in countries where ethics committees are prepared to consider such studies, the study plan must be submitted to the ethics committee for consideration;
- c. The study plan must be approved by the Member Company's scientific service and 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)), while the aforementioned service must maintain records of such reports for a reasonable period of time. The Member Company must send the relevant summary report to all HCPs that participated in the study. Upon request, the summary report should also be made available to self-regulatory bodies and/or committees responsible for monitoring and implementing the Applicable Codes. 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;¹¹ 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.

18.03. To the extent possible, Member Companies are encouraged to comply with Section 18.02 for all other types of non-interventional studies, including epidemiological studies and registries and other studies that are retrospective in nature. In any case, such studies are subject to Section 15.01 of this Code.

SECTION 19. MEDICAL SAMPLES

19.01. Medical Samples may only be issued in exceptional cases.

Medical Samples must not be given as an incentive to recommend, 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, no more than four Medical Samples of a particular Medicinal Product he/she is qualified to prescribe for two

¹¹ Member Companies are encouraged to publicly disclose the summary details and results of the non-interventional studies in a manner that is consistent with the parallel obligations with respect to clinical trials.

years after the HCP first requested samples of each particular Medicinal Product (i.e., the “4x2” standard)¹².

For the purposes of this Code, a new medicinal product is a newly registered medicinal product* – either a new registration or the expansion of an existing line with new recommended doses/formulae that also come with new indications. The expansion of an existing line with new recommended doses/formulae with unchanged indications or package sizes (number of units per package) cannot be considered as a new medicinal product.

*) The starting date is the date on which the medicinal product is placed on the market.

Without prejudice to the ban on medical sampling of Medicinal Products 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 for Medical Samples must be signed and dated by the HCP.

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 their Medical Sales Representatives. This system must also clearly establish the number of Medical Samples supplied to each HCP in accordance with Section 19.01. of this Code.

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 SAMPLE”.

SECTION 20. MEMBER COMPANY EMPLOYEES

20.01. All Member Company employees must be fully acquainted with the relevant requirements of the Applicable Code, as well as the laws and regulations.

- a. Each Member Company must establish a scientific service responsible for providing information on the Medicinal Products offered by that Member Company, as well as for approving and monitoring non-interventional studies. Member Companies are free to decide how best to establish such service(s) in accordance with the requirements of this Paragraph (i.e., whether there should be one service in charge of both duties or separate services with clearly delineated duties), taking their own resources and organisational needs into account. 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 promotional material in its final form and that in his or her opinion it is in accordance with the requirements of the Applicable Code and any relevant laws and regulations, is consistent with the Medicinal Product description and is a fair and truthful representation of the facts concerning 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 non-interventional study (including the review of any responsibilities relating to such studies, particularly with respect to any responsibilities assumed by Medical Sales Representatives). This person must certify that he or she has inspected the relevant non-interventional study protocol and that, in his or her opinion, it complies with the requirements of the Applicable Code and regulatory enactments.

¹² Paragraphs 27.8 and 27.9 of Cabinet Regulation No. 378 “Procedures for Advertising Medicinal Products and Procedures by Which a Medicinal Product Manufacturer is Entitled to Give Free Samples of Medicinal Products to Physicians”.

- b. 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 are met;

20.02. Each Member Company must ensure that its Medical Sales Representatives are familiar with the relevant requirements of the Applicable Code, 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, 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. In accordance with the applicable laws and regulations, the Medical Sales Representatives must provide (in electronic form) the descriptions of every Medicinal Product they have promoted to each person they have visited in regard to the promotion of a Medicinal Product.
- 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 incentives or subterfuge to gain an interview. During 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 COOPERATION WITH PATIENT ORGANISATIONS

SECTION 21. COOPERATION WITH PATIENT ORGANISATIONS

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

1. The independence of POs, in terms of their political opinions, policies and activities, must be assured.
2. Cooperation between POs and Member Companies must be based on mutual respect, with the views and decisions of each partner having equal value.
3. Member Companies must not request, nor shall POs undertake, the Promotion of a particular Prescription Medicine.
4. The objective and scope of any collaboration must be transparent. Transfers of Value from Member Companies must always be clearly acknowledged.
5. Member Companies support the attraction of POs funding from various financial sources.

21.02. EU and national laws and regulations prohibit the advertising of Prescription Medicines to the general public.

21.03. When Member Companies provide financial support, significant indirect support and/or significant non-financial support to POs, they must have a written agreement in place.

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., covering the service costs of a public relations agency and the nature of the services provided by the company) and significant non-financial support.

21.04. Member Companies must not influence the contents of sponsored POs materials 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 a POs, Member Companies may contribute to the drafting of the relevant text from a fair and scientifically accurate perspective.

CHAPTER 5. INFORMATION REGARDING TRANSFERS OF VALUE FROM MEMBER COMPANIES

SECTION 22. INFORMATION REGARDING TRANSFERS OF VALUE TO HEALTHCARE PROFESSIONALS, HEALTHCARE ORGANISATIONS AND PATIENT ORGANISATIONS

22.01. Time of Disclosure

Disclosures must be made by each Member Company within six months after the end of the relevant Reporting Period and the information disclosed must remain in the public domain for a minimum of three years after the first disclosure of such information unless (i) a shorter period is required under applicable national laws or regulations, or (ii) the relevant legal basis for data protection (e.g. legitimate interests, legal obligation or the Recipient's consent relating to a specific disclosure) is no longer applicable.

The reporting period for the disclosure of Transfers of Value to Recipients is set from 20 to 30 June of each year at the latest.

SECTION 23. INFORMATION REGARDING TRANSFERS OF VALUE TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

23.01. Justification

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

23.02. Implementation and Deviations

This Section sets out the minimum standards which the EFPIA considers applicable to all Member Associations. All Member Associations shall fully adapt the provisions of this Section to their respective National Codes, unless the provisions of this Section conflict with applicable national laws and regulations. In this case, derogations shall be permitted to the extent necessary to comply with the requirements of the relevant national laws and regulations.

Where a Member Association has determined that this Section cannot be implemented in full due to a national law or regulation, such Member Association will not be in breach of its obligations under this Section 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 Section and an applicable law or regulation governing a Member Company which would make adherence to this Section unreasonable or impossible, the Member Company must comply with such law or regulation and such lack of adherence will not constitute a breach of this Section.

23.03. Disclosure Obligation

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

Exceptions Without limitation to the aforementioned, ToV do not fall within the scope of the disclosure obligation described above in “General Obligation” if they (i) are not listed in Section 23.05., such as Items of Medical Utility (governed by Section 17), catering (governed by Section 10, especially Section 10.05.), Medical Samples (governed by Section 19); or (ii) are part of ordinary purchase and sales procedures of Medicinal Products by and between a Member Company and a Healthcare Specialist (such as a pharmacist) or a Healthcare Organisation.

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 the provisions of the Section titled “Form of Disclosure” detailed below, for consistency purposes, disclosures pursuant to this Section shall be made using the template provided in Annex A to this Code, reflecting the requirements of this Section. Deviations from the aforementioned template shall only be permitted if legal requirements make it impossible to adapt the provisions of this Section in full. This means that only one type of template can be used per country.

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

- (i) on the relevant Member Company’s website in accordance with the section “Applicable National Code”; or
- (ii) 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 are made, so far as possible, following the template provided in Annex A to this Code.

Applicable National Code Disclosures must be made pursuant to the National Code of the country wherein the Recipient operates. If a Member Company, its subsidiary or affiliate is not located in the country where the Recipient’s physical address is located, the Member Company must disclose such Transfer of Value in a manner consistent with the relevant National Code.

Language of Disclosure Information must be disclosed in the official state language. Member Companies are asked to disclose information not only in the state language but also in English.

Documentation of Information and Retention of Records Member Companies must document all information on ToV and such information must be submitted in accordance with Section 23.03. of this Code. Information disclosed in accordance with the provisions of this Section shall be kept for at least five years after the end of the relevant Reporting Period, unless a shorter period is specified in the applicable national laws and regulations.

23.05. Individual and Aggregate Disclosure

Individual Disclosure Except as expressly provided by this article, ToV 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 ToV made to such Recipient in each

Reporting Period which can be reasonably allocated to one of the categories set out below. Such ToV may be aggregated on a category-by-category basis, provided that itemised disclosure is made available upon request to (i) the relevant Recipient, and/or (ii) the relevant authorities.

1. For ToV to an HCO, amounts related to any of the categories set forth below:

(a) Donations and Grants (Targeted Support). Donations and Grants to HCOs supporting healthcare, including donations and grants (in cash or otherwise) to institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare (Donations and Grants are governed by Section 12 of this Code).

(b) Support in Relation to Event Costs. Support in relation to event costs, provided through HCOs or Third Parties¹³, including sponsorship of HCPs for participation in Events, such as:

(i) Registration fees;

(ii) Sponsorship agreements with HCOs or with Third Parties appointed by an HCO to organise an Event; and

(iii) Travel and accommodation expenses (to the extent governed by Section 10 of this Code).

(c) Fees for Services and Consultations Transfers of Value resulting from or related to contracts between Member Companies and HCOs under which such HCOs provide any type of service to a Member Company or any other type of funding not covered in the previous categories. Service Fees and Transfers of Value in relation to expenses agreed upon in a written agreement concerning the relevant activities shall be disclosed as two separate amounts.

2 Amounts relating to ToV to HCPs:

(a) Support in relation to event costs. Support in relation to event costs, such as:

(i) Registration fees; and

(ii) Travel and accommodation expenses (to the extent governed by Section 10 of this Code).

(b) Fees for Services and Consultations. ToV resulting from or related to contracts between Member Companies and HCPs under which such HCPs provide any type of service to a Member Company or any other type of funding not covered in the previous categories. Service Fees and ToV in relation to expenses agreed upon in a written agreement concerning the relevant activities shall be disclosed as two separate amounts.

Aggregate Disclosure For ToV 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 ToV 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

¹³ See Guidance for Indirect ToV through Third Parties and Sponsorship/Support of Events through Professional Conference Organisers in Annex B of this Code.

absolute basis and as a percentage of all Recipients, and (ii) the aggregate amount attributable to ToV to such Recipients.

Non-Duplication Where a ToV required to be disclosed pursuant to Section 23.05. is made to an individual Healthcare Professional indirectly via a Healthcare Organisation, such ToV shall only be disclosed once. To the extent possible, such disclosures must be made for each identified HCP separately pursuant to Section 23.05.

Research and Development Transfers of Value Research and Development ToV 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 report summarising the methodologies used in preparing the disclosures and identifying ToV for each category described in Section 23.05. The report, which must include a summary and/or country-specific considerations, must describe the identification methodology used. For the purposes of this Section, the report should also include, as appropriate, information on multi-annual contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of ToV.

SECTION 24. INFORMATION REGARDING SUPPORT AND SERVICES PROVIDED TO PATIENT ORGANISATIONS

Each Member Company must publish a list of POs to which it provides financial support and/or significant indirect/non-financial support or which it has contracted for the provision of certain contractual services.

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:

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

- b. 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 it used in the preparation of the disclosures and identification of provided support and services.

CHAPTER 6. PROCEDURAL REQUIREMENTS

SECTION 25. ENFORCEMENT

25.01. Enforcement through Member Associations

Member Associations must, observing 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 an immediate cessation of the offending activity from the offending company and a signed undertaking by the company to prevent a recurrence.

Each Member Association shall adopt Implementation and Procedure Rules (as set forth in more detail in Section 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, fair competition and other laws and regulations.

25.02. Disclosure Requirements Differing from those Established in Section 23 of the EFPIA Code

This Section sets out the minimum standards that Membership Associations must comply with, unless they conflict with applicable national law. In this case, derogations shall be permitted to the extent necessary to comply with the requirements of the relevant national laws and regulations. Any provisions contained in National Codes that embody higher standards than those of this Section shall not be deemed as constituting deviations from this Section.

Any proposal to transpose Section 23 of the EFPIA Code into a National Code, or to amend any provision transposing Section 23, that requires disclosures that differ from those required under this Section, shall be clearly and conspicuously identified in the relevant Member Association's consultative process and any materials relating to such a proposal. In such case, the EFPIA Board shall be asked to confirm consistency with this Section, following 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 Section.

If the applicable national law or regulation, the relevant national code or other self-regulation provision 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 Section 23 of the EFPIA Code.

SECTION 26. AMENDMENTS AND GUIDANCE REGARDING COMPLIANCE WITH THE EFPIA CODE

26.01. Compliance with the Code

The EFPIA Codes Committee shall assist Member Associations regarding compliance with their obligations under this Code. The key tasks of the Committee are set forth in Section 28.

26.02. Amendments to the 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 resolution 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.

SECTION 27. AWARENESS AND EDUCATION

Member Associations must, observing current applicable laws and regulations, facilitate companies' awareness of and education about the EFPIA Code, including but not limited to means such as 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 within the scope of the regular meetings organised by the EFPIA (see Section 28.02.) and through the IFPMA.

SECTION 28. IMPLEMENTATION AND PROCEDURE RULES

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

28.01. Member Association Implementation

Each Member Association is required to:

- a. Establish national procedures and structures for receiving and processing complaints, determining sanctions and publishing appropriate details regarding the same including, at a minimum, the formation of a national body of the Member Association that is responsible for handling complaints and consists of a non-industry chairman 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 the EFPIA Codes Committee (defined below), with an annual report summarising the work undertaken by it in connection with the implementation, development and enforcement of its National Code during the year.

28.02. EFPIA Codes Committee Formation and Key Tasks

The EFPIA Codes Committee must assist Member Associations regarding compliance with their obligations under Section 28.01. above.

- a. A representative from each national body shall be part of the EFPIA Codes Committee; they shall elect a chairperson from among their peers, assisted by one person from the EFPIA staff.
- b. The EFPIA Codes Committee must monitor the process of adopting the National Code and ensure that it complies with the set requirements. This is one of the main tasks performed by the Codes Committee in order to assist the Member Associations in ensuring compliance with the National Codes. The EFPIA Codes Committee shall not participate in the adjudication of any individual complaint under any National Code.
- c. In order to promote the EFPIA Code and exchange best practices, the EFPIA Codes Committee must, at least once a year, invite representatives of Member Associations and Member Companies to participate in a meeting at which the participants are encouraged to share their respective 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 summarises 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, i.e. prior to the General Assembly meeting, 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) inform the EFPIA Board of its work and operations and the work and operations of the Member Associations, as summarised in the Member Association annual reports; and (ii) together with the EFPIA Board, review any additional recommendations regarding the improvement of the EFPIA Code with a view towards increasing transparency and openness within the pharmaceutical industry and among Member Associations and Member Companies.

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 to which the complaint has been sent for processing and resolution.
- c) In addition, upon receipt by the EFPIA of multiple external complaints (i.e. several complaints regarding the same or similar subjects lodged from outside the industry against several subsidiaries of a single company), the EFPIA must communicate these complaints to the parent company Member Association or the EU subsidiary Member Association designated by the parent company.

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 a 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 offence disclosure together with a fine 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 the imposable sanctions. Where offence disclosure 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 resolutions made by its national body. Such procedures and appeals should also take place at a national level.

- f. National bodies shall ensure that any final decision taken in an individual case shall be disclosed in its entirety or, where only selected details are disclosed, in a level of detail that reflects the seriousness and/or recurrence of the breach as follows:
- (i) in the case of a serious/repeated breach, the company name(s) should be disclosed together with details of the case;
 - (ii) in the case of a minor breach, or where there is no breach, the disclosure 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 cases where no breach was found to have occurred may both have such value and/or interest).

The process used by the EFPIA is set out in the standard operating procedure (see Annex D of this Code).

Imants Sinka
Chairman of the Board of
Association of International Innovative
Pharmaceuticals Producers

Egils Jurševics
Chairman of the Board of
Latvian Generic Medicines Association

ANNEX A (binding)
Standardised Disclosure Template

Disclosure template
Version: 27 June 2019

GUIDANCE ON DISCLOSURE OF NON-INTERVENTIONAL STUDIES

Background

In accordance with the EFPIA HCP/HCO Disclosure Code, the exemption from individual reporting of Transfers of Value relating to non-interventional studies is limited to **prospective non-interventional studies**. The Code prescribes that **retrospective non-interventional studies** must be reported on an individual name basis of each identified Recipient, in line with applicable codes.

Member Companies informed EFPIA that it was not always possible to distinguish Transfers of Value relating to prospective non-interventional studies (included in the aggregated reporting of Transfers of Value in relation to Research and Development) and retrospective non-interventional studies (to be reported on an individual basis).

The Ethics and Compliance Committee had considered that definitions in the new EU Clinical Trials Regulation No. 536/2014¹⁴ could be used for reference when implementing disclosure requirements, thus anticipating changes in the regulations and ensuring alignment with the new regulations.

On 13 June 2017, the EFPIA Board approved the Guidance on Disclosure of all non-interventional studies on an individual basis in cases where Transfers of Value relating to prospective and retrospective non-interventional studies cannot be distinguished.

This Guidance provides a basis for distinguishing between prospective versus retrospective non-interventional studies and aims at ensuring consistency in reporting of Transfers of Value relating to non-interventional studies.

Relevant EFPIA Disclosure Code Provisions

Annex 1: Terms Used

Transfers of Value for Research and Development – 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 No. 536/2014¹⁵); or (iii) **prospective non-interventional studies** that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the purposes of the study (see Section 15.01 of the HCP Code).

¹⁴ Implementation date of the new Clinical Trials Regulation No. 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 to occur in the second half of 2019. The effective implementation date of the Regulation will not change the definitions set therein, these definitions are considered as an appropriate reference for the consistent implementation of provisions relating to the disclosure of Transfers of Value relating to non-interventional studies.

¹⁵ In the EFPIA HCP/HCO Disclosure Code, the definition of “Transfers of Value for Research and Development” refers to EU Directive 2001/20/EC on Clinical Trials. This legal instrument is replaced by EU Regulation No. 536/2014. The definition under the EFPIA HCP/HCO Disclosure Code shall refer to updated regulatory provisions.

Guidance

ToV relating to non-interventional studies that are not included in the definition of ToV for Research and Development under the EFPIA Disclosure Code must be reported on an individual basis. In this regard, prospective versus retrospective non-interventional studies shall be distinguished following the classification provided in the table below:

Prospective non-interventional studies	Retrospective non-interventional studies
Prospective cohort studies in which the prescription of a particular medicinal product to a patient is independent from the inclusion of the patient in the study	Purely observational database review and/or research
Retrospective studies to which a prospective element is subsequently introduced	Retrospective review of records where all events of interest have already taken place - e.g., case-control, cross-sectional, and retrospective cohort studies
Long-term extension studies with patient follow-up beyond the observational period specified in the trial protocol and the active collection of additional data	Studies in which the prescriber later becomes a researcher after the prescription has already occurred - e.g., retrospective data collection from individual medical records available to the researcher

For the sake of clarity, activities not falling within the definition of ToV for Research and Development, including non-interventional studies that are not conducted to maintain a registered status (in the application and following definitions of Clinical Trials Regulation No. 536/2014), shall be disclosed under “consultancy/service fees”.

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

DISCLOSURE OF INDIRECT TRANSFERS OF VALUES THROUGH THIRD PARTIES

Support/Sponsorship of Events conducted through Professional Conference Organisers

Background

Third parties¹⁶ provide support to Member Companies in a variety of capacities, impacting the activities regulated by the EFPIA Codes to a greater or lesser degree. Such activities would be reported as **indirect Transfers of Values (ToVs)** following the provisions of the EFPIA Disclosure Code. When Member Companies provide support/sponsorship to professional conference organisers involved in the organisation of scientific Events, it is understood that the Member Companies' intention is to provide *indirect* support to HCPs/HCOs.

An indirect ToV is support provided on behalf of a Member Company for the benefit of a Recipient, or support provided through an intermediate and where the Member Company knows or can identify the HCP/HCO that will benefit from the ToV.

In consideration of the multiple ways that collaboration with third parties can be contracted, it may be difficult to report in full in accordance with the EFPIA Disclosure Code. For this reason, the disclosed information regarding ToV by companies provided through third parties may be incomplete. The purpose of this supplementary guidance is to achieve a consistent approach to improving the quality of disclosed information, where possible in accordance with the requirements of applicable laws and regulations.

This Guidance clarifies reporting of Indirect ToV to HCOs made through Professional Conference Organisers¹⁷.

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

Relevant EFPIA Disclosure Code Provisions

Section 3.01.1(b)

Support regarding Event costs, through HCOs or third parties, including HCP sponsorship to attend Events, must be disclosed individually under the name of the Recipient; such costs may relate to:

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

Annex 1: Terms Used

¹⁶ 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 in relation to the company's product. These third parties include distributors, travel agents, consultants and contract research organisations. **This Guidance applies to Professional Conference Organisers as third parties involved in Events that Healthcare Organisations take part in.**

¹⁷ A Professional Conference Organiser is a company/individual specialised in organising and conducting congresses, conferences, seminars and similar events (hereinafter Events). For the application of this Guidance, commercial companies involved in the organisation of travel (travel agencies) or accommodation (hotels, banqueting functions in hotels, etc.) are not considered PCOs.

An Indirect Transfer of Value is support provided on behalf of a Member Company through an intermediate party for the benefit of a Recipient, where the Member Company knows or can identify the HCP/HCO that will benefit from the ToV.

Guidance

Support provided for Events through a PCO – that would therefore be the Recipient of the ToV – must be considered as an indirect ToV.

When a Member Company provides support for 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;
- ToV through PCOs are disclosed by indicating:
 - either the name of the benefitting HCO (with a note that the support is provided through an intermediate party – the Professional Conference Organiser – indicating the name of the Recipient), if the relevant ToV is not indicated as direct support for the HCO in question; or
 - the name of the Recipient PCO (with a note that the true beneficiary is the HCO, indicating the name of the relevant HCO).

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

For further clarification, the attached table reviews scenarios of support/sponsorship for Events provided through PCOs which may help with disclosure preparation according to this Guidance.

It should be noted that support related to Event costs and provided through third parties in favour of a specific HCP, which can be identified by the Member Company, should be reported as an indirect ToV to the HCP. The relevant information must be disclosed on a case-by-case basis, indicating the name of the Recipient.

Further Recommendations

EFPIA recommends that Member Companies confirm support/sponsorship of 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 the appropriate reporting of Transfers of Value in accordance with the EFPIA Disclosure Code.

Member Companies are encouraged to describe the process they followed when collecting 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 otherwise) to the HCO as the PCO may retain a “service fee”.

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

**Additional Guidance regarding Transfers of Value provided through
Professional Conference Organisers
SPONSORSHIP/SUPPORT OF EVENTS
THROUGH PROFESSIONAL CONFERENCE ORGANISERS**

For further clarification, the attached table reviews scenarios of support/sponsorship for Events provided through PCOs which may help with disclosure preparation according to these EFPIA provisions.

Examples of Event Support Scenarios

These examples are offered to help Member Companies with disclosure report preparation aiming to optimise the reporting of Events which they sponsor/support.

Recipient Professional Conference Organiser receiving ToV	Beneficiary HCP/HCO benefitting from the support provided	Form of Disclosure
Professional Conference Organiser on behalf of/in cooperation with the HCO	where the Member Company knows the HCP/HCO benefitting from the support provided	Individual disclosure in accordance with the guidance
Professional Conference Organiser on behalf of/in cooperation with the HCO	where the Member Company does not know the HCP/HCO benefitting from the support provided	Although the relevant information should be disclosed for each individual case, indicating the name of the relevant HCP/HCO, the Member Company may consider disclosing the relevant information under the name of the PCO with an indication of their speciality area
The Professional Conference Organiser in cooperation with the Scientific Committee of the HCO	where the relevant HCO is known to the Member Company	Individual disclosure in accordance with the guidance
The Professional Conference Organiser in cooperation with the Scientific Committee of the HCP	where the relevant HCP is known to the Member Company	Individual disclosure following relevant EFPIA HCP/HCO Disclosure Code provisions
The PCO planning/organising an Event at its own initiative (independent event)	where the Member Company knows the HCP/HCO participating in the Event	Individual disclosure in accordance with the guidance
The PCO planning/organising an Event at its own initiative (independent event)	where the Member Company does not know the HCP/HCO participating in the Event	Although the relevant information should be disclosed for each individual case, indicating the name of the relevant HCP/HCO, the Member Company may consider disclosing the relevant information under the name of the PCO with an indication of their speciality area

Disclosures on an individual name basis are subject to appropriate consent; where such consent cannot be secured, related ToVs will be disclosed 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).

Section 10. Events and Hospitality

The Member Association must set an expenditure limit in the National Code. If this is not done, the EFPIA will set an expenditure limit in place of the relevant Member Association.

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

Section 15. Contracted Services

Member Associations must provide guidance on the meaning of “minimal” as used in Section 15.04 or in connection with any Applicable Code(s).

Section 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 Section 17.

Section 21.03.

Member Associations must provide guidance on the meaning of the term “significant”.

IMPLEMENTATION AND ENFORCEMENT OF CODES

Processing of Complaints and Questions submitted to EFPIA

Background

Organisations that are members of EFPIA – be it a full or affiliate member, or member of a specialised group, commit to uphold the 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 the EFPIA, and may therefore decide to exclude organisations that violate EFPIA’s general policy in accordance with 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 EFPIA requirements, including:

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

Under these provisions each Member Association is required to:

- (a) **Establish national procedures and structures for receiving and processing complaints**, determining sanctions and disclosing appropriate details regarding the same including, at a minimum, the formation of a national body of the Member Association that is responsible for handling complaints and consists of a non-industry chairman and, besides any industry members, membership from other stakeholders as needed;
- (b) Ensure that its National Code, together with its **administrative procedures and other relevant information, is easily accessible** through, at a minimum, the publication of its National Code on its website; and
- (c) Prepare, and provide the EFPIA Codes Committee with an **annual report** summarising 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 the 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 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. The 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 the 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 the EFPIA is involved in the 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 the EFPIA before such a meeting.

A Complaints received by the EFPIA¹⁸

Section 3 of the “Implementation and Procedural Rules” further provides that **complaints received by the 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).

¹⁸ EFPIA considers any concerns raised about an EFPIA Member Company regarding its materials or activities as a complaint related to *EFPIA Codes’* implementation and/or enforcement.

- ii. 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 resolution.
- iii. In addition, upon the receipt by the EFPIA of multiple external complaints (i.e., several complaints regarding the same or similar subjects lodged from outside the industry against several subsidiaries of a single company), the EFPIA must communicate these complaints to the parent company national association or the EU subsidiary national association designated by the parent company.

Procedural Steps

- 1 When a complaint is received by the 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 handling the complaint;
- 2 Simultaneously, the Compliance Officer will inform the responsible senior employee in writing¹⁹ of the company(ies) against which the complaint is made. If the complaint involves a number of countries, the EFPIA will forward the complaint to the Member Association of the parent company and to the relevant company subsidiary(ies);
- 3 The Member Association(s) must acknowledge receipt of the complaint from the EFPIA within 30 days following the EFPIA's communication;
- 4 The Member Association(s) should consider the complaint under its usual procedure, including timelines. During the adjudication period, the EFPIA will not intervene, and will not answer questions, neither from the complainant nor from the Member Company(ies) involved in the case;
- 5 When the Member Association has completed its consideration of the matter, the 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 the EFPIA as the matter proceeds no later than six months after the receipt of the complaint, and subsequently within each following quarter until a final decision is made on the complaint (within a reasonable timeframe);
- 6 A summary of decisions made on cases submitted to the EFPIA will be published in the EFPIA's Codes Activity Report – once the complaint has been concluded, what is learnt 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 the decision of the competent adjudication bodies), the 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 the 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

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*.

The “Applicability of Codes” section in each of the EFPIA Codes makes it clear that Member Companies must comply with any applicable codes as well as 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 the 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 cases, the EFPIA should be informed, the EFPIA should then decide on the next steps, taking the responsibilities associated with EFPIA membership into account.

EFPIA will not consider the merits of the case – this is the role of the Member Associations. The role of the EFPIA is to assess whether the Member Company in question has fulfilled its membership obligations. Where appropriate, the EFPIA must 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

- 1 When a Member Association, following the completion of the adjudication of a complaint is unable to achieve the resolution of a complaint concerning an EFPIA Member Company, the Association will inform the EFPIA, indicating the reasons²⁰ why it cannot achieve the resolution of the complaint;
- 2 Within 10 working days of notification of the issue, the EFPIA’s Compliance Officer will inform, in writing, the responsible senior employee²¹ of the Member Company concerned with the Member Association’s request for the EFPIA’s intervention;
- 3 Based on the respondent Member Company’s comments (that should be provided to the EFPIA within 30 days of the EFPIA’s request), the 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 the EFPIA Board. The Codes Committee Chairs should agree on these actions within 60 days;
- 4 No later than 120 days following the Member Association’s initial information, the EFPIA will inform the Member Company of steps that it is expected to take in accordance with its EFPIA membership obligations;
- 5 Within 30 days, the Member Company should inform the EFPIA of follow-up actions put in place, and the Member Association will confirm with the EFPIA that the issue has been settled;
- 6 If no response is received from the Member Company or the response is not adequate, the EFPIA will take the opinion of the Codes Committee on the next steps to be taken.

²⁰ 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.

²¹ 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*

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 The Applicable Codes are not binding for the relevant Member Company

Member Companies that are not within the membership of the 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 the 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 to become 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 generic). *This is similar to the scope of the EU Pharma Regulation²²*. 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. It includes the following responsibilities:

- 4 **In their dealings with external stakeholders, the Member Companies must adhere to high and transparent standards of conduct**, including:
 - (a) Abiding by the rules of the EFPIA including **rules laid down in the EFPIA Codes**;
 - (c) **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 thereunder);
 - (d) 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 the 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.²³

²² 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.

²³ See the Section "Applicability of the Code" in the EFPIA Codes.

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

Procedural Steps

1. 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 the EFPIA, in writing, providing details of its actions and the Member Company's response;
2. 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 the EFPIA's request;
3. If the EFPIA Member Company still does not agree to respond to the EFPIA's request to confirm its adherence to applicable national codes (including submission to the national sanction system), the Board will be informed;
4. 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 regarding 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.

Procedural Steps

1. When the EFPIA establishes that a Member Association does not have the required national procedures and body in place to receive and process complaints, it shares the elements on which its assessment is based with the Member Association, with a request to provide a written explanation within 30 days.
2. If the EFPIA maintains its view that the Member Association's arrangements for the implementation of its code are inconsistent with those required by the EFPIA Codes, the EFPIA will refer to the Codes Committee that will hear the Member Association at its next upcoming meeting.
3. 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 the implementation of proposed measures (which should not exceed 3 months).
4. 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 the EFPIA for the clarification of Code provisions

The EFPIA Codes set out the minimum standards which the 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 the 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 the EFPIA, the Compliance Officer will provide clarification of the provisions of the EFPIA Codes, which are minimum standards that must apply in all countries where the 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 that are 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 adjudication bodies.

When questions are submitted about the EFPIA Codes, the EFPIA will provide clarification, and – where applicable – may revert to the Member Association(s) concerned.

Procedural Steps

1. EFPIA will acknowledge the receipt of a question submitted by a Member (either a company or an association) within 10 days;
2. When an EFPIA Member submits a question that goes beyond the factual clarification of an EFPIA Code provision, the 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 supplement the prepared answer. It is expected that input from Codes Committee Chairs and Member Associations will not delay the EFPIA's response beyond 1 month following the date of the question;
3. Where the Codes Committee Chairs consider that the question must be submitted to the full Codes Committee, the 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;

4. The answers concerning the interpretation of the codes in a broader sense are summarised and published in the annual report on the implementation and application of the codes. They can serve as a basis for a recommendation on EFPIA guidelines to be submitted to the Management Board for approval, and thus contribute to the consistent implementation of the EFPIA codes.

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

DISCLOSURE “GATEWAY” ON MEMBER ASSOCIATION WEBSITES

Background

In the application of the EFPIA Disclosure Code, ToVs to HCPs/HCOs are published in line with applicable laws and regulations using one of the following forms. Information can be disclosed:

- on the websites of Member Companies;
- through an Associations platform operating as a “gateway” to individual company websites;
- on a platform set up by stakeholders;
- on a government platform.

Following disclosure in 2016, media have criticised poor access to the data, denouncing a lack of transparency. On 14 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 following months, Correctiv provided access to a similar database for Switzerland and Austria.

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

In view of this trend, the Management Board supported the Code Committee's proposal to take appropriate measures to ensure full transparency. It is essential that the pharmaceutical industry maintains its initiative in the field of disclosure.

Relevant EFPIA Disclosure Code provisions

2.04. Form of Disclosure

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

- (i) on the relevant Member Company’s website in accordance with Section 2.05.; or
- (ii) 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, as far as possible, using a structure set forth in Annex 2 of this Code.

Recommendations

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 the information disclosed.

Each Member Association will frame the “Gateway” in consideration of the national context and in line with the application of 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 a recommendation aiming at improving transparency and openness.

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

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

2 We act with INTEGRITY, therefore we:

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

3 We treat all stakeholders with RESPECT, which is why we:

- Are conscious of the importance of providing accurate, fair and objective information about medicinal products so that rational decisions can be made about their appropriate use
- Support the independence of the prescribing decisions of HCPs
- Assure mutual respect and independence, in terms of political judgement, policies and activities, in all partnerships with patient organisations
- Promote an attitude and environment of mutual regard for other stakeholders, taking differences in cultures, views and work styles into account

4 Our activities are OPEN, which is why we:

- Share clinical trial data in a responsible way
- Publish details of the ToV made to HCPs and HCOs
- Publish details of financial support and significant non-financial support to patient organisations
- Clearly indicate pharmaceutical company sponsorship of any material relating to medicinal products and their uses
- Disclose activities through other relevant registers (such as the European Institutions' Transparency Register).

ANNEX G
PO Disclosure template

To be developed