Translation from Croatian language

Pursuant to Article 18 of the Statute, General Assembly of the **Innovative Pharmaceutical Initiative** on its session held on **27 February 2023** in Zagreb adopted the following

CODE OF CONDUCT
OF INNOVATIVE PHARMACEUTICAL COMPANIES
in interactions with healthcare professionals, healthcare organizations and patient organizations

Contents

ANNEXES:

DEFINITIONS

The following terms used in this Code shall have the following meanings:

Member Companies	companies and their branch offices and representative offices with registered seat in the Republic of Croatia which are members of the Association which are or may be affiliated with manfuacturers of innovative medicinal products with registered seat outside the Republic of Croatia. For the purposes of this Code, Member Companies which are members of the Association and their affiliates shall be deemed to constitute a single entity to which this Code i.e. EFPIA codes apply.
Donation	support with no counter-obligation on the part of the Recipient. Donation means, generally, disbursements in cash or in-kind (e.g. in assets or services) provided by Member Company for the purpose of supporting healthcare, scientific research or education.
EFPIA	European Federation of Pharmaceutical Industries and Associations, representative body of the research-oriented pharmaceutical industry in Europe.
Hospitality	permitted costs related to participation of Healthcare Professionals in Events i.e. travel, meal (food and beverages), accommodation and participation fee.
Reporting Period	one calendar year relevant for disclosure of Transfer of Value.
Code	valid Code of Conduct of Innovative Pharmaceutical Companies in Interactions with Healthcare Professionals, Healthcare Organizations and Patient Organizations.
Medicinal Product	any substance or combination of substances presented as having properties for curing or preventing disease in human beings and any substance or combination of substances which may be used or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis.
International Event	Event (as defined hereunder) being organised and taking place outside the territory of the Republic of Croatia or on the territory of the Republic of Croatia provided that participants or organizers of such Event are international.
Venue	logistic place where the Event or International Event is organized (e.g. hotel, congress center).
Non-interventional study	a study where the Medicinal Product is prescribed in the usual manner in accordance with the terms of the marketing authorisation. The

	assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of Medicinal Product is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological method shall be used for the analysis of the collected data.
Promotion	any activity undertaken, organised or sponsored by Member Company or, with its authority, any Third Party which promotes prescription, supply, sale, administration, recommendation or consumption of the prescription-only Medicinal Product of the respective Member Company, irrespective of the form and media in which such activity is performed.
Personal Health Data	any information related to the physical and mental health or to the inherited or acquired genetic characteristics of a natural person, including the provision of health care services, which reveal information about his or her physiology or health status.
Item of Medical Utility	constitutes small and inexpensive item aimed directly at the education of Healthcare Professionals enhancing the provision of medical services and patient care, related to the Healthcare Professional's medical practice and that do not offset routine business practices of the Healthcare Professionals.
Patient Organization Representative	legal representative of Patient Organization and person who has been empowered by the Patient Organization for expressing collective views of the Patient Organization on issues related to specific issues or diseases.
Recipient	Healthcare Professional and Healthcare Organisation and Patient Organizations (as defined hereunder).
Transfer of Value	direct or indirect transfer of monetary (e.g. in cash, in kind) or non-monetary value (e.g. in services, in rights and any other benefits), made for the purposes of Promotion or any other purposes in connection with the development and sale of prescription-only Medicinal Products. For the avoidance of doubt: i. direct transfers of value are those made directly by a Member Company for the benefit of the Recipient; ii. indirect transfers of value are those made by Third Parties, acting on behalf of a Member Company, and all transfers of value made through an intermediate providing that the Member Company knows or can identify Healthcare Professional or Healthcare Organisation that will benefit for the transfer of value.
Research and Development Transfer of Value	transfer of value to Healthcare Professional or Healthcare Organisation related to the planning or conduct of following studies (as defined in valid laws, binding regulations of the European union and implementation regulations in the area of manufacturing and

	marketing of Medicinal Products, clinical studies and good clinical practice and good laboratory practice): (i) non-clinical studies, (ii) clinical studies or (iii) non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, Healthcare Professionals specifically for the study.
Event	promotional, scientific or professional meetings, congresses, conferences, symposia, smaller business meetings and other similar events, including but not limited to advisory board meetings, visits to research or manufacturing facilities and planning, training or investigator meetings for clinical trials and non-interventional studies organised or sponsored by a Member Company or by a Third Party on behalf of a Member Company.
Sponsorship	support with counter-obligation on the part of the Recipient who organises the sponsored activity (e.g. project, Event or similar). Sponsorship means, generally, contribution in cash or in-kind provided by Member Company for the purpose of supporting Recipient's activity permitted by law by receiving, in return, the right to promote the product or services of the Member Company or other form of public presentation.
Medical Representative	persons engaged on activities of promotion of Medicinal Products including personnel retained by Member Companies for performance of such activities.
Contributions to Event-related Costs	payment of Hospitality to support the attendance of an individual Healthcare Professional or Patient Organization Representative to an Event, in accordance with Art. 13 (*Sponsoring Healthcare Professionals to Attend Events*)
Lifelong Learning in healthcare	non-promotional education related to human health and diseases.
Third Party	legal or natural person who represents a Member Company and, on behalf of the Member Company or in relation to Medicinal Product promoted by such Member Company, interacts with third parties such as, e.g.: distributors, wholesalers, consultants, contract research organizations, service providers (e.g. market research agencies, promotional services, Event organizers, public relation agencies, advertising agencies, research and development-related services and similar).
Association	Innovative Pharmaceutical Iniciative as representative body of manufacturers of innovative Medicinal Products doint business in the Republic of Croatia via Member Companies.
Patient Organization	non-for-profit legal person (including the umbrella organisation to which it belongs) which business address, place of incorporation or primary place of operation is in the Republic of Croatia, mainly composed of patients and/or caregivers, that represents and/or

supports the needs of their members.

Medical Sample has the meaning set forth in Art. 21 (Distribution of Medical Samples) of this Code.

Healthcare Professional member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities and in line with applicable laws, may prescribe, purchase, supply, recommend or administer a Medicinal Product and whose primary practice, principal professional address is in the Republic of Croatia or other EU member-state. For the avoidance of doubt, the definition of Healthcare Professional includes:

(i) any official or employee of a government agency or other organization (whether in the public or private sector) that may prescribe, purchase, supply or administer Medicinal Products and
(ii) any employee of a Member Company whose primary occupation is that of a practicing Healthcare Professional and
(iii) handicrafts owned by Healthcare Professionals and members of their families within the meaning of the Law on Prevention of Conflict of Interest[1].

The following persons shall not be deemed as Healthcare Professional under this definition: all other employees of a Member Company and a wholesaler or distributor of Medicinal Products.

Healthcare Organisation means:

a. legal person with registered seat in the Republic of Croatia established and acting under valid Law on Health Protection, Law on Mandatory Health Insurance, Law on Mandatory Insurance of Occupational Health, Law on Institutions, Company Law, Concessions Law and other laws providing for rules of performance of healthcare activities in the Republic of Croatia.
b. legal person of healthcare sector (e.g. medicinal, dental, pharmaceutical-biochemical and similar) engaged in teaching, research or scientific activities;
c. professional organisations of Healthcare Professionals established under mandatory provisions of the laws on medical professions;
d. associations, foundations and other forms of voluntary participation of Healthcare Professionals for the purpose of accomplishment of particular interests (except Patient Organisations, as defined under this Code),
e. legal entities owned by Health Professionals and member of

[1] A spouse, in a marital or non-marital union with the Healthcare Professional, lifelong partner and non-formal life partner, blood relatives in vertical hereditary line, brothers and sisters and adoptive parent or adoptee of the Healthcare Professional

their families in the sense of the Law on Prevention of Conflict of Interest;

f. and other legal forms employing or otherwise engaging Healthcare Professionals and/or legal forms that can be used as vehicle for rendering services by one or more Healthcare Professionals.

Scientific Service scientific service established within the structure of each Pharmaceutical Company in charge of information about its Medicinal Products, approval of activities mentioned in this Code and supervision of Non-interventional Studies of Medicinal Products, approval of promotional materials / activities, organisation and management of non-promotional events, medical training of Medical Representatives and other employees who call on Healthcare Professionals.

PREAMBLE

The Association Innovative Pharmaceutical Initiative is the representative body of research-based manufacturers of Medicinal Products doing business in the Republic of Croatia through Member Companies. The Association is member of EFPIA, representative body of the research-based pharmaceutical industry in Europe. Most of the member companies of EFPIA conduct their activities in the Republic of Croatia through membership of their affiliates i.e. Member Companies in this Association.

Goals and activities of the Association are determined by its Statute and the mission of the Association is to support and promote the technological and economic development of research-based pharmaceutical industry acting in the territory of the Republic of Croatia by discovering, developing and marketing new Medicinal Products for the purposes of improvement of quality of human health and healthcare system in general.

Ethical conduct in promotion of Medicinal Products is crucial for accomplishment of such mission since providing of objective, accurate and scientifically supported information on Medicinal Products to Healthcare Professionals constitutes condition precedent for passing of rational decisions in prescribing of Medicinal Products to patients.

Adopting this Code the Association wishes to set forth transparent and clear rules and procedures applicable to its Member Companies in promotion of Medicinal Products to Healthcare Professionals in a manner which would ensure, to the largest extent possible, professional and ethical conduct, as well as transparency in practices for the purpose of accomplishment of rational pharmacotherapy and ensuring of quality, patient-oriented health protection targeted at the benefit of patients in the Republic of Croatia.

Interactions between the pharmaceutical industry and Healthcare Professionals have a profound and positive influence on the quality of patient treatment based on orientation towards patients and their needs, but also the value of future research. At the same time, the integrity of the decision of a Healthcare Professionals to prescribe a Medicinal Product, including pharmacotherapy decisions, is one of the pillars of the healthcare system. The aim of this Code is, among other, to remove doubts on the potential for conflicts of interest in interactions between the industry and Healthcare Professionals wishing to ensure appropriate public disclosure of such interactions to meet not only requirements of transparency and reinforcement of the integrity of all participants in such interactions but also to provide objectivity in assessing the existence of inappropriate influence or potential conflict of interest.

In that context, the Association supports conclusions contained in the document accepted, among other signatories, by EFPIA, titled a „***List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector***“, hereinafter: **the Guiding Principles**). In line with these Guiding Principles and EFPIA decisions on their implementation, this Code includes the rules on disclosure of data regarding the nature and scope of the interactions between pharmaceutical industry and Healthcare Professionals and Healthcare Organisations with the goal of contributing to the confidence of stakeholders in the pharmaceutical industry.

The Association encourages competition among Member Companies. Therefore, the purpose of this Code is not to restrain or interfere with the promotion of the Medicinal Products conducted in line with good business practice and which does not represent unfair competition. The purpose of this Code in to ensure that Members Companies conduct promotion of Medicinal Products in a fair and responsible manner, avoiding deceptive practices and potential conflicts of

interest with Healthcare Professionals, to act always in compliance with applicable Croatian laws and regulations, observing political and social environment in which they are performing their business. The Code thereby aims to foster an environment where the general public can be confident that choices regarding their Medicinal Product by the Healthcare Professional are being made on the bases of the merits of each product and the healthcare needs of each patient.

In this sense, Member Companies recognize the fact of sharing common interests between pharmaceutical industry and Patient Organizations in health- and social-care.

In our conduct, we are committed 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 will ultimately benefit patients. Our primary contribution to society is to make high quality medicinal products and to encourage their appropriate and rational use in the care pathway.
- We act with INTEGRITY, interact in a responsible manner and aim to ensure that our communications with stakeholders are accurate, legitimate and balanced. We are accountable for our decisions, actions and interactions and we encourage others to follow the same high ethical standards.
- We interact with all our stakeholders with RESPECT. We commit to approach our stakeholders in an open manner, with a responsive, constructive and learning attitude and mutual respect. We value the importance of independent decision making by stakeholders, based on evidence and including patient interest. With respect to society, we listen to what is expected from us and adapt our way of working accordingly. We act in compliance with laws and make ethical decisions in personal data processing.
- We are committed to ensure that TRANSPARENCY is respected. We are open about our activities and interactions and encourage stakeholders to act with the same openness.

SECTION 1: GENERAL PROVISIONS

Article 1: Scope

1. This Code applies to:
   a. the promotion of prescription-only Medicinal Products to Healthcare Professionals in the Republic of Croatia.
   b. interactions between Member Companies and Healthcare Professionals, Healthcare Organizations and Patient Organizations;
   c. the disclosures regarding transfers value - monetary (e.g. in cash, in-kind) or non-monetary (e.g. in services, in rights and otherwise) – made by Member Companies for the benefit of Healthcare Professionals, Healthcare Organisations and Patient Organizations
   d. procedural requirements applicable to breach of this Code.

2. This Code **DOES NOT APPLY TO**:
   a. the activities of providing information to the public on Medicinal Products within the meaning of the valid Law on Medicinal Products and by-laws providing for manner of rendering of information on Medicinal Products,
   b. to the following activities:
      - statutory labelling of Medicinal Products and accompanying package leaflets which are subject to the approval of competent authorities for issuance of marketing authorisations,
      - correspondence that may be supported with non-promotional materials provided in response to individual enquiries on particular Medicinal Product,
      - true, informative announcements and reference material relating to authorised Medicinal Products e.g. package changes, adverse reaction warnings, trade catalogues and price lists, provided they include no product claims,
      - non-promotional information relating to human health or diseases,
      - activities which relate solely to non-prescription Medicinal Products,
      - non-promotional, general information about Member Companies (such as information directed to investors or to current/prospective employees), including financial data, description of research and development programmes and discussion of regulatory developments affecting a Member Company and its product.

3. All Members Companies shall primarily adhere to the valid Croatian legislation providing rules on advertising of Medicinal Products having precedence before this Code in all dubious cases of interpretation or application. In addition to the valid laws of the Republic of Croatia, this Code has been prepared in accordance with the principles established in the following regulations:

- IFPMA Code of Pharmaceutical Marketing Practices, 2019 revision of International Federation of Pharmaceutical Manufacturers Association, effective from 1 January 2019 and its subsequent amendments.
- EFPIA Code of Practice ratified by EFPIA General Assembly on 27 June 2019 and its subsequent amendments.
- Directive 2001/83/EC and 2004/27/EC on the Community Code Relating to Medicinal Products for Human Use, as amended by Directive 2004/27/EC, ECJ No. L 311/67, 136/34 and its subsequent amendments.

4. Member Companies must comply with this Code, also in the event where they engage Third Parties on behalf of the Member Companies to perform activities of creation, implementation or undertaking of activities defined in this Code.

5. The following binding documents are attached to this Code, representing its integral part:

Annex A:	**Standardized disclosure template**
Annex B:	**EFPIA Guidance on disclosure of non-interventional studies and disclosure of indirect transfers of values through third parties**
Annex C:	**EFPIA Guidance obligations for member Associations under EFPIA Code**
Annex D:	**EFPIA Standard Operating Procedure related to processing of complaints and questions submitted to EFPIA**
Annex E:	**EFPIA e4ethics rules and procedures**

SECTION 2: GENERAL PRINCIPLES OF PROMOTION

Article 2: Marketing authorisation

1. It is prohibited to promote:
- Medicinal Product, which is not granted with marketing authorisation, and
- indication not covered by the marketing authorisation.

2. Prohibition from the previous paragraph will not apply to rendering information on unlicensed Medicinal Product at professional and scientific meetings and professional journals, subject to following requirements: that the marketing authorisation process for such Medicinal Product is pending, that only international non-proprietary name for the Medicinal Product is used, without mentioning Medicinal Product manufacturer. These limitations are not applicable to International Events held in the Republic of Croatia.

3. Where request for information is made by the Healthcare Professional regarding unlicensed products/indications, the Pharmaceutical Company must refer the inquiry to the Medical Department.

Article 3: Information to be made available.

1. Promotion of Medicinal Product and all promotional material must be consistent with the information given in the approved summary of product characteristics and the instructions for use in the Republic of Croatia.

2. Providing that such form of promotion is compliant with applicable regulations on advertising of Medicinal Products in the Republic of Croatia, the requirements of previous paragraph need not be complied if an advertisement is intended as the reminder, provided that reminder includes, minimum, the name of the Medicinal Product or its international non-proprietary name (INN) and / or the Medicinal Product manufacturer's or Member Company name, as well as trademark(s) or possible other forms of protection of visual identity of the Medicinal Product and/or Medicinal Product manufactuer.

3. Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the Healthcare Professional to form his or 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 scientific evidence and reflect that evidence clearly. Promotion must no mislead by distortion, exaggeration, undue emphasis, omission or in any other way.

4. Promotion must encourage 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.

5. Where following materials are used in promotional materials the following information must be included:
- **published studies** – clear reference to precise source should be given;
- **quotations from medical and scientific literature or form personal communication** – must be faithfully reproduced (except where adaptation or modification is required in order to comply with any applicable legislation or code, in which case it must be clearly

stated that the quotation has been adapted and/modified) and the precise sources identified;

- **artwork**, **including graphs, illustrations, photographs and tables taken from published studies** – must conform to the following requirements:
    a. clearly indicate the precise source of the artwork;
    b. be faithfully reproduced; and in case of any modification or adaptation it must be clearly stated that the artwork has been adapted and/or modified;
    c. must not mislead about the nature of the Medicinal Product (e.g. whether it is appropriate for use in children) or mislead about a claim or comparison (e.g. by using incomplete or statistically irrelevant information or unusual scales)

6. Any comparison between different Medicinal Products must rely on relevant and comparable product characteristics. All forms of false advertising are prohibited, within the meaning of the Law on Prohibited Advertising and its subsequent amendments.

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

8. The word "**new**" must not be used to describe any Medicinal Product or any indication which has been generally available and promoted on the market of the Republic of Croatia for more than one (1) year.

9. Claim "**first choice, first line product**" for a specific indication may be used only on the basis of written guidelines (consensus or recommendation) issued by a relevant Croatian association of specialists and, in case Croatian guidelines do not exist, guidelines of the European or world associations of which Croatian professional associations are members shall apply.

10. It is prohibited to claim that Medicinal Product has no side effect, toxic hazards or risks of addiction or dependency.

Article 4: Documentation

1. Promotion must be capable of substantiation, which must be promptly provided in response to reasonable requests from Healthcare Professionals. Substantiation need not be provided, however, in relation to the validity of elements approved in the marketing authorisation of the specific Medicinal Product.

2. Claims about side effects must reflect available evidence or be capable of substantiation by clinical experience. Substantiation requirement need not be fulfilled in relation to validity of elements approved in the marketing authorisation of the specific Medicinal Product.

Article 5: Acceptability of Promotion

Member Companies must maintain high ethical standards at all times. Promotion therefore must:

a. never be such as to bring discredit upon or reduce confidence in pharmaceutical industry;
b. always be of a nature which recognises the special nature of Medicinal Products and the

professional standing of the recipients;
c. not be likely to cause offence.

Article 6: Distribution of promotional materials

1. Promotion of Medicinal Products may only be directed to Healthcare Professionals.

2. Mailing lists of Healthcare Professionals must be kept up to date. Requests by Healthcare Professionals to be removed from promotional mailing lists must be immediately complied with.

3. The use of faxes, telephones, electronic mail and other electronic data communication is prohibited except with the prior permission of the Healthcare Professional.

Article 7: Transparency of Promotion

1. Promotion must not be disguised.

2. Clinical and Non-interventional studies (including those that are retrospective in nature) and market researches must not be disguised Promotion. Such studies and assessments must be conducted with a primarily scientific or educational purpose.

3.Where a Member Company pays for or otherwise secures or arranges, directly or via Third Parties, the publication of promotional materials in journals, such promotional material must not resemble independent editorial matter.

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

Article 8: Promotion towards the public

1. Promotion of prescription-only Medicinal Products to the public is prohibited.

2. In case of requests of individual members of the general public for advice on personal medical matters, the inquirer should be advised to consult a Healthcare Professional.

Article 9: Use of Internet in Promotion

1. **Transparency of web site origin, content and purpose.** Each website shall clearly identify:
- the identity and physical and electronic addresses of the sponsor of the website;
- the source of all information included on the website, the date of publication of the source and the identity of credentials (including the date credentials were received) of all individual/institutional providers of information included on the website;
- the procedure followed in selecting the content included on the website;
- the target audience of the website (Healthcare Professionals, patient and general public or a combination thereof); and
- the purpose or objective of the website.

2. **Content of website.** Information included in the website shall be regularly updated and shall clearly display, for each page and/item, as applicable, the most recent date as of which such

information was updated.

Examples of information that may be included in a single website or multiple website are:

a) **general information of the Pharmaceutical Company** – information that would be of interest to investors, the news media and the general public, including financial data, descriptions of research and development programmes, discussion of regulatory developments affecting the company and its products, information for perspective employees etc. The content of this information is not regulated by this Code or provisions of medicines advertising law.
b) **health education information** – non-promotional information about the characteristics of disease, methods of prevention and treatments, as well as other information intended to promote public health. They may refer to Medicinal Products, provided that the discussion is balanced and accurate. Relevant information may be given about alternative treatments included, where appropriate, surgery, diet, behavioural change and other intervention that do not require use of Medicinal Products. Websites containing health education information must always advise persons to consult a Healthcare Professional for further information.
c) **information intended for Healthcare Professionals including promotional information** – information directed to Healthcare Professionals that constitutes promotion as well as their content and format must comply with this Code and valid laws of the Republic of Croatia on promotion of Medicinal Products towards Healthcare Professionals. Such information must be clearly identified as information for Healthcare Professionals.
d) **non-promotional information for patients and the general public** – websites may include non-promotional information for patients and the general public on Medicinal Products (including information on their indications, side-effects, interactions with other Medicinal Products, proper use, reports of clinical research, etc.), provided that such information is balanced, accurate and consistent with the approved summary of product characteristics. For each Medicinal Product that is discussed, the website must contain full, unedited copies of the current summary of product characteristics and patient leaflet. These documents should be posted in conjunction with other information about the Medicinal Product or be connected with that discussion by a prominent link advising the reader to consult them. In addition, the website may provide a link to the full, unedited copy of any public assessment report issued by Croatian Agency for Medicinal Products and Medicinal Devices or other competent authority. Brand names must be accompanied by international non-proprietary names. The website may include links to other websites containing reliable information on Medicinal Products, including websites maintained by government authorities, medical research bodies, Patient Organizations, etc. The website must always advise persons to consult a healthcare professional for further information.

3. **E-mail enquiries.** Websites may invite electronic mail communication from Healthcare Professionals and the general public seeking further information regarding the Medicinal Products or other matters (e.g. feedback regarding the website). The Member Company may reply to such communication in the same manner as it would reply to inquiries received by post, telephone or other media. In communication with patients and members of the general public discussion of personal medical matters must be avoided. If personal medical information is revealed, it must be held in confidence. Where appropriate, replies shall recommend that a Healthcare Professional be consulted for further information.

4. **Links from other websites.** Links may be established to accompany sponsored websites from websites sponsored by other persons but Member Company should not establish links

from websites designed for general public to Member Company-sponsored websites that are designed for Healthcare Professionals. In the same manner links may be established to separate websites sponsored by the Member Company or by other persons. Links should ordinarily be made to the homepage of a website or otherwise managed so the reader is aware of the identity of the website.

5. **Websites addresses in packaging.** Subject to any applicable laws and regulations, uniform recourse locators (URLs) of Member Company sponsored websites that comply with these guidelines may be included in packaging of medicinal products.

6. **Scientific review.** Member Companies should ensure that their Scientific Service or appropriately educated Third Party review beforehand the accuracy and compliance of scientific and medical information intended for publication on the website with this Code and applicable Croatian regulations.

7. **Privacy.** The website must conform to legislation and applicable codes of conduct governing the data privacy, security and confidentiality of personal data.

SECTION 3: INTERACTIONS WITH HEALTHCARE PROFESSIONALS, HEALTHCARE ORGANISATIONS AND PATIENT ORGANIZATIONS

Article 10: Events

1. All Events organised or sponsored by a Member Company or by a Third Party on behalf of Member Company must be held in an appropriate Venue that is conductive to the main purpose of the Event and may offer Hospitality only following criteria stated in Article 11. (*Hospitality*) of this Code and binding **Annex C**.

For the purpose of this Code **appropriate Venue** of the Event and Internation Event held in the Republic of Croatia shall be a separate, dedicated conference center or – if such conference center is integrated into accommodation facility classified as hotel – a hotel that fulfils criteria provided in a binding **Annex C**, which shall in no event be recognized or renowned for leisure and extravagance.

The binding **Annex C** of this Cose provides for guidelines on definitions of terms "*appropriate*", "*renowned*" and "*extravagant*" in the context of the former provision.

In all cases of doubt on appropriateness of the particular Venue, Association's Management Board will have the power of interpretation.

2. The main purpose of the Event must be exchange of educational, professional or scientific information, whereas promotional and all other contents must be auxiliary in relation to the main purpose of the Event. To that extent, the scientific/educational contents must be prevailing.

3. It is prohibited to organise or sponsor International Events except in the following cases:
   (a) unless most of the invitees are from third countries, and given the country of origin of most of the invitees, it makes greater logistical sense to hold the Event outside Croatia,
   (b) unless, given the location of the relevant source or expertise that is the object or subject matter of the Event, it makes greater logistical sense to hold the Event outside Croatia.

4. In the event of organisation of International Events in Croatia or abroad, promotional materials of the Member Company exhibited on temporary exhibition stands at the Venue of the Event aimed at distribution to participants of the Event may refer to Medicinal Products (or uses) which are not registered in the country where the Event takes place providing that:
   a. any such promotional material is accompanied by a suitable statement indicating countries in which the Medicinal Product is registered and makes clear that the Medicinal Product or use is not registered in the country of the Event; and
   b. any such promotional material which refers to the prescribing information (indications, warning etc.) authorised in countries where the Medicinal Product is registered should be accompanied by an explanatory statement indication that registration conditions differ internationally.

5. When Events are (co)sponsored by a Member Company, that fact must be disclosed in all documents relating to the Event and in all published literature and other written materials. The declaration of sponsorship must be visibly displayed on all materials and Venues of the Event.

Article 11. Hospitality

Member Companies must comply with the following criteria when offering Hospitality:

a. Hospitality can be provided only to Healthcare Professional, member of a Healthcare Organization and the Patient Organization Representative being participant in Event, whether passive, sponsored to attend the Event within the meaning of Article 13 (*Sponsoring Event Attendance*) or active, engaged in accordance with Art. 16.1. (*Services of Healthcare Professionals*) of this Code. In exceptional cases of established health needs (e.g. disability or injury), the travel, meals, accommodation and genuine registration fee costs of an accompanying person can be reimbursed within the same criteria.
b. costs of Hospitality must be equal to their actual value, as invoiced by suppliers, and Member Companies should follow the following basic rules when arranging Hospitality:
    1. travel expenses may be paid only for economy class air travel and only exceptionally in business class providing that the flight in one direction from the place of residence of the participant of the Event to the venue exceeds 4 hours in continuity,
    2. choice of accommodation in the Venue of the Event shall be primarily made between accommodation facilities the quality of which is defined as appropriate Venue in line with Art. 10. para 1 (*Events*) of this Code;
    3. costs of accommodation may only be paid where it is necessary with regard to the length of the Event (for one overnight stay the minimum duration of the Event should be 5 hours) or the time of beginning and ending of the Event (e.g. morning and evening Events) as well as in cases where the distance between the place of residence of the participant and the Venue of the Event exceeds 50 km.
    4. Costs of meals:
        - must be limited to refreshments and/or meals during the Event, and
        - must be of moderate value amounting to maximum amount as determined in the binding **Annex C**.

    In case of International Events, the maximum value of meals set in the country where the respective Event takes place (i.e. the "host country") shall prevail.

c. It is prohibited to organise and sponsor events of entertaining or social character during the Event and activities related to leisure, except entertainment of a modest nature during breaks for refreshments and/or meals.

Article 12: Prohibition of Gifts

No gift may be supplied, offered or promised to a Healthcare Professionals, Healthcare Organizations or Patient Organiziation Representatives (directly or indirectly) For the purpose of this Code, a gift is defined as payment in money, in-kind irrespective to value, in rights, services and other benefits in kind provided to Recipients free of charge (e.g. promotional items which are not Items of Medical Utility).

Article 13: Sponsoring Event attendance

Member Companies may sponsor Healthcare Professionals and Patient Organization Representatives to attend Events and International Events at the cost of the Member Company, irrespective whether the Member Company is (co)sponsor of such Event or not, providing that the following criteria are met:

a. funding must not be offered to Event participant to compensate merely for time spent in attending the Event;
b. sponsoring Event attendance must not be provided in exchange for recommending, prescribing, purchasing, supplying, selling or administering Medicinal Product;
c. in the case of International Events, the legality of all payments provided by Member Companies to Healthcare Professionals and Patient Organization Representatives shall be subject to the rules of the jurisdiction where such Event participant carries out his or her profession, as opposed to those in which the International Event takes place;
d. Hospitality in line with the Art. 11. (*Hospitality*) of this Code may be provided. In case of International Meetings, any Hospitality extended shall be made in accordance with the rules of the jurisdiction in which the International Events takes place.

Article 14: Use of logo and proprietary materials and ensuring visibility

1. The public use of an Healthcare Organization's or Patient Organization´s logo and/or proprietary material by a Member Company requires written permission from the respective organisation. In seeking such permission, Member Company must clearly state the specific purpose and the way the logo and/or proprietary material will be used.

2. Member Companies must ensure that information on their sponsorship to Healthcare Organizations and Patient Organizations is always clearly acknowledged and apparent from the outset.

Article 15: Donations to Healthcare Organizations

1. Donations to Healthcare Organisations are only allowed if following criteria are cumulatively fulfilled:
a. that Donations are made for the purpose of supporting healthcare or research, and
b. that Donations are documented in written form providing that the parties preserve the documentation related to the transactions, and
c. that Donations do not constitute counter-obligation for Healthcare Organisation and an inducement to recommend, prescribe, purchase, supply, sell or administer a specific Medicinal Product, and
d. that all approvals of competent state authorities, if such approvals are required under applicable legislation of the Republic of Croatia, are provided.

2. Member Companies are encouraged to make available publicly information about Donations made by them to Healthcare Organisations.

3. Donations to individual Healthcare Professionals employed with Healthcare Organizations under this provision are prohibited. Those Healthcare Professionals may be sponsored by Member Company to attend Event under conditions provided under Article 13. (*Sponsoring Event attendance)* of this Code.

Article 16: Contracted Services

16.1. Services of Healthcare Professionals

1. Member Companies are allowed to engage Healthcare Professionals, whether in groups or individually, for performance of the following types of services: speaking at and chairing Events, involvement in medical/scientific studies, clinical trials or training services, participation in advisory board meetings and participation in market research where such participation involves remuneration and/or travel. The arrangements that cover these services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

a. the services are provided for the purpose of supporting healthcare and research;
b. legitimate business interests of the Member Company for certain service from the potential service provider must be determined in advance;
c. a written agreement agreed in advance of the commencement of the service which specifies the nature of the services to be provided and the basis for payment of those services;
d. the criteria for selecting service provider are directly related to the identified need for the particular service and the persons responsible for selecting the service providers have the expertise necessary to evaluate whether the particular Healthcare Professional meets those criteria;
e. the number of Healthcare Professionals retained is not greater than the number reasonably necessary to achieve the identified need;
f. the contracting Member Company maintains records concerning and makes appropriate use thereof;
g. the hiring of the Healthcare Professional to provide the relevant service is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular Medicinal Product, and
h. the compensation for the services is reasonable and reflects the fair market value of the services provided. In this regard, consultancy arrangements should not be used to justify compensating Healthcare Professionals.

2. Limited participation of Healthcare Professionals in market research activities, such as replying to questionnaires of market-research agencies (via phone, regular or electronic mail, Internet and the like) are excluded from the scope of this Article 16.1 of this Code provided that the remuneration payable to Healthcare Professional does not exceed the value threshold defined in binding **Annex C**.

3. If a Healthcare Professional attends an Event (International or other) in advisory capacity or as service provider the relevant provisions of Article 10 (*Events*) and Article 11 (*Hospitality*) of this Code shall apply.

4. Association strongly encourages Member Companies to include provisions in their written contracts with Healthcare Professionals - irrespective to the employment status of the Healthcare Professional (employed on full time basis with the Healthcare Organization or on a part-time basis with other employer, if (s)he still practices her/his profession in the remaining working hours) - regarding the obligation of the Healthcare Professional to declare that he/she is engaged by the particular Member Company whenever he/she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that Member Company.

16.2. Services of Healthcare Organisations

Contracts between Member Companies and Healthcare Organisations under which such Healthcare Organisations provide any type of services to Member Companies are only allowed if such services:

- are provided for the purpose of supporting healthcare or research, and
- do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administrate specific Medicinal Product.

16.3. Services of Patient Organizations and Patient Organization Representatives

It is permitted for a Member Company to contract Patient Organizations and Patient Organizations' Representatives as experts and consultants for services such as, e.g. participation at advisory board meetings, speaking at Events, participation in market research activities in which case criteria provided in Art. 16.1. (*Services of Healthcare Professionals*) will apply accordingly.

Article 17: Member Company Funding

1. No Member Company may require that it be the sole funder or sponsor of Patient Organization or Healthcare Organization or any of their programmes.

2. Member Companies welcome broad funding and sponsorship of Patient Organizations and Healthcare Organizations from multiple sources.

SECTION 4: SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH HEALTHCARE PROFESSIONALS, HEALTHCARE ORGANISATIONS AND PATIENT ORGANIZATIONS

Article 18: Lifelong Learning in Healthcare

1. Lifelong Learning in Healthcare is organized and performed with the purpose of increasing the scientific knowledge and professional competence of Healthcare Professionals aimed at enhancing medical practice and treatment outcomes.

2. Member Companies can organize, finance and support different types of Lifelong Learning in Healthcare activities provided that such activities must not constitute Promotion. These activities can be e.g.: 1) independent medical education or education organized and provided by an independent Third Party and funded by the Member Company; 2) programs that are developed in collaboration with another stakeholder; or 3) Lifelong Learning in Healthcare activities organized by Member Companies.

3. When organizing or funding independent Lifelong Learning in Healthcare 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.

4. The contents of Lifelong Learning in Healthcare must must have content that is fair, balanced and objective, designed to allow the expression of diverse evidence-based science and fulfill unmet educational needs in healthcare.

Article 19: Informational or Educational Materials and Items of Medical Utility

1. The transmission of informational or educational materials is permitted, provided that individual gross purchase price of such materials does not exceed modest financial value of gift provided under valid By-law on Manner of Promotion of Medicinal Products and that such materials are relevant to the practice of Healthcare Professionals and Healthcare Organisations and that they are beneficial to the care of patients. The transmission of such materials shall not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a Medicinal Product.

2. Items of medical utility aimed directly at the education of Healthcare Professionals and patient care can be provided if the individual gross purchase price of such materials does not exceed the models financial value of gift provided under valid By-law on Manner of Promotion of Medicinal Products and that such items do not offset routine business and professional practices of the Recipient.

3. The provision of objects stipulated in paragraphs 1 and 2 of this Article may not constitute a circumvention of the prohibition on gifts defined under Art. 12 (*Prohibition of Gifts*) of this Code.

Article 20: Non-interventional studies

1. Non-interventional studies that involve collection of patient data from or on behalf of individual or groups of Healthcare Professionals specifically for the study must comply with all

of the following criteria:

a. the study is conducted with a scientific purpose;
b. there is (i) a written study plan (protocol) and (ii) there are written contracts between Healthcare Professionals and/or the Healthcare Organisations at which the study will take place, on one hand, and the company sponsoring the study, on the other hand, which specify the nature of the services to be provided and subject to clause c) immediately below the basis for payment of those services;
c. any remuneration provided is reasonable and reflects the fair market value of the work performed;
d. Member Companies must provide approval for conducting of Non-interventional studies from the Central Ethics Committee and any other approvals and/or fulfil other requirements as provided by valid legislation of the Republic of Croatia applicable to conduct of Non-interventional studies;
e. rules on personal data privacy must be respected by Member Companies;
f. the study must not constitute an inducement to recommend, prescribe, purchase, supply sell or administer a particular Medicinal Product;
g. the study protocol must be approved and the study must be supervised by the Member Company's Scientific Service (in line with Article 22 of this Code);
h. the study results must be analysed by or on behalf of the sponsor and a summary thereof must be prepared and maintained by the Scientific Service for a reasonable period of time. The Member Company should send summary reports to all Healthcare Professionals that participated in the study and should make the summary report available to industry self-regulatory bodies and/or committees that are in charge of supervising or enforcing of the Code, upon their request; and
i. Medical Representatives may only be involved in administrative capacity and such involvement must be under the supervision of the Scientific Service that will also ensure that the Medical Representatives are adequately trained. Such involvement must not be linked to the promotion of any Medicinal Product.

2. To the extent applicable, Member Companies are encouraged to comply with the criteria stipulated in this Article for all other types of studies including epidemiological studies and other studies that are retrospective in nature. In any case, such studies are subject to Article 16.2 (*Services of Healthcare Organisations*).

Article 21: Medical Samples

1. Free Medical Sample may be given to a Healthcare Professional at her/his written request, to familiarize them with the product but only once per each year, in a maximum quantity of 2 (two) smallest original packages of the product and only in a period of first 2 (two) years from the date of the first request of the Healthcare Professional for providing simple of the particular Medicinal Product, providing that other rules on sampling comprised in applicable Croatian laws are applied. No free Medical Samples shall be supplied as an inducement to recommend, prescribe, purchase, supply, sell or administer a particular Medicinal Product. Free Medical Sample may be given only to a Healthcare Professional who can initiate or prescribe such Medicinal Product.

2. 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 Representatives.

3. Each Medical Sample must be marked "*free Medical Sample – not for sale*" or words to that

effect and must be accompanied by a copy of the summery of product characteristics.

4. No Medical Samples may be supplied for Medicinal Products which contain substances defined as psychotropic or narcotic as determined under applicable legislation of state authorities.

Article 22: Member Company Staff

1. **Medical Representatives**. Each Member Company must ensure:
   a. that its Medical Representatives – including any subcontractors (persons contracted by Member Companies for services) - are familiar with the relevant requirements of this Code, and all applicable laws of the Republic Croatia and are adequately trained and have sufficient scientific knowledge to be able to provide precise and complete information about the Medicinal Products they promote.
   b. That Medical Representatives comply exercise their duties responsibly and ethically.
   c. That Medical Representatives during each visit must give the Healthcare Professional printed or digital version of the latest approved summary of the product characteristics for each Medicinal Product they present or to direct such Healthcare Professional to visit webpage of the Agency for Medicinal Products and Medicinal Devices or European Medicines Agency.
   d. That Medical Sales Representatives must transmit to the Scientific Service of the Member Companies forthwith any information they receive in relation to the use of Medicinal Products, particularly reports of side effects. Medical Representatives must ensure that all off-label inquiries are transferred to Scientific Service for response.
   e. That the frequency, timing and duration of visits made by Medical Representatives to Healthcare Professionals and Healthcare Organizations, together with the manner in which they are made, do not cause daily working routine of visited persons.
   f. That Medical Representatives must not use any inducement or subterfuge to gain an interview with a Healthcare Professional. In an interview, or when seeking an appointment for an interview, Medical 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.

2. **Scientific Service**. All Member Companies must establish a Scientific Service or designate a person responsible for performance of works within the scope of the Scientific Service, taking into account actual organizational and human resources at their disposal. Scientific Service must include at least one medical doctor or a pharmacist and the other employees of Scientific Service must have completed under-graduate and graduate study or integrated under-graduate and graduate university study in the area of biomedicine and healthcare. Scientific Service approves the final form of the promotional material and confirms that it is in accordance with the requirements of this Code or any other applicable advertising law, is consistent with the summary of product characteristics and is fair and truthful presentation of the facts about the Medicinal Product. In addition, Scientific Service is responsible for conduct of Non-interventional studies of the Medicinal Product, including examination of all responsibilities relating to such studies, particularly with respect to any responsibilities assumed by Medical Representatives.

3. **Person responsible for supervision of the adherence to standards under this Code**. Each Member Company must appoint at least one experienced senior employee who shall be responsible for supervising the Member Company to ensure that the standards of this Code or any other codes applicable to a Member Company are met.

SECTION 5: SPECIFIC REQUIREMENTS IN INTERACTIONS WITH PATIENT ORGANIZATIONS

Article 23: Basic principles of cooperation

Cooperation between Member Companies and Patient Organisations must be made in an ethical and transparent manner with full commitment to the following principles:

1. the independence of Patient Organisations in terms of their political judgement, policies and activities shall be assured;
2. mutual respect with the views and decisions of each partner having equal value;
3. prohibition of the Promotion of prescription-only Medicinal Product;
4. transparency of the objective and scope of any partnership with obligation of ensuring clear acknowledging of financial and non-financial support provided by the Member Company.
5. encouraging broad funding of Patient Organisations from multiple sources.

Article 24: Written agreements

1. Member Company and a Patient Organisation must have in place a written agreement when Member Company provides financial support, significant indirect support and/or significant non-financial support to the Patient Organisation. Written agreements must state, minimum:

- the amount of funding,
- the purpose (e.g. unrestricted grant, specific meeting or publication etc.), description of significant indirect support (e.g. donation of public relations donation agencies, time and nature of their involvement) and significant non-financial support.

Article 25: Editorial control

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

SECTION 6: DISCLOSURE OF TRANSFER OF VALUE TO HEALHCARE PROFESSIONALS, HEALTHCARE ORGANIZATIONS AND PATIENT ORGANIZATIONS

Article 26: Disclosure obligation

1. Each Member Company shall document and disclose Transfers of Value it makes, directly or indirectly, to or for the benefit of a Recipient, as described in more detail in Article 28 (*Manner of Disclosure*).

2. Transfers of Value made in exercising of following activities do NOT fall within the scope of the disclosure obligation from previous paragraph:

a. activities of Promotion and rendering information on over-the-counter Medicinal Products;
b. activities not listed in Article 28 (*Manner of Disclosure*) of this Code which includes, e.g. informational or educational materials and Items of Medical Utility governed by Article 19 (*Informational or Educational Materials and Items of Medical Utility),* costs of meals governed by Article 11.b.4 (*Hospitality*) of this Code up to value threshold, purchase costs of Medical Samples governed by Article 21 (*Medical Samples*) of this Code; and
c. activities of ordinary course of purchases and sales of Medicinal Products by and between the Member Companies and Healthcare Professionals (such as pharmacists) and Healthcare Organisations.

Article 27: Dynamics, forms and other requirements regarding disclosures

1. Disclosures of the Transfer of Value must be made on an annual basis and each Reporting Period is a full calendar year.

2. Disclosures shall be made within six (6) months after the end of the relevant Reporting Period and shall be required to remain in the public domain for a minimum of three (3) years after the time such information is first disclosed, unless, in each case, (i) a shorter period is required under applicable national data privacy or other laws or regulations, or (ii) the Recipient's consent relating to a specific disclosure has been revoked. The common reporting period for publication of Transfers of Value to Recipients is set during the time interval from 20th to 30th June each year.

3. For consistency purposes, disclosures pursuant to this Code will be made using a structure set forth in **Annex A** which constitute integral part of this Code and shall be applied on all disclosures in the Republic of Croatia. Possible deviations from this **Annex A** will be acceptable exceptionally, where such deviations are consequence of application of mandatory laws.

4. Disclosures will be made on a central platform, provided by Association's website which is linked to Member Companies websites and on the websites of each Member Company.

5. Disclosures on websites shall be made in Croatian language but may be bi-lingual with English language translations.

6. Disclosures shall be made in the country where the Recipient has its personal or professional residence or seat, irrespective if the Transfer of Value for the benefit of the Recipient was made in the country of Recipient's residency / seat or in a third country.

7. Each Member Company shall document all Transfers of Value required to be disclosed and maintain the relevant records of the disclosures in line with applicable Croatian accountancy record retention laws and keep the relevant records for a minimum of five (5) years after the end of the relevant Reporting Period. The 5-year Transfer of Value document retention timeline shall not apply when mandatory Croatian data privacy laws and other mandatory business document retention laws provide for a shorter or longer periods of document retention.

Article 28: Manner of Disclosure

28.1: Individual disclosure

Except as expressly provided by this Code, Transfers of Value shall be disclosed on an individual basis meaning that the data on Transfers of Value in each Reporting Period made for the benefit of each clearly identifiable Recipient allocated to one of the categories of co-operation set in items A. an B. of this paragraph (28.1.) hereunder will be available. Such Transfers of Value may be aggregated on a category-by-category basis, provided that itemized disclosure shall be made available upon request to (i) the relevant Recipient, and/or (ii) the relevant authorities.

A. **Transfers of Value to an Healthcare Organisation**, includes all payments made in relation to any of the categories set forth below:

(i) Donations governed by Art. 15 (*Donations to Healthcare Organizations*) of this Code;

(ii) costs related to Events paid directly to Healthcare Organisations or third parties, including costs of governed by Art. 14. (*Sponsoring Event attendance*), such as:

a. costs of Hospitality, taking into consideration the exception under Art. 26 para 2 item b. (*Disclosure Obligation*) of this Code;

b. amounts of Sponsorship under agreement between Member Companies and Healthcare Organisations or with Third Party appointed by the Healthcare Organisation to organize the Event in the name and for the account of the Healthcare Organisation;

By this Code the binding Annex B to EFPIA Code: ***Guidelines on Disclosure of Non-interventional Studies and Indirect Transfers of Values through Third Parties*** is made integral part of this Code in a form od **Annex B**.

B. **Transfers of Value to Healthcare Professionals**, includes all payments made in relation to any of the categories set forth below:

(i) costs of Hospitality, taking into consideration the exception under Art. 26. para 2 item b. (*Disclosure Obligation*) of this Code;

(ii) fees for services of Healthcare Professionals governed by Art. 16.1. (*Services of Healthcare Professionals*) para. 1 and 2 (where the identity of the Healthcare Professional participating in market research activities is known to the Member Company) of this Code paid under service contracts with Healthcare Professionals and the amount of any other type of funding not covered in the previous categories. In such case, two separate amounts will be disclosed (a) fees for services and (b) expenses related to performance of respective services, if contracted.

28.2: Aggregate disclosure

1. For Transfers of Value where certain information - which can be otherwise reasonably allocated to one of the categories set forth in the previous paragraph - cannot be disclosed on an individual basis for legal reasons, a Member Company shall disclose such information on an aggregate basis. Such aggregate disclosure shall identify, for each category, (i) the number of Recipients covered by such disclosure, on an absolute basis and as a percentage of all Recipients, and (ii) the aggregate amount attributable to Transfers of Value to such Recipients.

2. Research and Development Transfers of Value in each Reporting Period shall be disclosed on an aggregate basis. Costs related to events that are clearly related to activities of research and development can be included in the aggregate amount under the "*Research and Development Transfers of Value*" category. Appropriate guidelines of binding **Annex B** to this Code will apply to disclosures of Transfers of Value made in the context of Non-interventional Studies.

3. Where a Transfer of Value is made to an individual Healthcare Professional indirectly via a Healthcare Organization, such Transfer of Value shall only be required to be disclosed once, to the extent possible, within the obligation of disclosure on individual basis in the sense of Art. 28.1. (*Individual Disclosure*) item B (*Transfers of Value to Healthcare Professionals*) of this Code.

Article 29: Disclosure of information on cooperation with Patient Organizations

1. Each Member Company must disclose a list of Patient Organizations to which it provides financial support and/or significant indirect/non-financial support or with whom it has engaged to provide contracted services for that Member Company during Reporting Period. Term "significant support" is defined in binding Annex C hereto.

2. This disclosure must include:

- the name of the Patient Organization,
- 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,
- for monetary support: the monetary value of financial support and of invoiced costs,
- for non-monetary support: the description of benefit that the Patient Organization receives when the non-financial support cannot be assigned to a meaningful monetary value.
- for contracted services: the total amount paid per Patient Organization over the Reporting Period.

3. This information must be disclosed on an annual basis on the Member Company website (either on a national (if any) or internationals, at the level of the group with which Member Company is affiliated).

Article 30: Methodology

Each Member Company shall publish a note summarizing the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category described in Art. 28.1.A. (*Transfers of Value to Healthcare Organizations*) and B (*Transfers of Value to Healthcare Professionals*) of this Code. The note shall describe - including a general summary and/or specific

considerations applicable in the Republic of Croatia - the recognition methodologies applied by each Member Company, and should include the treatment of multi-year contracts, tax aspects, currency aspects and other issues related to the timing and amount of Transfers of Value for purposes of this Code.

SECTION 7: ENFORCEMENT

Article 31: Two-instances

Member Companies are aware that the keystone of public confidence in their integrity is their compliance with this Code. Following articles describe the two-intances process which shall be conducted by:

a) **President of the Ethics Committee,** in the first instance,
b) **Ethics Committee** in the second instance, and
c) **Extended Ethics Committee,** only in case provided in Art. 39 para 2. Item d. of this Code.

Article 32: Appointing Ethics Committee

1. **Ethics Committee** has a president and three (3) members: two (2) members from Member Companies representatives in the Association's Task Force Ethics & Compliance and one (1) member being a distinguished Healthcare Professional, appointed from the valid List of External Candidates for Ethics Committee Membership. The List of External Candidates for Ethics Commit tee Membership is adopted by the Management Board biannually.

2. Association's Task Force Ethics & Compliance appoints the head of each matter at hand.

3. In case of complaint against the first instance decision, the President of the Ethics Committee proceeds as follows:

1. appoints two (2) members of the Ethics Committee from Member Companies, by alphabetical or other order, minding the potential conflict of interest of such members with respect to the matter at hand and one (1) member from the List of External Candidates for Ethics Committee Membership,
2. submits report to the Ethics Committee on the subject of the appeal and provides the Ethics Committee with the file, and
3. exempts her-/him-self from the decision-making process related to appeal.

3. **Extended Ethics Committee** is body shall be formed only in case of appeal of the concerned Member Company against the decision of the Ethics Committee defined in Art. 39 para 1 item. d) (*Second instance process – deciding about the appeal*) of this Code. Extended Ethics Committee comprises of five (5) members: three (3) members from Member Companies representatives in Association's Task Force Ethics & Compliance, providing that such members are in no conflict of interest with respect to the matter at hand and two (2) members – distinguished Healthcare Professionals from the List of External Candidates for Ethical Committee Membership.
The President of the Ethics Committee shall within fifteen (15) days from the date of receipt of the appeal against the Ethics Committee defined in Art. 39 para 1 item b) hereunder elect the Extended Ethics Committee who shall render decision on appeal. Decision of the Extended Ethics Committee is final and no remedy is allowed.

Article 33. Filing complaint

1. **Filing right:** All (including the Management Board of the Association) have right of filing complaint in cases of breach of the Code. All complaints received by EFPIA shall be transferred to handling by the Association, in applicationof this Code and EFPIA Standard Operative

Procedures constituting integral part of this Code in a form of **Annex D**.

2. **Acceptance of the complaint:** Complaint may be filed against the Member Company for alleged breaches of the Code only if such breaches occurred after the respective Company's membership in the Association.

3. **Limitation period:** A complaint alleging breach of the Code cannot be filed with respect to all incidents that occurred more than 1 (one) year before the date of filing of the complaint. Absolute limitation period occurs after expiry of 3 (three) years from the date of the breach of the Code.

4. **Form and content of the complaint:** The Code infringement procedure starts by written complaint delivered to the President of Ethics Committee, addressed at the registered address of Association's seat or by e-mail at the address: info@ifi.hr The complaint shall comprise information on:

- the identity of the complainant and the respondent Member Company (company name, business address),
- description of facts leading to the complaint substantiated with evidence in support of the facts stated in the complaint (in a form of original documents or copies thereof) and
- quote of such provision(s) of this Code which are, in the opinion of the complainant, infringed by the respondent Member Company.

5. Anonymous complaints will also be processed, unless the complaints are obviously made with the purpose of abusing of the complaint filing institute set under this Code.

Article 34: Preliminary examination of the complaint

If the complaint has no information on identity of the perpetrator and the description of facts of alleged breach, the President of Ethics Committee shall invite the complainant (if known) in writing to amend the complaint within maximum 15 (fifteen) days from the date of receipt of request for amendment of the complaint. Failure of complainant to adjust the amendment request within given timeline will result in President of Ethics Committee dismissal of complaint on the grounds of incompleteness or taking the matter into consideration, despite the incompleteness of the complaint.

Article 35: First instance process – 1st phase

1. The President of the Ethics Committee may a) reject the complaint as inadmissible if it does not relate to the breaches of the Code or if the complaint, especially anonymous, is obvious abuse of the complaint institute under this Code and b) dismiss the complaint as incomplete if the complaiant fails to cure the deficiencies in the complaint in a timeline provided in Art. 34 of this Code (*Preliminary examination of complaint*).

2. If the complaint is not dismissed, the President of the Ethics Committee shall invite the responding Member Company to submit written response about the circumstances levelled against her within 8 (eight) days from receipt of the complaint.

3. The accused Member Company shall within 15 (fifteen) days from the date of receipt of the summon to file the response, provide the President of the Ethics Committee with written response, addressed at the registered seat of the Association. Written response of the accussed Member Company may comprise signed:

- statement of admittance of breach with obligation of immediate stop of breaching activities or omissions and restraining from activities which may lead to another infringement (hereinafter: **Corrective Statement**);
- statement of denial of the alleged infringement of the Code stating reasons for such position.

4. If the President of the Ethics Committee finds the statement of denial of the alleged breach as justified, (s)he will inform the complainant in written form thereof within 15 (fifteen) days from receipt of the statement of denial and invite the complainant to respond to the standpoint on non-existence of breach within 8 (eight) days from the date of receipt of the invitation of the President of the Ethics Committee.

5. Upon expiry of the deadlines for the response referred to in the preceding paragraphs of this Article, the President of the Ethics Committee carries out the first instance procedure – 2nd part aimed at making a decision on the merits.

Article 36: First instance process – 2nd phase

1. In order to fully establish the facts and answer the question of whether there has been a breach of the Code in the particular case, the President of the Ethics Committee conducts the procedure of determining the facts on the basis of received and collected documentation and decides about necessity of providing subsequent responses from the involved parties and delivering other evidence (e.g. by taking testimonies of the parties, witnesses, making insights into documents etc.).

2. If taking testimonies from the parties or Third Parties is necessary, or on the basis of explicit request of the parties to have a hearing during the procedure (if that is considered relevant), the President of the Ethics Committee will summon the parties and proposed Third Parties for a hearing, defining the date, place and time of the hearing. If a Member Company or a Third Party fails to appear at the hearing without justification, the President of the Ethics Committee can pass the decision without conducting the hearing.

3. The President of the Ethics Committee, in conducting the first-instance proceeding, especially in more complex cases, may use the professional assistance of individuals from Member Companies, minding potential conflict of interest.

4. The President of the Ethics Committee shall carry out the first instance process and pass the decision on the complaint as soon as possible and within 120 (one-hundred-twenty) days, at its latest, from the date of filing of the complaint. Only exceptionally, where the reasons of such extension justify the delay, the timeline defined in this paragraph may be reasonably extended.

Article 37: Decisions of the President of the Ethics Committee

1. President of the Ethics Committee may pass the following decisions:
- decision on rejection of the complaint as unjustified in case it would be established that the subject matter of complaint does not represent a breach of the Code or if there are circumstances which exclude liability of the responding Member Company or if it would be established that she was not committing the breach,
- decision on finding the respondent Member Company guilty for the breach of the Code.

2. Written decision of the President of the Ethics Committee with detailed reasons and mandatory remedy instructions – right of filing appeal shall be delivered to the complainant (if known) and the responding Member Company.

3. If the complainant is not one of the Member Companies, the President of the Ethics Committee shall only provide written notice to the complainant whether the final decision is convicting or the complaint is rejected.

Article 38: Right of appeal

1. The following persons have a right of appeal against the decision of President of the Ethics Committee passed in the first instance:

a) complainant being a Member Company, only in the event of rejection decision as unjustified, and
b) respondent Member Company, only in the event of convicting decision.

In case of convicting decision, complainant's appeal against the decision on sanctions (the type and the scope) is not allowed.

2. Appeal must be filed within 15 (fifteen) days from the date of receipt of written decision of the Ethics Committee. The appeal is filed with the President of the Ethics Committee at the address stated in the appealed decision. The President of the Ethics Committee shall:

- upon confirming that the appeal is filed timely and by authorised appellant, prepare a file of the case for the Ethics Committee competent for the second instance decision,
- in case of late appeal, dismiss the appeal as non admissible.

Article 39: Second instance process – deciding about the appeal

1. If the appeal is filed in time and by authorised appellant, the President of the Ethics Committee delivers the entire file to the Ethics Committee for a further procedure.

2. The Ethics Committee decides on a closed session, and exceptionally, if it considers it useful, may invite the parties and conduct additional hearings and may take the following decisions:

a) reject the appeal as unjustified and uphold the decision of the President of the Ethics Committee,
b) adopt the appeal and abolish the decision of the President of the Ethics Committee, and dismiss the appellant's complaint as inadmissible or rejected as unfounded,
c) adopt the appeal and modify the decision of the President of the Ethics Committee with regard to the decision on sanction,
d) adopt the appellant's complaint and modify the decision of the President of the Ethics Committee rejecting the application as unfounded and declare the Member Company guilty of violation of the Code.

3. The decision of the Ethics Committee is made by the majority of votes, and the President of the Ethics Committee can participate in the work of the Ethics Committee on the appeal as a reporter, without the right to vote.

4. Decision of the Ethics Committee on the appeal is final and no legal remedy is allowed against it, except against the decision of the Ethics Committee referred to in paragraph 2. d) of this Article.

5. In the case of a decision of the Ethics Committee referred to in paragraph 2. d) of this Article, a sentenced Member Company may submit an appeal to be decided by the Extended Ethics Committee referred to in Article 32 para 5 of this Code. The decision of the Extended Ethics Committee is final and no remedy is allowed.

Article 40: Sanctions

1. President of the Ethics Committee, Ethics Committee and the Extended Ethics Committee may impose the following sanctions in their decisions upon finding the respondent Member Company guilty:

A. In case of minor violations of the Code – reprimand,
B. In case of more serious violations of the Code or repetition of violations:

- **fine in maximum amount of EUR 47.000,00.**
- **informing the parent company** i.e. founder of the guilty Member Company about the legally valid decision of the Association by which such Member Company was found guilty for the breach of the Code;
- **publication of the convicting decision** on Association's website;
- **proposal to Association's General Assembly for expelling the convicted Member Company** from the membership in the Association.

2. The sanctions provided by this Code, except reprimand, may be cumulative. Fines are payable within 30 days from the date of passing of final decision subject to Association's invoice to that effect.

3. The following aspects will be taken into consideration in determining and assessing sanctions:

- gravity of breach,
- potential impact of the breach on public perception of Member Company's integrity and the integrity of the Association;
- if breach of the Code by the Member Company is accidental or recurrent;
- consequences on the part of the sanctioned Member Company;
- to what extent the accused Member Company tried to oppose the breach of the Code within its organisation;
- internal reactive penalties and organisational measures intended, undertaken and enforced by the accused Member Company related to the sanctioned breach, generally and in the particular matter;
- the overall attitude and cooperation of the accused Member Company during the process before the bodies of the procedure.

Article 41: Confidentiality of pending proceedings data

All parties involved in the process, members of Ethics Committee, members of the Ethics & Compliance Task Force, Management Board and persons acquaintained in any manner with the process and related to the functioning of the Association, shall keep confidential all information about their activities and information they become aware of.

Article 42: Enforcement of decisions

Legally effective decisions of the President of the Ethics Committee, Ethics Committee and

Extended Ethics Committee passed in the proceedings for breach of the Code in which the fine had been imposed are enforcement deeds and the Association is entitled to enforce them at the expense of the convicted Member Company.

Article 43: External reporting

Depending on the nature of the breach, and especially in case of existence of reasonable doubt that the breach of the Code constitutes also violation of valid laws on Medicinal Products and their promotion, Ethics Committee may report competent authorities thereof (Ministry of Health, Croatian Health Insurance Institute, Agency for Medicinal Products and Medicinal Devices).

Article 44: Internal reporting

1. The President of the Ethics Committee shall prepare half-yearly reports (every six (6) months, hereinafter: Reporting Period) on final decisions on breaches of Code passed during each Reporting Period. In exception to the definition of the Reporting Period and taking into account the date of adoption of this Code, the first Reporting Period is period between 27.02.2023. and 30.06.2023. For the avoidance of doubt, the President of the Ethics Committee shall make the report hereunder even if no final decisions were passed.

2. The President of the Ethics Committee will submit the report from this article to Member Companies within thirty (30) days from the end date of each Reporting Period.

3. Each report must comprise the following information:

- in case of severe breaches of the Code: the name of the Member Company and the description of violations, minding that no individual's personal data are disclosed in such report,
- in case of less severe breaches of the Code: the description of violations without identity of the Member Company, minding that no individual's personal data are disclosed in such report,
- in case of no decisions in a Reporting Period: information on this fact.

Article 45: Final provisions

1.This Code is adopted by the Assembly of the Association at its session held 27 February 2023 in line with Article 18 of the Statute of the Association.

2. As of effective date of this Code the previous Code (effective as of 01 January 2021) shall be replaced.

3. The effective date of this Code is the date of its adoption and this Code shall be binding for all Member Companies of the Association thereupon.

* * *

President of the Association:

Signature: _____
Name: Rina Musić

ANNEX A

Standardised Disclosure Template
(pursuant to the Art. 27 para. 3)

Translation from Croatian language

Annex A – template												Disclosure date: _____
	Full name **(Art. 26.1.)**	**HCPs:** City of Principal Practice HCOs: city where registered **(Art. 27.6)**	Country of Principal Practice **(Art. 27.6. related to Art. 26.)**	Principal Practice Address **(Art. 27.6.)**	Unique country local identifier (optional) **(Art. 23.6.)**	Donations to HCOs **(Art. 28.1.A.(i))**	Contribution to costs of Events (**Art. 28.1.A.(ii) and 28.1.B(i)**)			Fee for Services (**Art. 28.1.A.(iii) and 28.1.B(ii)**)			**TOTAL** Optional
							Sponsorship agreements with HCOs /Thrid Parties appointed by HCOs to manage Event	Registration Fees	Travel & Accommodation	Fees	Related expenses agreed in the fee for services contract		
HCPs	**INDIVIDUAL NAMED DISCLOSURE – one line per HCP (i.e. all Transfers of Value during a year for an individual HCP will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only as appropriate)**												
	Dr. A					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount		
	Dr. B					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount		
	Etc.					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount		
	OTHER, NOT INCLUDED ABOVE – where information cannot be disclosed on an individual basis for legal reasons												
	Aggregate amount attributable to ToV to such RecipientS – Art. 28.2.1.					N/A	N/A	Aggr. HCPs	Aggr. HCPs	Aggr. HCPs	Aggr. HCPs		Optional
	Number of Recipients in aggregate disclosure – Art. 28.2.1.					N/A	N/A	number	number	number	number		Optional
	% of the number of Recipients included in the aggregate disclosure in the total number, by category, of Recipients disclosed – Art. 28.2.1.					N/A	N/A	%	%	%	%		N/A
HCOs	**INDIVIDUAL NAMED DISCLOSURE – one line per HCO (i.e. all Transfers of Value during a year for an individual HCO will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only as appropriate)**												
	HCO 1					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount		Optional
	HCO 2					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount		Optional
	etc.					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount		Optional
	OTHER, NOT INCLUDED ABOVE – where information cannot be disclosed on an individual basis for legal reasons												
	Aggregate amount attributable to ToV to such Recipient – Art. 28.2.1.					Aggr. HCOs	Aggr. HCOs	Aggr. HCOs	Aggr. HCOs	Aggr. HCOs	Aggr. HCOs		Optional
	Number of Recipients in aggregate disclosure – Art. 28.2.1.					number	number	number	number	number	number		Optional
	% of the number of Recipients included in the aggregate disclosure in the total number, by category, of Recipients disclosed – Art. 28.2.1.					%	%	%	%	%	%		N/A
AGGREGATE DISCLOSURE													
Research & Development	Transfers of Value for Research & Development under Art. 28.2.2.											TOTAL	OPTIONAL

ANNEX B (binding)
EFPIA guidance

GUIDANCE ON DISCLOSURE OF NON-INTERVENTIONAL STUDIES

Background

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

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

The Ethics & Compliance Committee (E&CC) had considered that definitions in the new EU Clinical Trials Regulation 536/2014[1] could be used for reference when implementing the Disclosure requirements, thus anticipating and align with the regulatory change that will eventually take place.

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

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

Relevant EFPIA Disclosure Code provision

Schedule 1: Definition of Terms

Research and Development Transfers of Value – Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Regulation N° 536/2014[2]); or (iii) non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (Section 15.01 of the HCP Code).

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

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

Guidance

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

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

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

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

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

DISCLOSURE OF INDIRECT TRANSFERS OF VALUES (ToVs) THROUGH THIRD PARTIES

SUPPORT TO / SPONSORSHIP TO EVENTS THROUGH PROFESSIONAL CONFERENCE ORGANISERS (PCOS)

Background

Third parties[3] provide support to Member Companies in a variety of capacities, impacting more or less on the conduct of activities regulated by the EFPIA Codes. Such activities would be reported as indirect Transfers of Values (ToVs) following provisions of the EFPIA Disclosure Code. When Member Companies provide support / sponsorship to PCOs involved in the organisation of scientific Events, it is understood that the Member Companies' intention is to provide support to HCPs/HCOs at arm's length.

Indirect ToVs are those made on behalf of a Member Company for the benefit of a Recipient, or ToVs through an intermediate and where the Member Company knows or can identify the HCP/ HCO that will benefit from the ToV[4].

In consideration of the multiple ways collaboration with third parties can be contracted, it may not be straightforward to report in application of the EFPIA Disclosure Code in full. As this may lead to underreporting of ToVs through third parties, further Guidance aims at providing a consistent approach towards improved reporting wherever possible in compliance with applicable law and regulations. This Guidance clarifies reporting of Indirect ToVs to HCOs made through Professional Congress Organiser (PCOs[5]). In consideration of legal issues that may arise in the reporting of ToVs through Distributors on behalf of a Member Company, reporting of such ToVs are not within scope of this Guidance. Where appropriate, EFPIA may consider further Guidance for this category of (and other categories of third parties involved in) ToVs.

Relevant EFPIA Disclosure Code provision

Section 3.01.1.b

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

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

Schedule 1: Definitions
Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient, or transfers of value made through an intermediate and where the Member Company knows or can identify the HCP/HCO that will benefit from the Transfer of Value.

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

[4] Definition of an indirect ToV in EFPIA's HCP/HCO Disclosure Code Schedule 1

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

Guidance

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

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

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

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

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

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

Further recommendation

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

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

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

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

Additional Guidance on ToVs through PCOs
SUPPORT TO / SPONSORSHIP TO EVENTS THROUGH PROFESSIONAL CONFERENCE ORGANISERS (PCOS)

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

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

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

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

ANNEX C (binding)

Guidance obligations for Member Associations under the EFPIA Code

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

Article 10 EFPIA Code: Events and hospitality - Member Association must set a **monetary threshold** in its National Code, failing which EFPIA will set such threshold in lieu of such Member Association. Member Associations must provide guidance on the meaning of the term "*reasonable*", as used in the Article 10. Member Associations must also provide guidance on "*appropriate*", "*renowned"* and "*extravagant*" Venues, as used in the Article 10 of EFPIA Code.

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

Article 21.03 EFPIA Code: Significant indirect or non-financial support to Patient Organizations - Member Associations must provide guidance on the meaning of the term "*significant*", as used in Article 21.03. of EFPIA Code.

Guidance on the meaning of terms under the IFI Code

IFI Code Article	Term	Definition
10	**"Appropriate" (venue)**	• a separate, dedicated conference center; • a hotel which, according to valid Croatian laws on categorization of accommodation facilities, has maximum 4 (four) stars and which is providing appropriate conference and business services prevailing over spa, wellness and/or other leisure offers; • a hotel classified as "special standard hotel" (exclusively): HOTEL BUSINESS (Poslovni), HOTEL MEETINGS (Za sastanke) or HOTEL CONGRESS (Kongresni), in line with valid By-law on Classification, Categorization and Special Standards of Hospitality Facilities – Hotels. • hotels in which no conferences are organized or held during July and August, if located on the Croatian coast or islands[1]
	"**Renowned for leisure"**	hospitality facilities known for providing special entertaining services as prevailing activities (not related to conference activities) e.g. wellness and spas, casinos, golfing facilities and similar.
	"**Extravagant or exclusive**"	all five (5) star categorized hotels on the territory of the Republic of Croatia in accordance with valid categorization of accommodation facilities managed by the Ministry of Tourism and Sports of the Republic of Croatia.
	"Reasonable hospitality "	means that the value of hospitality shall not exceed the amount which the Recipient would have been prepared to pay by her/him-self i.e. **maximum amount 80,00 EUR, without VAT, per person and per meal**.
16	**"Limited participation of Healthcare Professionals"**	means the fee payable to the Healthcare Professional for participation in market research activities, not exceeding the **net amount of 50,00 EUR, without any taxes and contributions**.
19	**"Modest financial value"**	means that the individual gross purchase price of such informative and educational materials and Items of Medical Utility does not exceed the amount provided in the valid By-law on Manner of Advertising on Medicinal Products (**9,29 EUR, without VAT**).
24	**"Significant support"**	means all forms of support the value of which does not exceed the amount provided in the valid Law on Prevention of Conflict of Interest (**66,36 EUR**).

[1] Events subject to e4ethics assessment CVC criterion shall apply, consult: https://www.ethicalmedtech.eu/conference-vetting-system/assessment-criteria/

ANNEX D (binding)

EFPIA standard operating procedure related to processing of complaints and questions submitted to EFPIA

IMPLEMENTATION & ENFORCEMENT OF CODES
PROCESSING OF COMPLAINTS & QUESTIONS SUBMITTED TO EFPIA

Background

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

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

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

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

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

Under these Rules each member association is required to:

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

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

This SOP does not cover the process that should ensure that EFPIA Codes are transposed into national codes, in line with national laws and regulations. This task is entrusted to the Codes

Committee that reports yearly to the Board on issues arising from the transposition, implementation and enforcement of applicable codes.

Relevant EFPIA Code Provision

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

ANNEX A to the EFPIA Codes is attached for reference.

STANDARD OPERATING PROCEDURES (SOP)

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

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

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

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

Common procedure rules

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

A. COMPLAINTS[1] RECEIVED BY EFPIA

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

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

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

Procedural Steps

- When a complaint is received by EFPIA, the Compliance Officer forwards it, within 10 working days, to the relevant Member Association(s) for action under the Member Association(s)'s procedure for dealing with complaints, and the complainant will be informed of which Member Association(s) are responsible for dealing with the complaint
- Simultaneously, the Compliance Officer will inform, in writing, the responsible senior employee[2] of the company(ies) against which the complaint is made. If the complaint involves a number of countries, EFPIA will forward the complaint to the Member Association of the parent company and to the relevant company's subsidiary(ies)
- The Member Association(s) must acknowledge receipt of the complaint from EFPIA within 30 days following EFPIA's communication
- The Member Association(s) should consider the complaint under its usual procedure, including timelines. During the adjudication period, EFPIA will not intervene, neither will it answer questions neither from the complainant nor from the Member Company(ies) involved in the case
- When the Member Association(s) has(ve) completed its(their) consideration of the matter, EFPIA must be so informed of the decision(s) made by the adjudication bodies, including, where appropriate, the sanction imposed. The Member Association(s) should provide updates to EFPIA as the matter proceeds no later than 6 months after it receipt of the complaint, and subsequently within each following quarter until a final decision is made on the compliant (within a reasonable timeframe)
- A summary of decisions made on cases submitted to EFPIA will be published in EFPIA's Codes Activity Report – once the complaint has been concluded, the learnings might lead to further discussion by the Codes Committee including enhancing code consistent implementation, where relevant.

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

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

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

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

[2] 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

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

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

Procedural Steps

When a Member Association, following completion of the adjudication of a complaint is unable to achieve resolution of a complaint concerning a EFPIA Member Company, the Association will inform EFPIA, indicating the reasons[3] why it cannot achieve resolution of the complaint;

- Within 10 working days of notification of the issue, EFPIA's Compliance Officer will inform, in writing, the responsible senior employee[4] of the Member Company concerned with the Member Association's request for EFPIA's intervention;
- Based on the respondent Member Company's comments (that should be provided to EFPIA within 30 days of EFPIA's request), EFPIA's Compliance Officer will consult with the Codes Committee Chairs to agree on follow-up actions that could be recommended. These actions could be to report to the Codes Committee and/or to EFPIA Board. The Codes Committee Chairs should agree on these actions within 60 days;
- No later than 120 days following the Member Association's initial information, EFPIA will inform the Member Company of steps that it is expected to take in accordance with its EFPIA membership obligations;
- Within 30 days, the Member Company should inform EFPIA of follow-up actions put in place, and the Member Association will confirm with EFPIA that the issue has been settled;
- If no response is received from the Member Company or the response is not adequate, EFPIA will take the opinion of the Codes Committee on next steps to be taken. The Codes Committee could decide on further action, such as reporting the matter to the EFPIA Board that will decide on the recommended action that should be agreed.

C. MEMBER COMPANY NOT SUBMITTED TO APPLICABLE CODES

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

Member Associations must ensure that the arrangements for application of national codes cover any EFPIA Member Company when such company is not a member of the national Member Association. Each Member Association must have a process to allow non-members of that Member Association to agree to comply with their national code and to accept the jurisdiction of

[3] 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.

[4] 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

that Member Association's adjudication body. However, Member Associations must not oblige the EFPIA Member Company becoming a member of the Member Association. The arrangements and conditions should be clear and transparent.

Scope and Applicability of EFPIA Codes

The EFPIA Codes apply to activities relating to prescription-only medicines (POM) (whether patented or off-patent, branded or generics*). This is similar to the scope of the EU Pharma Regulation*[5]. The Codes are applicable to all activities relating to POM and relationships with Healthcare Professionals, Healthcare Organisations and Patient Organisations (as defined in the Codes and excluding commercial activities).

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

- Implement high and transparent standards of conduct in dealings with external stakeholders, including:
    - Abiding by the rules of EFPIA including rules laid down in the EFPIA Codes
    - Signing-off the national self-regulatory codes in all the countries where the Member Company operates, and confirm that it is bound by such member association's code (including any applicable sanctions that may be imposed there under);
    - Each Member Company must appoint at least one senior employee who shall be responsible for supervising the company and its subsidiaries to ensure that the standards of the Applicable Code(s) are met;

For application of the EFPIA Codes, the term "company" shall mean any legal entity that organises or sponsors promotion, or engages in interactions with healthcare professionals covered by an Applicable Code, which takes place within Europe, whether such entity be a parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation.[6]

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

Procedural Steps

- When actions undertaken by a Member Association aiming at ensuring that an EFPIA Member Company is subject to that Member Association's national code are unsuccessful, the Member Association will inform EFPIA, in writing, providing details of its actions and the Member Company's response;
- EFPIA will intervene directly when an EFPIA Member Company does not submit to the national applicable codes and require that the Member Company formalises its adherence to national applicable codes including their adjudication arrangements within 2 months of EFPIA's request;
- If the EFPIA Member Company still does not agree to respond to EFPIA's request to confirm its adherence to applicable national codes (including submission to the national sanction system), the Board will be informed;

[5] 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
[6] See Section "Applicability of the Code" in the EFPIA Codes

- As part of its yearly review of code activities, the Codes Committee will provide an update on the status of EFPIA Member Companies and their obligations under the EFPIA Codes. Where the Codes Committee establishes a pattern of non-adherence – i.e. a Member Company has not agreed to be subject to national applicable codes in more than one country, or countries where a majority of EFPIA Member Companies are not subject to the Member Association's code – the Codes Committee will make proposals to address the situation and is likely to request the Board's intervention.

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

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

Procedural steps

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

E. QUESTIONS SUBMITTED TO EFPIA FOR CLARIFICATION OF CODE PROVISIONS

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

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

<u>Deviations and Variations</u>

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

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

Clarification and interpretation of Code provisions

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

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

Procedural steps

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

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

ANNEX E (binding)

EFPIA e4ethics rules and procedure

1. Background

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

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

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

2. e4ethics decisions binding and mandatory assessments

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

3. Collaboration with MedTech Europe

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

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

A. KEY ELEMENTS

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

CVS software to allow profile separation, while keeping a shared history of knowledge and an optimisation of service level.

Common back end[1]: In the back end, all assessment requests will be received by MedTech Europe Compliance Officers, which will become the Compliance Officers also for Pharma Events.

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

B. ALIGNMENT OF CRITERIA
The criteria applying to e4ethics will be aligned to those of CVS:

- The submission for events assessment must be done proactively and online by the EFPIA member companies or the congress organisers.
- The travel arrangements and meals & drinks threshold will no longer be part of the criteria assessed. Therefore, the EFPIA Member Associations will not be consulted.
- Submission in e4ethics will be mandatory, i.e. EFPIA Member Companies need to verify that an e4ethics positive assessment is available for the Event prior to being able to provide any kind of support, from the first day of the pilot phase. The submission for such assessment can be made by the Member Company or the Congress Organiser (HCO/PCO).
- Binding nature of all decisions rendered by e4ethics on the EFPIA members during and after the pilot phase, meaning that an Event assessed as non-compliant cannot receive any form of support from EFPIA members.
- Full MedTech Europe/EFPIA alignment on the approach and interpretation of the six assessment criteria23, which means that there will not be a difference on how Pharma and MedTech Events will be assessed.

C. IMPORTANT CONSIDERATIONS
The following considerations are important:

- Decisions are rendered on the basis of the documents and information provided to the CVS Compliance Officer via the online submission form. The CVS Compliance Officer does not independently verify whether the information or documents are up to date.
- Decisions do not consider, nor supplant national and local laws, regulations or professional and company codes that may impose more stringent requirements upon members, HCPs, HCOs or PCOs.
- The schedule and relevance of scientific programme sessions of an Event are reviewed, but not their value or quality.
- The sole purpose of the vetting system is to assist corporate members in determining the appropriateness for member companies to provide support to an Event.

4. Procedure applicable to e4ethics
A. APPEAL
The assessments for e4ethics will follow the CVS process: the MedTech compliance panel will be in charge of the appeal procedure for the assessments. An appeal of the CVS Compliance Officer's assessment is possible. The body responsible for reviewing such appeals is the MedTech Europe

[1] For the IT project, were underlined the importance to build-in data analytics tools as well as necessity to transfer historic data of e4ethics, to be used for later data analytics purposes. 23 - Event Programme - Geographic Location - Event Venue Facility – Hospitality - Event Registration Packages - Communication Support

Compliance Panel, given the value of having one single authority overseeing the decision processes respectively pertaining to MedTech and Pharma Events.

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

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

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

B. COMPLAINT RELATED TO AN EVENT

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

COMPLIANTS[2] RECEIVED BY EFPIA

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

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

Procedural Steps

- When a complaint is received by EFPIA, the EFPIA Compliance Officer forwards it, within 10 working days, to the relevant Member Association(s) for action under the Member Association(s)'s procedure for dealing with complaints, and the complainant will be informed of which Member Association(s) are responsible for dealing with the complaint;
- Simultaneously, the EFPIA Compliance Officer will inform, in writing, the responsible senior employee[3] of the company(ies) against which the complaint is made. If the complaint involves a number of countries, EFPIA will forward the complaint to the Member Association of the parent company and to the relevant company's subsidiary(ies);

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

[3] 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 Member Association(s) must acknowledge receipt of the complaint from EFPIA within 30 days following EFPIA's communication;
- The Member Association(s) should consider the complaint under its usual procedure, including timelines. During the adjudication period, EFPIA will not intervene, neither will it answer questions neither from the complainant nor from the Member Company(ies) involved in the case;
- When the Member Association(s) has(ve) completed its(their) consideration of the matter, EFPIA must be so informed of the decision(s) made by the adjudication bodies, including, where appropriate, the sanction imposed. The Member Association(s) should provide updates to EFPIA as the matter proceeds no later than 6 months after it receipt of the complaint, and subsequently within each following quarter until a final decision is made on the compliant (within a reasonable timeframe);
- A summary of decisions made on cases submitted to EFPIA will be published in EFPIA's Codes Activity Report – once the complaint has been concluded, the learnings might lead to further discussion by the Codes Committee including enhancing code consistent implementation, where relevant.

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