Translation from Croatian language

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Pursuant to Article 16 of the Statute, General Assembly of the **Innovative Pharmaceutical Initiative** on its session held on **15 May 2017** in Zagreb adopted the following

CODE OF CONDUCT
OF INNOVATIVE PHARMACEUTICAL COMPANIES

Table of Contents:

Preamble

The Croatian association Innovative Pharmaceutical Initiative (hereinafter: **the Association**) is the representative body of research-oriented manufacturers of medicinal products that are duly organised and act in the Republic of Croatia in line with applicable legislation. The Association is member of European Federation of Pharmaceutical Industries and Associations (hereinafter: **EFPIA**), one of the leading representative bodies of the research-oriented pharmaceutical industry in Europe. Most of the member companies of EFPIA conduct their activities in the Republic of Croatia via the 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 medicines for the purposes of improvement of quality of human health and health 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 of conduct in promotion of medicinal products (hereinafter: **the Code**) the Association wishes to set forth transparent and clear rules and procedures applicable to its members 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 professional to prescribe a medicine, 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 scale 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 pharmaceutical 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 the members of the Association 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 medicines by the healthcare professionals are being made on the bases of the merits of each product and the healthcare needs of each patient.

TITLE I: GENERAL PROVISIONS

Article 1: Applicability of the Code

1. This Code applies to:
   a. the promotion of prescription-only Medical Products to Healthcare Professionals in the Republic of Croatia and interactions between Healthcare Professionals and Pharmaceutical Companies;
   b. 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 Pharmaceutical Companies for the benefit of Healthcare Professionals and Healthcare Organisations in connection with the activities described in the previous item a. and the research and development of Medicinal Products.

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, nor it applies to the following activities:
      - statutory labelling of Medicinal Products and accompanying package leaflets which are subject to the approval of competent state 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 Pharmaceutical 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 Company and its product.

   b. to information on support granted by Pharmaceutical Companies to patient

organisations in the sense of Code of practice on relationships between Pharmaceutical Companies and patient organisations.

3. All Members Companies of the Association 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:

1) IFPMA Code of Pharmaceutical Marketing Practices, 2006 revision of International Federation of Pharmaceutical Manufacturers Association, as revised 2006, effective from 1 January 2007 and its subsequent amendments.

2) EFPIA Code of Practice on the Promotion of Prescription-Only Medicine to and Interactions with Heath Professionals and the Code on Disclosure of Transfers of Value From Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations, as revised and adopted on 2013, and their subsequent amendments

3) 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 of the Association must comply with this Code, also in the event where they engage third persons (e.g. commercial representatives, consultants, market-research agencies, marketing agencies, public relations agencies etc.) on behalf of the Members of the Association to perform activities of creation, application or undertaking of activities defined in this Code.

Article 2: Definitions

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

Member Companies companies and their branch offices with registered seat in the Republic of Croatia which are members of the Association which are or may be affiliated – in the sense of Croatian Company Law – with the companies with

	registered seat outside the Republic of Croatia. For the purposes of this Code, Companies which are members of the Association and their affiliated companies shall be deemed to constitute a single entity to which this Code i.e. EFPIA codes apply.
Donation	donation made either in cash or in kind given to Healthcare Organisations (as defined hereunder).
Hospitality	following costs related to participation of Healthcare Professionals in Events which may be paid by Pharmaceutical Companies: travel costs, costs of meal (food and drink), acommodation and participation fee.
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,
Medical Department	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.
International Event	Event (as defined hereunder) being organised and taking place outside the territory of the Republic of Croatia.
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 Parmaceutical Company or, with its authority, any third person which promotes prescription, supply, sale, administration, recommendation or consumption of the prescription-only Medicinal Product of the respective Pharmaceutical Company, irrespective of the form and media in which such activity is performed.
Recipient	Healthcare Professional and Healthcare Organisation (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 Pharmaceutical Company for the benefit of the Recipient; ii. indirect transfers of value are those made by third persons (e.g. contract research organisations) acting on behalf of a Pharmaceutical Company and all transfers of value made through an intermediate providing that the Pharmaceutical 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 Law on Medicinal Products, By-law on Clinical Trials of Medicinal Products and Good Clinical Practice and By-law on 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.

Pharmaceutical Company	Member Company, its branch office and all affiliated companies within the meaning of the Company Law.
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 or on behalf of a Pharmaceutical Company
Professional Administrative Staff	persons occupying management positions in private and public healthcare organisations, as well as persons employed by state authorities competent for implementation of the legislation of pharmaceutical sector (e.g. Ministry of Health, Agency for Medicinal Products and Medicinal Devices, Croatian Health Insurance Institute etc.) and appointed in advisory bodies of state authorities and institutions (e.g. members of ethical committees and other committees etc.)
Medical Representative	persons engaged on activities of promotion of Medicinal Products including personnel retained by Pharmaceutical Companies by way of contract for their account, as well as any other Pharmaceutical Company representatives interacting with Healthcare Professionals and Healthcare Organisations.
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, may prescribe, purchase, supply, recommend or administer a Medicinal Product and whose primary practice, principal professional address is in the Republic of Croatia. 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 Pharmaceutical 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 Pharmaceutical 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, in the sense of the separate Code),
e. legal entities owned by Health Professionals and member of their families in the sense of the Law on Prevention of Conflict of Interest;

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.

2. Unless otherwise provided in this Code, capitalized terms will have the meaning accredited in the previous paragraph.

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

TITLE II: GENERAL PRINCIPLES OF PROMOTION

Article 3: Marketing authorisation

1. It is prohibited to promote:
   - 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 meetings 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 4: 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 the advertisement includes, minimum, the name of the Medicinal Product or its international non-proprietary name (INN) and / or the trademark(s) or possible other forms of protection of visual identity of the Medicinal Product / Pharmaceutical Company.

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:
   1) **published studies** – clear reference to precise source should be given;
   2) **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;
   3) **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 5: 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 6: Acceptability of Promotion

Pharmaceutical 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) 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 7: 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 8: 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 Pharmaceutical 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 Pharmaceutical Company must clearly indicate that it has been sponsored by that Pharmaceutical Company.

Article 9: 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 10: Use of Internet in Promotion

10.1. 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.

10.2. Content of websites

1. 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.

2. 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 products distributed by the Pharmaceutical Company (including information on their indications, side-effects, interactions with other medicines, 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 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 products 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 a relevant national competent authority. Brand names should 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.

10.3. 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 Pharmaceutical 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.

10.4. Links from other websites

Links may be established to accompany sponsored websites from websites sponsored by other persons but Pharmaceutical Company should not establish links from websites designed for general public to Pharmaceutical Company-sponsored websites that are designed for Healthcare Professionals. In the same manner links may be established to separate websites sponsored by the Pharmaceutical 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.

10.5. Websites addresses in packaging

Subject to any applicable laws and regulations, uniform recourse locators (URLs) of Pharmaceutical Company sponsored websites that comply with these guidelines may be included in packaging of

medicinal products.

10.6. Scientific review

Pharmaceutical Company should ensure that scientific and medical information prepared by them for inclusion in their websites is reviewed for accuracy and compliance with this Code and applicable Croatian regulations. The Medical Department established within the Pharmaceutical Company may perform this function or it may be entrusted to other appropriately qualified persons.

10.7. Privacy

The website must conform to legislation and applicable codes of conduct governing the data privacy, security and confidentiality of personal information

TITLE III: INTERACTIONS BETWEEN PHARMACEUTICAL COMPANIES AND HEALTHCARE PROFESSIONALD AND HEALTHCARE ORGANISATIONS

Article 11: Events and Hospitality

11.1. Events

1. All Events organised or sponsored by or on behalf of a Pharmaceutical 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 11.2. of this Code.

   For the purpose of this Code **appropriate venue** for Events and International Events, in case where later are organized 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 which, according to valid Croatian laws on categorisation of accommodation facilities, has maximum 4 (four) stars and which is principaly known for providing mainly business services, i.e. hotel classified as special standard hotel, confirmed by the competent authority to satisfy either of the following standards (exlusively): BUSINESS (Poslovni), MEETINGS (Za sastanke) or CONGRESS (Kongresni), in line with Art. 12.d., Art. 64 and Art. 65 of the By-law on Classification, Categorisation and Special Standards of Hospitality Facilities – Hotels (Official Gazette No. 88/07, 58/08, 62/09, 63/13, 33/14 and 92/14).

   The guiding principle in hotel selection process under the previous paragraph of this Art. 11.1.1.1, should be predominance of hotel's business features in terms of appropriate congress facilities or conference rooms capable of receiving any given number of attendees, whereby the hotel with predominantly spa, wellness or leisure features will in no event be deemed as the appropriate venue.

   Management Board of Association will have the power of interpretation, in all cases of doubt on appropriateness of the particular hotel.

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 which appears 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 Pharmaceutical 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.

11.2. Hospitality

1. Pharmaceutical Companies must comply with the following criteria when offering Hospitality:

   a. Hospitality can be provided only to Healthcare Professionals being participants in Events (whether active or passive within the meaning of Article 14.1 of this Code) - not for persons accompanying the participants (spouses and other accompanying persons);
   b. costs of Hospitality payable by Pharmaceutical Companies must be equal to their actual value, as invoiced by third party suppliers, and Pharmaceutical 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 hotels with no more than the equivalent of Croatian 4 star hotel with has predominantly business features i.e., if the Event also takes place in such hotel, a special standard hotel as designated in the Art. 11.1.1., sub-paragraphs 2 and 3 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.

c. Costs of meals during the Event shall be paid:
   - up to maximum amount of HRK 500,00 / person / meal; and
   - this form of Hospitality must be limited to refreshments and/or meals during the Event.

   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.

d. 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 to Healthcare Professionals

No gift may be supplied, offered or promised to a Healthcare Professionals. 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 Healthcare Professionals free of charge.

Article 13: 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 the symbolic value of gift provided under valid Law on Prohibition of Conflict of Interest and that such materials are

relevant to the practice of Healthcare Professionals i.e. 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 symbolic value of gift provided under valid Law on Prohibition of Conflict of Interest and that such items do not offset routine business and professional practices of the Recipient.

3. The scope 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 of this Code.

Article 14: Sponsoring Healthcare Professionals to attend Events and International Events

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

i. funding must not be offered to Healthcare Professionals to compensate merely for time spent in attending the Event;
ii. sponsoring Healthcare Professionals to attend Event must not be provided in exchange for recommending, prescribing, purchasing, supplying, selling or administering Medicinal Product;
iii. in the case of International Events, the legality of all payments provided to Healthcare Professionals by the Pharmaceutical Company shall be subject to the rules of the jurisdiction where such Healthcare Professional carries out his or her profession, as opposed to those in which the International Event takes place;
iv. Hospitality in line with the Art. 11.2. of this Code may be provided to Healthcare Professionals at sponsored Events. 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 15: Donations to Healthcare Organisations

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. Pharmaceutical 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 Pharmaceutical Company to attend Event under conditions provided under Article 14. of this Code

Article 16: Services of Healthcare Professionals and Healthcare Organisations

16.1. Services of Healthcare Professionals

1. Pharmaceutical 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 Pharmaceutical 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 Pharmaceutical 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 gross amount of HRK 380,00.

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

4. In their written contracts with Healthcare Professionals, Association strongly encourages Member Companies to include provisions regarding the obligation of the Healthcare Professional to declare that he/she is engaged by the particular Pharmaceutical 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 Pharmaceutical Company, 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 Pharmaceutical Company if, in the remainder of the working time, such Healthcare Professional still practices her/his profession).

16.2. Services of Healthcare Organisations

Contracts between Pharmaceutical Companies and Healthcare Organisations under which such Healthcare Organisations provide any type of services to Pharmaceutical 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.

Article 17: Non-interventional studies of Medicinal Products

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. Pharmaceutical 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 Pharmaceutical 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 Pharmaceutical Company's Medical Department (in line with Article 23 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 Medical Department for a reasonable period of time. The Pharmaceutical 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 Medical Department 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, Pharmaceutical Companies are encouraged to comply with the criteria stipulated in this Article 17.1. 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 18: Sampling

1. Free samples may be given to a Healthcare Professional at her/his written request, to familiarize them with the products 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 samples shall be supplied as an inducement to recommend, prescribe, purchase, supply, sell or administer a particular Medicinal Product. Free sample may be given only to a Healthcare Professional who can initiate or prescribe such Medicinal Product.

2. Pharmaceutical Companies must have adequate systems of control and accountability for samples which they distribute and for all Medicinal Products handled by their Medical Representatives.

3. Each 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 samples may be supplied for Medicinal Products which contain substances defined as psychotropic or narcotic as determined under applicable legislation of state authorities.

TITLE IV: DISCLOSURES

Article 19: 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 21.

2. Transfers of Value made in exercising of following activities do not fall within the scope of the disclosure obligation from previous paragraph:
   c. activities of promotion and rendering information on over-the-counter Medicinal Products;
   d. activities not listed in Article 21 of this Code which includes, e.g. informational or educational materials and items of medical utility governed by Article 13., costs of meals governed by Article 11.2.c. of this Code up to determined value, purchase costs of samples governed by Article 18 of this Code; and
   e. activities of ordinary course of purchases and sales of Medicinal Products by and between the Pharmaceutical Companies and Healthcare Professionals (such as pharmacists) and Healthcare Organisations.

3. For the purpose of fulfilment of obligation under this Article and obligations arising from valid Law on Protection of Personal Data, Member Companies are recommended when making any Transfer of Value, irrespective if under written contract or non-formally, to obtain consents of the Recipients to disclose Transfer of Value in accordance with provisions of this Code, by way of appropriate provision in the contract or in a form of a separate document.

Article 20: Dynamics, forms and other requirements regarding Disclosures

1. Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year (the "**Reporting Period**"). The first Reporting Period shall be the calendar year 2015.

2. Disclosures shall be made within 6 months after the end of the relevant Reporting Period and the information disclosed shall be required to remain in the public domain for a minimum of

3 years after the time such information is first disclosed, unless, in each case, (i) a shorter period is required under applicable national data privacy or other laws or regulations, or (ii) the Recipient's consent relating to a specific disclosure has been revoked.

3. For consistency purposes, disclosures pursuant to this Code will be made using a structure set forth in **Annex 1** which shall be applied on all disclosures in the Republic of Croatia. Possible deviations from this Annex 1 will be acceptable exceptionally, where such deviations are consequence of application of mandatory laws.

4. Disclosures will be made on the relevant website which shall be developed by the Association for the respective purpose and/or on the websites of each Member Company, with the right of unlimited access thereto by use of Internet. Disclosures will be made in the form of Annex 1.

5. Disclosures shall be made in Croatian language but, following resolution of the Association, the website may be designed as bi-lingual site with the option of availability of English language text.

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 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 periods of document retention.

Article 21: Manner of disclosures

21.1: 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. 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 a Healthcare Organisation**, includes all payments made in relation to any of the categories set forth below:

(i) Donations governed by Art. 15. of this Code;

(ii) costs related to Events paid directly to Healthcare Organisations or third parties, including costs of governed by Art. 14. (sponsorships to Healthcare Professionals to attend Events and International Events), such as:

1. costs of Hospitality, taking into consideration the exception under Art. 19.2.(b); ,
2. amounts of sponsorships under sponsorship agreements between Pharmaceutical Companies and Healthcare Organisations or with third parties appointed by the Healthcare Organisation to manage the Event in the name and for the account of the Healthcare Organisation;

(iii) fees for services of Healthcare Organisations governed by Art. 16.2. of this Code paid under service contracts with Healthcare Organisations 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.

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. 19.2.(b);

(ii) fees for services of Healthcare Professionals governed by Art. 16.1. and Art. 16.1.2. (where the identity of the Healthcare Professional participating in market research activities is known to the Pharmaceutical 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.

21.2: 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.

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. 21.1.B.

21.3: 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. 21.1.A. and B. 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.

TITLE V: PHARMACEUTICAL COMPANY STAFF

Article 22: Medical Representatives

1. Each Pharmaceutical Company shall ensure that its Medical Representatives - including sub-contractors (persons retained by Pharmaceutical Companies by way of contract for performance of such services) - are familiar with the relevant requirements of this Code and all applicable laws and regulations of the Republic of Croatia, adequately trained for performance of such tasks and have sufficient scientific knowledge to be able to provide precise and complete information about the Medicinal Products they promote.

2. Medical Representatives must approach their duties responsibly and ethically.

3. During each visit to Healthcare Professionals, Medical Representatives must give or offer the person visited to send via e-mail the last revision of a complete summary of the product characteristics and medicine instructions for all Medicinal Products presented during such visit, i.e. direct the Healthcare Professional on the website of the Agency for Medicinal Products and Medical Devices of Croatia or the European Medicines Agency.

4. Medical Representatives must transmit to the Pharmaceutical Company forthwith any information they receive in relation to the use of their Company's Medicinal Product, particularly reports of side effects. Medical Representatives must transmit all inquiries falling outside the scope of the approved summary of product characteristic to Medical Department.

5. Medical Representatives must ensure that the frequency, time and duration of visits to Healthcare Professionals, together with the manner in which they are made, do not disrupt the usual working process of visited persons.

6. Medical Representatives must not use any inducement or subterfuge to gain an interview with the 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 not mislead as to their identity or that of the Pharmaceutical Company they represent.

Article 23: Medical Department

1. All Pharmaceutical Companies must establish a Medical Department. Pharmaceutical Companies are free to decide how best to establish such service, taking into account their own resources and personnel they have on their disposal. Medical Department must include at least one medical doctor or a pharmacist and the other employees of Medical Department must have completed under-graduate and graduate study or integrated under-graduate and graduate university study in the area of biomedicine and healthcare. Medical Department 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, Medical Department 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.

2. Each Pharmaceutical Company must appoint at least one experienced senior employee who shall be responsible for supervising the Pharmaceutical Company to ensure that the standards of the applicable codes are met.

TITLE VI: ENFORCEMENT

Article 24: Two-stage process

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

a) **President of the Ethics Committee** in the first instance
b) **Ethics Committee** in the second instance
c) **Extended Ethics Committee**, only in cases described in Article 31.5. of this Code.

Article 25: Filing complaint

1. **Filing right:** All (including the Management Board of the Association) have the right of filing complaint in cases of breach of the Code.

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 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 is started by written complaint filed with the President of the 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 (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 the Code which are, in the opinion of the complainant, infringed by the respondent Member Company.

Anonymous complaints will also be processed, if it is not the case that complaints are obviously made with the purpose of abusing the complaint filing options set under this Code.

Article 26: Preliminary examination of the complaint

If the complaint does not contain data on the identity of the breaching party and the relevant facts, President of the Ethics Committee will 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 complaint. Failure of complainant to adjust the amendment request within given timeline, may also be the ground for the President of the Ethics Committee to procede with the process based on the complaint.

Article 27: First instance process – 1st phase

1. The President of the Ethics Committee may dismiss the complaint as inadmissible if it does not relate to the breaches of the Code or if the complaint is an obvious misuse of the right of filing complaint under this Code.

2. If the complaint is not dismissed, the President of the Ethics Committee shall within 8 days from the date of receipt of complaint or amended complaint, invite the responding Member Company to submit written response about the circumstances levelled against it.

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 may comprise:

a) statement of admittance of breach with obligation of immediate stop of breaching activities of the Code and restraining from activities which may lead to another infringement (hereinafter: **Corrective Statement**);
b) statement of denial of the alleged infringement of the Code, stating the 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 the date of receipt of the statement and invite the complainant to respond to the standpoint of the President of the Ethics Committee on non-existence of the 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 takes on the case in order to conduct proceedings and to make a decision on the merits of the matter.

Article 28: First instance process – 2nd phase

1. In order to fully establish the factual situation and answer the question of whether there has been a violation 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 during such process 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 persons is necessary, or on the basis of explicit request of the parties to have a hearing during the procedure (if that is considerd relevant), timely calls for hearings will be made in which the date, place and time of the hearing shall be specified. If a Member Company 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, while paying attention to a 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, and upon the expiry of the deadline s(he) is obliged to inform the President of the Association or the Management Board of the Association about the obstacles to comply with that deadline, i.e. about the need to extend this deadline, taking into account the potential conflict of interest of the person who s(he) intends to inform about the matter.

Article 29: Decisions of the President of the Ethics Committee on the complaint

1. The President of the Ethics Committee may pass the following decisions:

- 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 there is not enough evidence that the Member Company commited the breach or if the breach was not committed,

- on finding the respondent Member Company guilty for the breach of the Code.

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

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

Article 30: Right of appeal

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

a) complainant, if being one of the Member Companies, only in the event of rejection of the complaint as unjustified, and
b) respondent Member Company, in the case of the decision in which the Respondent Member Company is found guilty.

Appeal of the complainant against the sanctions imposed (kind and scope), in the case of a conviction, is not allowed.

Appeal must be filed within 15 (fifteen) days from the date of receipt of written decision of the President of the Ethics Committee.

2. The appeal is filed with the President of the Ethics Committee at the registered address of the Association, who shall, upon establishing if the appeal is filed within appeal-filing timeline, prepare the file for the session of the Ethics Committee, which will make a decision in the second instance process.

In case of late filing of the appeal, the President of the Ethics Committee shall render a decision on the rejection of the appeal, against which the appeal is not allowed.

Article 31: Second instance process – deciding about the appeal

1. If the appeal is filed within a timeline, the President of the Ethics Committee shall deliver the entire file of the matter to the Ethics Committee for further processing.

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 appelant'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 appelant'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 Member Company against which a complaint is filed, may submit an appeal to be decided by the Extended Ethics Committee referred to in Article 33.5. of this Code.

Article 32: Sanctions

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

- **reprimand**, in the case of minor violations of the Code;

In the case of more serious violations of the Code or repetition of violations;

- **fine up to maximum 350.000.00 Kn**
- **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 serious breach of the Code;

- **publication of the final decision** in the case when the Member Company is found guilty of serious breach of the Code on the Association's website
- **decision on expelling the convicted Member Company** from the membership in the Association.

2. The sanctions provided by this Code, except for reprimand, may be cumulative. Fines must be paid within 30 days from the date of passing of final decision.

3. The following aspects will be taken into consideration in determining and assessing the sanctions:
- gravity of breach,
- potential impact of the breach on public perception of Pharmaceutical Company's integrity and integrity of the Association;
- if breach of the Code by the Member Company is accidental or recurrent;
- consequences of the type of sanction on the sanctioned Member Company;
- to what extent the accused Member Company tried to oppose the breach of the Code within its organisation;
- internal reactive penalites 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 Association.

With regard to funds paid as fines, resulting from sanctions, the Association has a discretionary right of disposal, including the disposal of funds for humanitarian and other socially useful purposes.

Article 33: Appointment of the Ethics Committee

1. The Ethics Committee comprises of the President and 3 (three) members being employees or representatives of the Member Companies and, namely, representatives of the Ethics & Compliance Task Force.

2. The Ethics & Compliance Task Force appoints the President of the Ethics Committee.

3. The President of the Ethics Committee, in the case of a complaint regarding the decision filed in the first-instance, appoints 3 (three) members of the Ethics Committee, in alphabetical or other order, taking into account the potential conflict of interest of those members in the specific case. In

addition to the appointment of 3 members of the Ethics Committee and the function of a reporter, the President of the Ethics Committee is exempted from further proceedings and decision-making, and the decision is made by members of the Ethics Committee, by majority vote.

4. Members of the Ethics Committee elect the leader of the Ethics Committee, for each subject in particular.

5. The Extended Ethics Committee is the ad hoc body of the proceedings, which meets solely in the case of appeal filed by a Member Company on a decision of the Ethics Committee referred to in Article 31.2. d), and consists of 5 (five) members of the Association's Task Force Ethics & Compliance, who are not in conflict of interest in this particular case. Upon receipt of such an appeal, the Head of Task Force Ethics & Compliance shall within 8 (eight) days from the receipt of such an appeal, select an ad hoc Extended Ethics Committee to deal with this matter. The decision of the Extended Ethics Committee is final and no legal remedy is allowed against it.

Article 34: Confidentiality obligation with respect to pending proceeding

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 35: Enforcement of decisions

Legally effective decisions of the President of the Ethics Committee and the 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 guilty Member Company.

Article 36: Reporting to competent authorities

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 to competent authorities thereof (Ministry of Health, Croatian Health Insurance Fund, Agency for Medicinal Products and Medicinal Devices).

Article 37: Disclosure of final decisions

The final decisions on violations of the Code will be published annually, as a report to the Assembly of the Association, compiled and published by the Ethics & Compliance Task Force.

An individual announcement will include:
- the name of the company that committed the violation and the description of those violations, in the event of more severe or repeated violations of the Code;

i.e.,

- only a description of the breach, without mentioning the company's name, in the case of a minor violation of the Code, for which a reprimand was made, as a sanction.

Article 38: Final provisions

1. This Code is adopted by the Assembly of the Association at its session held 15 May 2017 in line with Article 16. of the Statute of the Association.

2. This Code shall enter into force on the date of its adoption and shall be binding for all members of the Association from that date.

* * *

President of the Association:

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Tatjana Tomljanović

ANNEX 1

Disclosure Template
(pursuant to the Art. 20.3. of the Code)

Translation from Croatian language

Annex 1 – template												Disclosure date: _____
	Full name **(Art. 19.1.)**	**HCPs:** City of Principal Practice HCOs: city where registered **(Art. 20.6)**	Country of Principal Practice **(Art. 20.6. related to Art. 21.)**	Principal Practice Address **(Art. 20.6.)**	Unique country local identifier (optional) **(Art. 20.6.)**	Donations to HCOs **(Art. 21.1.A.(i))**	Contribution to costs of Events (**Art. 21.1.A.(ii) and 21.1.B(i)**)			Fee for Services (**Art. 21.1.A.(iii) and 21.1.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 INDICATED ABOVE – where information cannot be disclosed on an individual basis for legal reasons												
	Aggregate amount attributable to ToV to such Recipient – Art. 21.2.1.					N/A	N/A	Aggr. HCPs	Aggr. HCPs	Aggr. HCPs	Aggr. HCPs		Optional
	Number of Recipients (named list, where appropriate) – Art. 21.2.1.					N/A	N/A	number	number	number	number		Optional
	% of total ToV to individual HCPs – Art. 21.2.1.					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 INDICATED ABOVE – where information cannot be disclosed on an individual basis for legal reasons												
	Aggregate amount attributable to ToV to such Recipient – Art. 21.2.1.					Aggr. HCOs	Aggr. HCOs	Aggr. HCOs	Aggr. HCOs	Aggr. HCOs	Aggr. HCOs		Optional
	Number of Recipients (named list, where appropriate) – Art. 21.2.1.					number	number	number	number	number	number		Optional
	% of total ToV to individual HCPs – Art. 21.2.1.					%	%	%	%	%	%		N/A
AGGREGATE DISCLOSURE													
Research & Development	Transfers of Value for Research & Development under Art. 21.2.2.											TOTAL	OPTIONAL