

Pursuant to Article 18, paragraph (1), subparagraph 3) of the Articles of Association, the Assembly of the Association of Research-Based Medicine Producers in Bosnia and Herzegovina, at its session held on 22<sup>nd</sup>, June 2018 in Sarajevo, rendered the following:

**CODE OF CONDUCT  
OF RESEARCH-BASED MEDICINE PRODUCERS  
IN BOSNIA AND HERZEGOVINA**



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## Preamble

The Association of Research-Based Medicine Producers in Bosnia and Herzegovina (hereinafter: **the Association**) is a voluntary, independent, non-partisan, nongovernmental and non-profit association whose members are legal entities licensed for placing the research-based medicinal products into circulation in Bosnia and Herzegovina, and registered to operate in Bosnia and Herzegovina in accordance with applicable regulations.

The Association aims at becoming a member of the European Federation of Pharmaceutical Industries and Associations, hereinafter: **EFPIA**), one of the leading bodies of the research-oriented pharmaceutical industry in Europe.

The Association's goals and business activities have been defined by the Articles of Association, number: UP 08-07-1-220/14, certified by the Ministry of Justice of BiH on 2 September 2014, while the mission of the Association is to encourage and promote technological and economic development of the research-oriented manufacturers of medicinal products operating on the territory of Bosnia and Herzegovina, by discovering, developing and placing into circulation the new medicinal products towards a better quality of people's health and healthcare.

Ethical conduct while advertising the medicinal products is essential for the implementation of the referenced mission, because providing the professional public (healthcare professionals) with full, precise, objective, accurate and science-based information about medicinal products is a precondition for forming one's own position about a therapeutic value of a medicinal product when subscribing the drugs to patients.

By adopting this Code of Conduct concerning the medicinal product advertising procedure (hereinafter: the **Code**) for the professional public, the Association wishes to establish transparent and clear rules and procedures binding for the members of the Association while carrying out the medicinal product advertising activities towards the healthcare professionals in a manner to secure in the best way possible the professional and ethical conduct and transparency by the healthcare professionals while working to reach rational pharmacotherapy and to secure quality healthcare protection oriented to wellbeing of patients in Bosnia and Herzegovina.

Cooperation between the research-based medicinal product manufactures and healthcare professionals undoubtedly has an in-debt and positive effect on the quality of therapeutic procedures oriented to patients and their needs and also to the values of the future researches. At the same time, independence of healthcare professionals in making decisions on the healthcare procedures, which also includes decisions on pharmacotherapy, is one of the basic requirements of any healthcare system. For the avoidance of doubt about partiality / conflict of interests of healthcare professionals in their relationships with the medicinal product manufacturers, the purpose of this Code is, inter alia, to make sure that the public is properly informed about cooperation between the research-oriented medicinal product manufacturers and healthcare professionals, which is intended to secure not only transparency and strengthening of integrity of participants in such relationship, but to also secure objectivity in judging the existence of inadequate influence and possible conflict of interest.

Therefore, regardless of not being a member of EFPIA, the Association supports the conclusions contained in the document which, among other signatories, has also been adopted by EFPIA under the title "List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector", hereinafter: the **Principles**).

The Association encourages competitiveness between the research-based medicinal product manufacturers. Therefore, it is not the purpose of this Code to restrict or influence the medicinal product advertising which is carried out in accordance with good business practice and which does not form an unfair market competition. The purpose of this Code is to secure that, while carrying out the medicinal product advertising activities, the members of the Association act honestly and responsibly, avoid a misleading practice and potential conflict of interest with the healthcare professionals, and always act in

compliance with the applicable regulations of Bosnia and Herzegovina, being mindful of the political and social environment within which they act. This Code is aimed at securing the conditions under which the citizens may be certain that the selection of a medicinal product by a healthcare professional was made based on the properties of any product and individual needs of every individual patient.

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## **PART ONE: GENERAL PROVISIONS**

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### **1. Implementation of the Code of Conduct**

1.1. This Code applies to the medicinal product advertising activities towards professional public, the products issued based on prescriptions only, and also to communication between the healthcare professionals and medicinal product manufacturers thereof.

1.2. This Code shall **not apply** to:

- a) the allowed medicinal product advertising activities towards the general public in accordance with the Law on Medicinal Products and Medicinal Devices of BiH and the Rulebook on Advertising the Medicinal Products and Medicinal Devices of BiH which stipulate the method(s) of advertising the medicinal products, and it shall also not apply to the following activities:
  - mandatory labelling of medicinal products, instructions for patients and summary of main properties of the medicinal products approved through the licensing procedure for placing the medicinal product into circulation,
  - correspondence including non-promotional material, which provides an answer to a specific question about a certain medicinal product,
  - informative announcements about the facts and professional material which, for instance, pertain to the changes of packaging, side-effects warnings or other altered safety information, commercial catalogues and medicinal products pricelists, provided that they do not include the advertising elements,
  - any unbiased, objective informing about illnesses, prevention and available treatment methods wherein it is not allowed to state the name of a certain medicinal product,
  - non-promotional information about human health and illnesses,
  - activities which are solely related to the medicinal products issued without a prescription,
  - non-promotional, general information about the medicinal product manufacturers (for example, information intended for investors or present / future employees), including financial data, information about the research and development programmes and discussions on the legislative environment and measures affecting a medicinal product manufacturer and its products,
- b) data on assistance the medicinal product manufacturers provide to the associations of patients under the *EFPIA Code of Practice on relationships between the pharmaceutical industry and patient organisations (amended by decision of the General Assembly in June 2011)*.

1.3. All members of the Association shall be obliged to primarily comply with the provisions of the applicable regulations in Bosnia and Herzegovina governing the medicinal product advertising activities, which have precedence over this Code in all cases of dispute arising from its interpretation or application.

1.4. Apart from the applicable regulations in Bosnia and Herzegovina, this Code is based on the principles foreseen in the following regulations:

- a) IFPMA Code of Pharmaceutical Marketing Practices (2006 Revision), International Federation of Pharmaceutical Manufacturers Associations, revised in 2006 and applicable as from 1 January 2007, as amended and supplemented,
- b) Code of Practice on the Promotion of Prescription-Only Medicines to and Interactions with, Health Professionals),
- c) Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC), EU Official Journal L 311/67, 136/34, as amended and supplemented

1.5. Members of the Association shall be primarily responsible for acting in compliance with this Code, even in cases when in any manner whatsoever they hire the third parties (exp. expert associates, consultants, market research agencies, advertising agencies, public relations agencies, and similar) to, on behalf of members of the Association, perform the activities on thinking out, application and implementation of the activities referred to in this Code.

## 2. Definitions

2.1. This Code includes the terms with the following meaning:

- a) **Member of the Association** – companies and their affiliates having their registered offices in Bosnia and Herzegovina being the members of the Association, which are or may be associated, within the meaning of the Law on Companies, with the companies having their registered offices outside Bosnia and Herzegovina. Within the meaning of this Code, members of the Association and any related companies, constitute a uniform entity to which this Code, that is, the foregoing EFPIA codes, applies.
- b) **Donation**- donation in cash, in kind or services to the healthcare organisations (within the meaning of the healthcare organisation definition below)
- c) **Hospitality** - allowed costs related to attendance to meetings by a healthcare professional, which means, travel costs, food and beverages, accommodation and conference fees.
- d) **Medicinal product** - is any substance or combination of substances, intended for treatment or prevention of human illnesses. A medicinal product shall include a substance or combination of substances which may be administered to people for the purpose of diagnosing, recovery or modification of physiological functions, and for achieving other medically justified goals.
- e) **Medical Department** – a scientific department or persons entrusted within the organisational structure of any member of the Association in charge of giving information about the medicinal products, with giving consents and performing supervision over the implementation of the non-intervention trials involving medicinal products, approving promotional materials / activities, organising and chairing non-promotional meetings, conducting medical training for expert associates and other employees in contact with healthcare professionals;
- f) **International meeting** – a meeting (within the meaning of the meeting definition as stated below) organised and held outside the territory of Bosnia and Herzegovina.
- g) **Non-intervention trial involving medicinal products** – any trial in which a tested medicinal product is prescribed in accordance with the approval for placing it into circulation. Involving patients into a certain therapeutic process is not beforehand defined by a trial plan, instead, it is implemented in accordance with a standard practice, while prescribing a medicinal product is independent on a decision that a patient should be included in the trial. Further diagnostic procedures and the patient monitoring processes are not applied, and the epidemiological methods for the collected data analysis are applied instead.
- h) **Advertising** - any form of information about medicinal products given to general or professional public to encourage prescribing of medicinal products, their supply, sale and consumption, in a written, pictorial, audio, oral, electronic or any other form.
- i) **Transfer of Values** – direct and indirect transfer of values, in cash, in kind or otherwise, made, whether for promotional or other purposes, in connection with the development and sale of prescription-only medicinal products exclusively for human use. Direct transfers of value are those made directly by a Member for the benefit of a recipient or transfers of value made by a Member through an intermediate and whereby the Member knows or can identify the Healthcare Professional or Healthcare Organisation that will benefit from the transfer of value.

- j) **Recipient** – healthcare professionals and healthcare organisations (within the meaning of the quoted terms definitions as stated below);
- k) **Medicinal product manufacturer** – a member of the Association of Research-based Medicine Producers in Bosnia and Herzegovina, its subsidiaries and all related companies within the meaning of the Law on Companies;
- l) **Meeting** – promotional, scientific or professional meetings, congresses, conferences, symposiums, minor business meetings and other similar events including, without limitation, meetings of advisory bodies, visits to research centres or plants, as well as planning and training or meetings of examiners held within clinical and non-intervention trials organised or financed by the medicine product manufactures or a third person on its behalf.
- m) **Professional administrative personnel** – persons performing managerial functions in private and public healthcare organisations, including persons employed with public authorities responsible for the implementation of the pharmaceutical regulations (exp. Agency for Medicinal Products and Medical Devices, Entity Ministries of Health, Cantonal Institutes for Health Insurance, and similar) and appointed into the advisory bodies within the public authorities and institutions (exp. members of ethics and other committees, and similar);
- n) **Expert associate** – persons promoting medicinal products, having university degree healthcare qualifications – including persons hired by the medicinal product manufacturers to perform these activities for their account – including all other representatives of the medicinal product manufacturers who get into contact with healthcare professionals and healthcare organisations;
- o) **Healthcare professional** – persons having healthcare education acquired at the respective Faculties of Medicine, Dental Medicine, Pharmacy-Biochemistry, Healthcare Studies and medical high schools, who prescribe, sell, that is, issue medicinal products, supply pharmacies and other healthcare institutions, that is, private practice, with medicinal products or influence in any way possible the procurement or use of medicinal products, and other professionals in the field of production and retail or wholesale trading in medicinal products and medical devices, as well as persons in the healthcare institution managements. Jointly with professionals employed with the Ministries of Health, in the health insurance organisations and Agency for Medicinal Products and Medical Devices of BiH, they constitute the professional public.
- p) **Healthcare organisation** means:
- a legal entity having its registered office in Bosnia and Herzegovina, established and operating based on the applicable laws and regulations governing the healthcare activities in Bosnia and Herzegovina (hospitals, healthcare centres, health centres and institutions...),
  - educational and scientific healthcare organisations (exp. in the field of medicine, dental medicine, pharmacy-biochemistry and similar field) in which teaching, research or scientific activities are performed,
  - vocational organisations of healthcare professionals joined by them based on the regulations on healthcare professions,
  - associations and other forms of voluntary membership of healthcare professionals, irrespective of the legal form of organisation, towards reaching special interests (other than the organisation of patients, within the meaning of a separate Code).
- 2.2. Unless otherwise stipulated in this Code, terms used and capitalised in this Code shall have the meaning assigned to them in the paragraph above.
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## PART TWO: BASIC PRINCIPLES OF ADVERTISING

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### 3. Authorisation for placing medicinal products into circulation (marketing authorisation)

3.1. It is prohibited to advertise:

- a medicinal product holding no licence for being placed into circulation (marketing authorisation), and
- indication holding no licence for being placed into circulation (marketing authorisation).

3.2. Prohibition referred to in paragraph 3.1 shall not apply to informing about a finished medicinal product which does not hold a licence for being placed into circulation at the professional and scientific meetings and in the professional references, provided that a procedure for granting authorisation for placing the medicinal product into circulation has been initiated, and that only a standard international unprotected name of the medicinal product (INN) is used, without stated the manufacturer. These restrictions do not apply to international meetings held in Bosnia and Herzegovina.

3.3. If the medicinal product manufacturer receives an enquiry about the unauthorised medicinal products/indications from a healthcare professional, it shall be obliged to forward the enquiry to the Medical Department for response.

### 4. Content of the promotional information

4.1. Advertising a medicinal product and overall promotional material must contain essential data on the medicine, identical to those stated in the summary of product characteristic and patient information leaflet approved in Bosnia and Herzegovina.

4.2. Advertising must be accurate, balanced, fair, objective and sufficiently complete so as to enable a healthcare professional to form his own opinion about the therapeutic value of the relevant medicine. It must be based on the latest assessment of the relevant scientific evidence and clearly reflect the content of such evidence. Advertising must not be misleading by way of deviations, exaggeration, unneeded accentuation, omissions or otherwise.

4.3. Advertising must encourage a rational use of medicine, presenting the medicine objectively and without exaggerated descriptions of its properties. Claims that could lead to an opinion that the medicine or its active substance has a special feature, quality or effect must not be stated if such a claim cannot be corroborated by evidence.

4.4. When the following is used in the promotional materials intended for advertising a medicinal product:

- **published studies** – their sources must be clearly indicated;
- **quotations, tables or other material taken from medical and scientific references or from personal communication** – must be transferred verbatim (unless the content is adjusted or altered as a consequence of the requirement for harmonisation with any applicable law or code, in which case it must be clearly stated that the content of the quotation is adjusted and/or amended) and their sources must be stated accurately;
- **pictorial presentations, including graphs, illustrations, photographs and tables adopted from the published studies** – must satisfy the following requirements:
  - (i) the source of a pictorial presentation to be clearly and accurately stated;
  - (ii) to be truly reproduced and, in the case of adjustment or modification, it is necessary to state that the pictorial presentation is adjusted and/or modified to meet the needs of the official languages in Bosnia and Herzegovina;
  - (iii) it must not be misleading in terms of the medicine nature (exp. that it is suitable for administration to children) or with regard to claims or comparisons (exp. by using incomplete or statistically irrelevant information or unusual criteria).



- 4.5. Any comparison of various medicines must be based on the relevant and comparable properties of the product. Any form of unpermitted advertising within the meaning of the Law on Medicinal Products and Medical Devices and the Rulebook on the method of advertising medicinal products and medical devices are prohibited.
- 4.6. The word “**safe**” shall never be used when describing a medicinal product without a required explanation.
- 4.7. The word “**new**” shall not be used when describing a medicinal product or any of its indications for a medicinal product available and advertised on the market of Bosnia and Herzegovina during a period of time longer than 1 (one) year.
- 4.8. Labelling a medicinal product as a “**medicine of choice, frontline medicine**” for a certain indication may only be used based on written instructions (consensus or recommendations) issued by the relevant associations of healthcare professionals – specialists in Bosnia and Herzegovina and, if there are no instructions thereof in Bosnia and Herzegovina, based on the instructions of the European or world umbrella associations of healthcare professionals – specialists, having the BiH associations of healthcare professionals as its members.
- 4.9. It is prohibited to claim that the medicinal product shall not manifest any side-effects and that it is not toxic or that there is no risk of addiction.

## **5. Documentation**

- 5.1. All information presented during advertising must be supported by documentation which, in response to the reasonable requests by the healthcare professionals, must be delivered to the healthcare professional without delay. A request for serving the documentation corroborating the promotional claims should not be answered in the case of information which has already been contained in the medicine-related documentation to which an authorisation for placing the relevant medicine in circulation refers.
- 5.2. Claims on side-effects presented during advertising must be based on available evidence or clinical experience. A request for serving the documentation corroborating the promotional claims should not be answered in the case of requested verifications of those elements which have already be contained in the approved summary of the main properties of the medicine.

## **6. Advertising adequacy**

- 6.1. Medicinal product manufacturers must always adhere to high ethical standards. Therefore, advertising:
- a) must never undermine reputation or weaken confidence in pharmaceutical industry,
  - b) must always consider a special nature of medicinal products and professional profile of persons they refer to,
  - c) must not be such that it could cause violation of the applicable laws and regulations.

## **7. Article 7: Distribution of promotional material**

- 7.1. Advertising of medicinal products may only be performed towards healthcare professionals.
- 7.2. Lists of addressees – healthcare professionals (so-called mailing lists) must be updated on a regular basis and run and maintained in accordance with the provisions of applicable regulations governing the protection of personal data in Bosnia and Herzegovina. A healthcare professional’s request to be deleted from the list of addressees for receiving promotional materials must be met immediately.
- 7.3. It is prohibited to perform advertising by phone, fax, electronic mail and other electronic data transfer systems without a prior written consent of the healthcare professional.

## 8. Advertising Transparency

- 8.1. Disguised advertising is not allowed.
- 8.2. Clinical and non-intervention trials (including those retrospective by nature) and market research must not disguise advertising. The referenced trials and studies must have scientific and educational purpose primarily.
- 8.3. When a medicinal product manufacturer orders, pays or otherwise organises, on its own or through third parties, the announcement of the promotional material in professional magazines, the said promotional material must not be shown as an independent editor's content.
- 8.4. The material pertaining to medicinal products and their use, promotional or not, which is funded by the medicinal product manufacturer must clearly indicate that it is funded by that particular medicine manufacturer.

## 9. Advertising towards population

- 9.1. It is prohibited to advertise medicinal products issued based on a prescription towards the general public, that is, population.
- 9.2. Citizens' individual requests for advice concerning their personal health problems should be rejected and they should be referred to counselling with a healthcare professional.

## 10. On-line advertising

- 10.1. Any website must contain clear data on:
  - identity and contact details (physical and electronic) of the party ordering the website development;
  - the source of all pieces of information contained on the relevant website, date of publication of the source and identity and documentation (including date of receipt of the documentation) on all individual or institutional authors/sources of information published on the website;
  - selection criteria/procedure contained on the website,
  - website users (exp. healthcare professionals, patients, population /public or a combination of possible users), and
  - the website purpose and aim.
- 10.2. The website content must be updated on a regular basis and it must clearly show, with regard to any website and/or topic covered, the date of the latest revision of the relevant content.
- 10.3. The website may, for example, include the following on individual or group/joint websites:
  - a) **genera data on the medicinal product manufacturer** – information of interest to investors, public release media and the public, including financial data, descriptions or research and developmental programmes, discussions on regulatory issues affecting the manufacturer and its products, information about employment and similar. Content of these pieces of information is free and unlimited by this Code or regulations on medicine advertising.
  - b) **health-educational information** – non-promotional information about the characteristics of illness, methods for their prevention and treatment, and any other health-promotion information. This information may refer to medicinal products, provided that the relevant content is balanced and accurate. Information about alternative forms of treatment may be offered, including, where appropriate, information about surgeries, diets, changes of lifestyle and other activities which do not require administration of medicines. Website containing health-educational information must always contain instructions to persons to consult their doctor for further information.
  - c) **Information intended for healthcare professionals also includes promotional information** – if this information is promotional, its content and format must be harmonised with the provisions of this Code and applicable regulations in Bosnia and Herzegovina about medicinal product advertising towards

healthcare professionals. These pieces of information must be clearly marked as information intended to healthcare professionals.

- d) non-promotional information intended for patients and general public** – websites may contain non-promotional information intended for patients and the public concerning the products of the medicinal product manufacturers (including information about indications, side-effects, interactions with other medicines, appropriate administration, clinical trial reports and similar) provided that all pieces of such information are balanced, accurate and consistent with the approved summary of product characteristics. With regard to any such product, a website must contain a complete text of the applicable and approved summary of product characteristics and patient information leaflets. The referenced documents must be posted on the website as an integral part of information about the medicinal product itself or the relevant documents should be referred to in the text itself by including visible links thereof, along with a recommendation to review the related documents. In addition, a website may contain a link to a complete text of any document published by the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina, that is, some other relevant body. Apart from the medicine trade names, standard names (INN) must be used. Such websites may contain links to other websites containing reliable information about the medicinal products, including the relevant bodies' websites and those of the research-oriented health organisations, associations of patients, etc. Such websites must always contain a piece of advice to users asking them to consult healthcare professionals for further information.

- 10.4. **Questions asked via electronic mail:** A website may enable communication with the healthcare professionals and population when further information about medicines or other issues (exp. a feedback about the website itself) are sought via electronic mail. A medicine producer may answer the relevant questions in the same manner as if the questions were received by mail, telephone or other means of communication. Discussion about personal health condition must be avoided in communication with patients and population. Any information about personal health condition disclosed during the communication must be confidential. Where necessary, the answers shall always refer the users to consult their doctor, dentist or pharmacist for further information.
- 10.5. **Links to other websites:** It is allowed to make links to a website of the medicine producer from a website funded by the third parties, however, a medicine producer should prevent linkage of websites intended for the population to the medicine producer's websites which are intended for healthcare professionals. Likewise, links with special websites, including those financed by the medicine producer or third parties, may be established. Links should usually be available from the initial website so that the user becomes aware of identity of the relevant website to which he is being linked.
- 10.6. **Scientific verification:** Medicinal product manufacturers should make sure that truthfulness and harmonisation with this Code (and applicable regulations in Bosnia and Herzegovina) of scientific and medical information prepared for publication on the websites are previously verified. The medicine manufacturer's Medical Department may be entrusted with the referenced verification or such task may be assigned to an adequately qualified person.
- 10.7. A website must satisfy all applicable regulations regulating the protection of data confidentiality and personal data protection.

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## PART THREE: RELATIONSHIPS BETWEEN THE MEDICINE MANUFACTURERS AND HEALTHCARE PROFESSIONALS AND HEALTH ORGANISATIONS

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### 11. Meetings and Hospitality

#### 11.1. Meetings

11.1.1. All meetings organised or financed by the medicinal product manufacturer or a third party acting on its behalf must be organised at an appropriate venue suiting the main purpose of the Meeting, while Hospitality may only be offered if in compliance with the criteria referred to in Article 11.2 of this Code.

For the needs of this Code, **an appropriate venue for holding** a Meeting and an International Meeting held in Bosnia and Herzegovina shall be deemed to be a separate, special-purpose conference centre or – if a conference centre is integrated into the accommodation facility within a group of hotels – a hotel which, according to the applicable regulations on categorisation of accommodation facilities, has no more than 4 (four) stars and which is mainly known for its predominantly business services, all of the foregoing in accordance with the regulations on classification, minimum conditions and categorisation of the hotel group facilities applicable in Bosnia and Herzegovina and its entities.

11.1.2. When selecting a hotel referred to in the paragraph above of this Article 11.1.1, it should be primarily guided with the fact that its offer is predominantly business-oriented, having adequate congress or hall, depending on the number of participants, wherein an appropriate venue for the Meetings shall certainly not be in a hotel with predominantly spa, wellness and entertaining services.

11.1.3. In the case of doubt in the hotel appropriateness, the Ethics Council of the Association shall be authorised to provide an interpretation thereof.

11.1.4. The main purpose of the Meeting must be to exchange information of educational, professional and scientific character, while promotional and all other elements must be secondary relative to the main purpose of the Meeting. Therefore, professional elements must be prevailing.

11.1.5. It is prohibited to organise or financially support the organisation of International Meetings, other than in the following cases:

- a) if the majority of the invited participants come from other countries and, considering the countries of origin of most of the participants, it is logistically more justified to hold a Meeting outside Bosnia and Herzegovina;
- b) if, considering the location of a significant source or expert being the subject matter or a topic of the Meeting, it is logistically more justified to hold a Meeting outside Bosnia and Herzegovina.

11.1.6. The fact that a medicinal product manufacturer is a (co)host of the Meeting must be published in all documents pertaining to the Meeting, including all published Collections of Papers and other written materials. A sign of the (co)host of the Meeting must be visibly displayed on all materials and places at which the Meeting is to be held.

#### 11.2. Hospitality

11.2.1. For all forms of Hospitality, the medicinal product manufacturers are obliged to comply with the following criteria:

- a) Hospitality shall only be paid for a healthcare professional attending the Meeting (passively or actively, hired within the meaning of Article 14.1 of this Code) – not for persons who could possibly accompany him (family members or any other third party);

- b) the Hospitality costs shall be paid in the amount of their actual value, based on the invoices issued by suppliers, therefore, it is recommended to the medicinal product manufacturers to comply with the following rules when rendering a decision on payment of Hospitality:
- travel costs may only be paid for the economy class flight and, exceptionally, for a business class, only if a one-way flight from the residence of the Meeting participant to the Meeting destination lasts longer than 4 hours in continuity,
  - when selecting accommodation at the Meeting location it should primarily be selected as an accommodation unit which, by its quality categorisation, matches a 4-star hotel maximum, and which predominantly offers business programmes, that is, provided that the Meeting shall be held there, as referred to in the provision 11.1.1.,
  - accommodation costs may only be paid if necessary due to the length of the entire Meeting (for one staying overnight, the Meeting should last 5 hours at least) or because of the time of the commencement or closure of the Meeting (exp. morning and evening Meetings), as well as in cases when the place of residence of the participants is more than 50 km away from the Meeting venue.
- c) Food and beverage costs during the Meeting shall be paid:
- up to the maximum amount of BAM 100 per person and a meal; and
  - this form of Hospitality must be restricted to refreshments and/or food and beverages during the Meeting.

In the case of organisation of the International Meetings, the maximum meal costs in the country in which the International Meeting is to be held (that is, the "host country" value criteria) shall apply.

- d) During the Meeting, it is not allowed to organise or finance the entertaining and social events and activities related to entertainment, other than modest forms of entertainment during the refreshments and/or meal breaks.

## **12. Prohibition on giving gifts to healthcare professionals**

- 12.1. It is prohibited to give, offer or promise gifts to healthcare professionals regardless of the related value, even a symbolic one. Within the meaning of this Code, gifts shall be deemed to be money, objects, rights, services and other forms of receipts in reality given to healthcare professionals without compensation.

## **13. Informative and educational materials and cases for medical use**

- 13.1. It is allowed to give informative or educational materials, provided that the individual gross purchase value of such materials is not higher than the amount the officials are not obliged to report on in accordance with the Law on Conflict of Interests in Governmental Institutions of BiH and that the referenced materials are important for the practice of the healthcare professionals, that is, healthcare organisations, and that they also include a wellbeing of patients. Giving of such materials shall not be deemed to be encouragement, prescription, issuance, selling or consumption of the medicinal products.
- 13.2. It is allowed to give objects for medical use, intended for direct education of healthcare professionals and also for wellbeing of patients, provided that the individual gross purchase value of such objects does not exceed the amount specified in the Law on Conflict of Interests in the Governmental Institutions of BiH and that giving of such objects shall not decrease the standard operating costs of the Recipient.
- 13.3. Giving of objects referred to in the previous provision of this Article may not, in its scope, constitute a circumvention/avoidance of prohibition on giving of gifts to healthcare professionals referred to in Article 12 of this Code.

## **14. Sending of healthcare professionals to Meetings and International Meetings**

14.1. Medicinal product manufacturers may enable the healthcare professionals to take part in Meetings and International Meetings, regardless of whether the medicinal product manufacturer is (co)host of such a Meeting or not, provided that the following requirements are satisfied while performing this activity:

- a) a healthcare professional must not be compensated for the time spent at the Meeting,
- b) sending a healthcare professional to the Meeting must not serve as the means for influencing encouragement of recommendation, prescription, buying, procurement, selling or issuing a medicinal product,

14.2. In the case of International Meetings, for legality of all payments to a healthcare professional made by the medicinal product manufacturer, the rules of the country in which the referenced healthcare professional performs his profession shall apply, and not the rules of the country in which the International Meeting is held;

14.3. When sending a healthcare professional to Meetings, it is allowed to pay Hospitality under the conditions referred to in the provision of Article 11.2. of this Code. In the case of International Meetings, it is allowed to pay Hospitality in accordance with the rules of the country in which the International Meeting is held.

## **15. Donations to Healthcare Organisations**

15.1. Donations to Healthcare Organisations are only allowed if the following cumulative requirements are met:

- a) they are given with the aim of providing support to health care or research activity , and
- b) they are made in writing, wherein the parties are obliged to keep the documents related to the performed legal transaction; and
- c) that the Healthcare Organisation is not obliged to do a reciprocal favour, that is, that the donation is not the means for stimulating recommendation, prescription, buying, procuring, selling or issuing a medicinal product, and
- d) that all approvals by the relevant public bodies are obtained, if such approvals have been foreseen in the applicable regulations of Bosnia and Herzegovina.

15.2. It is prohibited to give gifts to individual healthcare professionals employed with the Healthcare Organisations, under the requirements of this Article. The relevant healthcare professionals may only be enabled by the medicinal product manufacturer to take part in the Meetings, under the conditions referred to in Article 14 of this Code.

## **16. Services of Healthcare Professionals and Healthcare Organisations**

### **16.1. Services of Healthcare Professionals**

16.1.1. Medical product manufacturers may hire healthcare professionals, as a group or individuals, to provide the following types of services: presentations / speeches at the Meetings and chairing the Meetings, taking part in the medicinal/scientific researches, clinical trials or training, taking part in the advisory bodies meetings and in the market researches, if such participation includes the payment of allowance and/or travel costs. For all forms of ordering the foregoing services from the healthcare professionals, it is necessary, to the extent relevant for an individual relationship, to be guided by the following criteria:

- a) services to be provided for educational, research or scientific purposes;
- b) legitimate interest of the medicinal product manufacturer in terms of the need to order certain services from a potential implementer / service provider should be defined beforehand;
- c) by a written agreement, it is necessary to agree in advance upon the service provision requirements, along with a description of the subject matter and the price/compensation for the work performed,

- d) a service provider selection criterion should be directly connected with the established need for a certain service, therefore, persons entrusted with selection of service providers should have knowledge required for the assessment of the healthcare professional's capacities to meet the established need;
- e) the number of healthcare professionals to be hired for service provision must not exceed the number in relation to which it is reasonable to assume that it will be sufficient for meeting the established need;
- f) a medicinal product manufacturer shall be obliged to keep written documents on services provided and it shall use them in an appropriate manner;
- g) ordering of services from healthcare professionals must not be an encouragement for recommendation, prescribing, buying, procurement, selling or issuance of a medicinal product; and
- h) a compensation for a service provided must be reasonable and match the actual market value of the service offered. With that regard, agreements on advisory services must not be used for making unjustified payments to healthcare professionals.

16.1.2. If a hired healthcare professional is sent to a meeting (international or other) in his capacity as an advisor or service provider, the provisions of Article 11 (Meetings and Hospitality) of this Code shall apply appropriately.

16.1.3. The Association strongly recommend to its members that the written agreements on hiring the healthcare professionals, regardless of the employment status of the healthcare professional (full-time employment with the Healthcare Organisation or part-time employment with a member of the Association if, during the remaining working hours he still performs the professional activities), should always contain an obligation of the Healthcare Professional to, whenever addressing the public, either in writing or orally, with regard to services being the subject matter of the agreement with the medicinal product manufacturer or with regard to issues pertaining to the medicinal product manufacturer itself, he should always state that a specific medicinal product manufacturer hired him.

## 16.2. **Services of Healthcare Organisations**

16.2.1. Contracts between the medicinal product manufacturers and Healthcare Organisations based on which the relevant Healthcare Organisations provide any kind of services to the medicinal product manufacturer are allowed provided that the relevant services are offered:

- a) for educational, health, training or research purposes, and
- b) that the services are not used for stimulation of recommendation, prescribing, buying, procurement, selling or issuance of the medicinal product.

## 17. **Non-interventional studies of medicines**

17.1. Non-interventional studies of medicines which include collection of data on patients from individual Healthcare Professionals or groups of Healthcare Professionals must satisfy the following criteria:

- a) studies to be performed for scientific purposes;
- b) that there exists a written (i) trial plan (protocol) and (ii) contracts between the Healthcare Professionals and/or the Organisation in which the trial takes place as one party and a commercial company ordering the trial as the other, which contracts shall define the subject matter and price /compensation for the services performed;
- c) a reward for the service performed must be reasonable and match the actual market value of the service provided;
- d) medicinal product manufacturers shall be obliged to obtain an approval for carrying out the non-interventional studies from the Ethics Committees of the Clinical Centres and hospitals where the trial takes place and to report to the Clinical Trial Committee of the Agency for Medicinal Products and Medical Devices of BiH and to obtain all other approvals and/or meet all of the remaining obligations stipulated in the applicable regulations in Bosnia and Herzegovina about carrying out the non-interventional studies;
- e) medicinal product manufacturers are obliged to comply with the applicable regulations on the protection of personal data;

- f) carrying out the trial must not be an encouragement for recommendation, prescribing, buying, procurement, selling or issuance of the medicinal product;
- g) the trial plan must be approved and its implementation monitored by the Medical Department of the medicinal product manufacturer (pursuant to Article 20 of this Code);
- h) the party ordering the trial or a third party must analyse the trial results and prepare a report which the Medical Department shall be obliged to publicise and keep for a reasonable period of time. A medicinal product manufacturer shall be obliged to forward a summary report to all Healthcare Professionals who participated in the trial and to make it available to self-regulatory bodies of the industry and/or bodies in charge of monitoring the implementation of the Code, at their request.

17.2. To the extent to which it is possible to implement it, the medicinal product manufacturer shall comply with the criteria referred to in the provision 17.1 and while performing all other types of trials, including the epidemiological trials and other trials which are retrospective in nature. In any case while performing these trials, the provision 16.2 (Services of Healthcare Organisations) shall apply.

## **18. Distribution of samples**

18.1. Upon their written request, Healthcare Professionals may be provided with a free sample of the medicinal product to familiarise themselves with the medicinal product, only once in a year in the amount of not more than 2 (two) smallest original packaging, while also adhering to other rules for distribution of free samples of the medicinal product as stipulated in the applicable regulations in Bosnia and Herzegovina. Free samples of the medicinal product must not be distributed at all for the purpose of encouragement of recommendation, prescribing, buying, procurement, selling or issuance of the medicinal product. A free trial sample of the medicinal product may only be given to a Healthcare Professional who may initiate a treatment by applying that medicinal product or who may prescribe such medicinal product.

18.2. Medicinal product manufacturers must have in place the appropriate systems for monitoring and reliability of samples they distribute and also of all medicinal products held by the expert associates.

18.3. It must be clearly indicated on every sample that it concerns a sample, stating: "a free sample – not for sale", and every sample must be accompanied by an instruction for patients and an approved summary of the main properties of the medicinal product.

18.4. Medicine samples containing narcotic drugs and other psychotropic substances must not be distributed, based on the applicable regulations of the relevant authorities.

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## **PART FOUR: INFORMATION DISCLOSURE**

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### **19. Disclosure obligation**

**19.1.** Each Member of the Association shall document and disclose Transfers of Value it makes directly or indirectly to or for the benefit of a Recipient in relation to the activities as described in more detail in Article 21

**19.2.** The Transfers of Value made within the framework of the following activities shall not be subject to the disclosure obligation referred to in the previous paragraph:

- (a) advertising and informing on over-the-counter medicines;
- (b) activities not specified under Article 21 of this Code, including informational and promotional materials and items of medical utility listed under Article 13, costs of food and beverages referred to in Article 11 (2.c) of this Code up to the value established therein, supply costs of samples referred to in Article 18 of this Code, and
- (c) activities of regular purchase and sales taking place between the Medicinal Product Manufacturers and Healthcare Professionals (e.g. Pharmacists), or Healthcare Organisations.



**19.3** For the purpose of meeting the Disclosure Obligation referred to in this Article, as well as obligations set forth by the current Law on the Protection of Personal Data, Members of the Association are advised to obtain a Recipient's consent for disclosure of information on Transfers of Value in terms of this Code, in all related cases and regardless of whether the Transfers of Value are carried out based on a written contract or informally, either under an adequate contractual provision or a separate document.

## **20. Frequency, form and other requirements pertaining to disclosure of Transfers of Value**

20.1. Disclosure of information on Transfers of Values shall be made on an annual basis and, therefore, for the needs of this Code, the disclosure period shall be equal to a calendar year (hereinafter: **Reporting Period**). The first Reporting period shall be the 2019 calendar year.

20.2. The information on Transfers of Values shall be disclosed within six months after the end of the relevant Reporting Period and shall be available to public for a maximum of three years starting from the day such information is first disclosed, unless (i) a shorter period of availability of the information disclosed is required under the regulations on the protection of personal data and other applicable regulations or (ii) the Recipients' consent regarding a specific disclosure has been revoked.

20.3. With the aim of ensuring consistency of disclosures, the Code shall set forth a compulsory content of all disclosure templates in form of Annex 1, which shall apply to all disclosures across Bosnia and Herzegovina. Any departure thereof shall be possible only in exceptional cases when such departure is a consequence of the mandatory rules.

20.4. Disclosures shall be made on the central platform at the website organized by the Association for that purpose and/or on the websites of each Association Member, including the right to unlimited access to the website via Internet. Information to be disclosed on the website shall be presented, to the extent possible, using the Template from the Annex 1.

20.5. The disclosures shall be made in one of the official languages in use in BiH whereas, pursuant to the Association's Decision, the website may be designed as bilingual, including an option of reviewing the disclosures in English language as well.

20.6. Disclosures shall be published in a country where the Recipient has its place of residence or practice, that is, headquarters, regardless of whether the Transfer of Values for the benefit of a Recipient was carried out in the country of his residence/headquarters or in a third country.

20.7. Members of the Association shall keep records on business events related to the disclosures in accordance with the applicable BiH regulations on keeping and processing book-keeping data, and shall safeguard the information for a minimum of five years after the end of the relevant Reporting Period. The five-year deadline for safeguarding the records on Transfer of Values shall not apply in case when mandatory rules in the area of protection of personal data and other regulations on mandatory deadlines for safeguarding business documents set out shorter deadlines for keeping the relevant documents.

## **21. Disclosure arrangements**

### **21.1. Individual disclosure**

Except as explicitly provided for by this Code, all Transfers of Value shall be disclosed on an individual basis meaning that an insight into information shall be possible on each Transfer of Value made for the benefit of a clearly identified, individual Recipient in relation to some of the forms of cooperation referred to in Items 21.1.1 and 21.1.2. of this paragraph during each Reporting Period. Such Transfers of Value may be disclosed as an

aggregate report for each form of cooperation as well, but only under if an individual report can be presented upon the request of (i) the relevant Recipient and (ii) the competent public authorities.

**21.1.1. Transfers of Value to Healthcare Organisations**, encompass all payments made in relation to the following activities:

- (i) Donations referred to in Article 15 of the Code;
- (ii) Costs incurred in relation to Meetings, which are paid directly to Healthcare Organisations or third persons, including costs referred to in Article 14. (Sending of Healthcare Professionals to Meetings and International Meetings) such as:
  - (a) Registration fees;
  - (b) hospitality costs referred to in Article 11.2., taking into account exceptions referred to in Article 19.2.(b), and
  - (c) sponsorship amount set forth by the sponsorship contract between Medical Product Manufacturer and Healthcare Organisation or a third person organising the Meeting on behalf and for the account of the Healthcare Organisation;
- (iii) the amount of fees for Healthcare Organisations' services referred to in Article 16 (2) of this Code, paid on the basis of a service provision contract with Healthcare Organisations and the amount of all other allowances that may not be qualified under the aforementioned categories of activities. In that case, there shall be separate disclosures for
  - (a) the value of a fee paid for the Healthcare Organisation's services;
  - (b) the value of costs pertaining to execution of relevant service, if they have been contracted.

**21.1.2. Transfer of Value to Healthcare Professionals**, encompasses all payments made with regards to the following activities:

- (i) Registration fees;
- (ii) Hospitality costs, taking into account exemptions referred to in Article 19.2.(b);
- (iii) the amount of Healthcare Professionals' fees referred to in Article 16.1. and 16.1.2. (if the Medical product Manufacturer knows the identity of the Healthcare Professional taking part in the market research activities) of this Code, paid on the basis of a service provision contract with Healthcare Professionals as well as the amount of all other allowances that may qualify under the aforementioned categories of activities. In that case, separate disclosures shall be made on
  - (a) the value of the fee paid for the Healthcare Professionals' services;
  - (b) values of costs related to execution of relevant services, if they have been contracted.

## **21.2. Aggregate disclosure**

21.2.1. When, due to certain legal obstacles, information on Transfer of Value – that could otherwise be disclosed pursuant to individual disclosure obligation referred to in the previous paragraph – cannot be disclosed individually, it shall be disclosed on an aggregated basis. The aggregate disclosure of information implies disclosure enabling, for every form of cooperation, an insight into: (i) a total number of Recipients, on an absolute basis and as a percentage of all Recipients, and (ii) the total amount of the value transferred to the related Recipients.

21.2.2. The Research and Development Transfers of Value made during each Reporting Period shall be disclosed on an aggregate basis. All costs indisputably related to research and development activities can be included in the aggregate amount under the “Research and Development Transfers of Value” category.

21.2.3. In case of indirect Transfer of Value to Healthcare Professional through Healthcare Organisation, the disclosure obligation shall be met if the information is published once, under individual disclosure arrangement, pursuant to the individual disclosure obligation referred to in Article 21.1.2..

## **22. Methodology**

Each Member of the Association shall develop and publish individually a brief overview of the methodology used in preparing of reports on Transfers of Value and the method of identifying Transfer

of Value for each of individual forms of cooperation referred to in Articles 21.1.1 and 21.1.2. The overview, which may include an overall review of and all specific features pertaining to business operations in Bosnia and Herzegovina, shall describe the recognition methods applied by each Association Member and should also include the treatment of multiannual contracts, taxation-legal aspects, currency and exchange issues and all other issues pertaining to payment timeframe and the final amount of the Transfers of Value, for the purpose of meeting the obligations set forth in the Code.

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## **PART FIVE: ADVERTISING SERVICE ORGANISATION**

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### **23. Expert associates**

- 23.1. All medicinal product manufacturers must secure that expert associates – including subcontractors (persons hired by the medicinal product manufacturers to perform these activities based on the contract) – familiarise themselves with the content of this Code and all applicable regulations in Bosnia and Herzegovina, to be adequately trained to perform these activities and to have sufficient professional knowledge about the medicinal products they promote to offer accurate and complete information.
- 23.2. Expert associates must perform their tasks in a responsible and ethical manner.
- 23.3. Expert associates shall be obliged, whenever they visit a Healthcare Professional, to deliver the latest approved summary of the main properties of the medicinal product for all medicinal products they present during the visit.
- 23.4. Expert associates provide the medicinal product manufacturer with a feedback they receive concerning the use of the medicinal product, which particularly refers to side-effects. Expert associates must forward to the Medicine Department all enquiries about the medicinal product which go beyond the approved summary of the main properties of the medicinal product.
- 23.5. Expert associates must take care that the dynamics, time and duration of their visits to Healthcare Professionals and Healthcare Organisations, and the manner in which they pay visits, do not disturb the standard work process of the visited natural and legal persons.
- 23.6. Expert associates must not use any incentives or fraudulent methods to secure the term for paying a visit to a Healthcare Professional. While talking to a Healthcare Professional or negotiating the time for the visit, expert associates must take care from the very beginning of the dialogue to make sure that a Healthcare Professional is not misled about their identity and the identity of the manufacturer of the medicinal product they represent.

### **24. Medical Department**

- 24.1. All medicinal product manufacturers must have their Medical Departments. However, the medicinal product manufacturers have discretion in deciding on the organisational structure of the referenced Department taking into account the actual organisational and available human resources. A Medical Department must employ at least one medical doctor, dentist or pharmacist, while the remaining staff of the Medical Department must have a degree in the field of healthcare. A Medical Department shall approve the final version of the promotional material and confirm that it is consistent with the requirements of this Code and any other applicable regulation, in accordance with the approved summary of the medicinal product properties, and that it objectively and truthfully presents the facts about the medicinal product. Besides, the Medical Department shall be responsible for the implementation of all sorts of clinical trials of the medical product, including a review of all obligations arising from such researches.
- 24.2. Every medicinal product manufacturer must appoint at least one relevantly experienced employee to be tasked with supervising the medicinal product manufacturers over the implementation of the

provisions of this Code, and to provide the Association with a copy of such decision and any amendments and supplements thereof.

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## **PART SIX: PROCEDURE IN THE CASE OF VIOLATION OF THE CODE**

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### **25. Two-instance procedure**

Members of the Association are aware that, for public trust in the integrity of the members, it is essential to comply with the rules of this Code. Further provisions regulate a two-instance procedure to be conducted by:

- a) **Ethics Council** in the first instance, and
- b) **Assembly of the Association** in the second instance

### **26. Appointment of the Ethics Council**

26.1. Ethics Council consists of three members - a president and 2 members. The President shall be appointed pursuant to provision 26.2, whereas the remaining two members shall be appointed on an *ad hoc* basis for every single case to be reviewed before the Ethics Council in accordance with the provision set out by Article 26.3.

26.2. The President of the Ethics Council shall not be in a working relation with any Member, Association or any other third party dealing with production, import or sale of Medicinal Products, and shall be appointed by the Association Assembly for a two-year term. .

26.3. Upon receiving a report on violation, the President of the Ethics Council shall elect the remaining two members of the Ethics Council, one:

- (i) one member from the Association's Working Group for Legal Affairs and Compliance, in alphabetic or other order, being mindful of the conflict of interest in that particular case; and
- (ii) one member as representative of the HCP's, patient organisations or other stakeholders, depending on the circumstances of the case.

### **27. Report for violation of the Code provisions**

27.1. **The right to submission:** All members and non-members are entitled to submission of a report for violation of the provisions of the Code.

27.2. **Report acceptance:** It is possible to file a report against a Member of the Association only with regard to the alleged violations committed as of the date on which this Code of Conduct entered into force and the members of the Association began to implement it.

27.3. **Statute of limitations:** A procedure for the establishment of a member's responsibility for violation of the provisions of the Code may be instigated within 1 (one) year counting from the date of violation of the Code to the date of filing a report. Absolute statute of limitations shall take effect following expiry of 3 (three) years from the specific violation of the Code.

27.4. **Content and form of the report:** A procedure for violation of the Code shall be instigated by a written report forwarded to the Director of the Association to the address of the Association's registered office or by e-mail to the President of the Ethics Council which shall be available at the Association internet web page. The report should contain as many details as possible about the report submitting party and a member to which the report refers, a factual description of the reasons for the report, and evidence supporting the factual allegations and the Code provisions which are, in the opinion of the report submitting party, violated by the acts of the member to which the report pertains.

## 28. Preliminary examination of the Report

- 28.1. The Director of the Association shall preliminary examine the Report and, if the Report is appropriately developed, complete and filed in a timely manner, he shall forward it to the President of the Ethics Council for further procedure.
- 28.2. If the Director of the Association finds that the Report does not contain even minimum data referred to in the provision 27.4, he shall ask the report submitting party in writing to supplement the Report, setting a 15 (fifteen) –day deadline, counting from the date of receipt of the request, for the report to be supplemented. If the report submitting party fails to comply with the request for amendment and further development of the report within a set deadline, the Director of the Association shall forward the report to the President of the Ethics Council for further procedure.

## 29. First instance procedure – part one

- 29.1. A President of the Ethics Council may dismiss the Report as inadmissible if it does not refer to the violations of the Code or if it is evident that, by the Report, the possibility of reporting under this Code is seriously abused.
- 29.2. If he does not dismiss the Report, the President of the Ethics Council shall, within 8 (eight) days, invite the reported member of the Association to provide a written statement on the circumstances he has been charged with.
- 29.3. The reported member of the Association shall be obliged, within 15 (fifteen) days from the date of receipt of the invitation to make a comment and forward the comment to the President of the Ethics Council to the address of the Association's registered office. The written comment may contain:
- a) a declaration on admission of violation, along with the assumed obligation to immediately discontinue the actions constituting the violations and to refrain from the activities that could lead to the repeated violation, signing the statement on termination of violation of the Code (hereinafter: **Statement on Termination**);
  - b) a statement challenging the ill-founded Report on the alleged violation of the Code, stating the reasons thereof.
- 29.4. If the President of the Ethics Council finds that a statement challenging the ill-founded Report on the alleged violation is grounded, he shall render a Conclusion accordingly and forward it to the report submitting party and the member to which the Report pertains.
- 29.5. By a Conclusion referred to in the provision 25.4, the President of the Ethics Council shall invite him to comment the position of the President of the Ethics Council about the non-existing violation within 7 days, counting from the receipt of such conclusion.
- 29.6. The President of the Ethics Council shall convene a session of the Ethics Council in the following cases:
- a) if a reported Member of the Association fails to respond to the invitation to comment the alleged violation as referred to in the provision 29.3; or
  - b) if he finds that a statement challenging the ill-founded Report on the alleged violation is ungrounded; or
  - c) if the report submitting party objects in his comment referred to in the provision 25.5. the conclusion of the President of the Ethics Council on non-existing violation.

## 30. First instance procedure – part two

- 30.1. The President of the Ethics Council shall provide the members of the Ethics Council with a report and documents provided by the report submitting party and the reported Member of the Association, not later than 8 (eight) days before the session of the Ethics Council.
- 30.2. The Ethics Council shall conduct a procedure for the establishment of facts based on the received and collected documentation and it shall decide during the procedure on the need to receive additional comments of the parties to the procedure and presentation of other evidence (exp. by examination of the parties and witnesses, review of the documents and similar) in order to fully establish the state of facts and receive the answer to the question as to whether in that particular case the Code was violated.
- 30.3. In the case that it is needed to interview the parties or third parties, a session of the Ethics Council at which the examination will take place will be held within 45 (forty five) days at the latest from the date of the decision on convening the Ethics Council session. The Ethics Council shall in a timely manner forward the invitation for examination to the parties to the procedure and to persons it intends to hear, which invitations shall contain the date, venue and time of examination, giving them the possibility to make a written statement thereof if they are prevented from appearing to be examined. If the reported Member of the Association fails to respond to examination without a justified reason, the Ethics Council shall render a decision based on the information in the case file.
- 30.4. If, during the procedure, the Ethics Council finds that the report is evidently reasonable, it may invite the reported Member of the Association to submit a Statement on Termination in accordance with the provision 25.3. of the Code.
- 30.5. The Ethics Council shall be obliged to conduct the first instance procedure and to render a decision on the report as soon as possible and not later than within 120 days, counting from the date of receipt of the Report by the Director of the Association. If the Ethics Council fails to render a decision and deliver it to the party within the said deadline, the Director of the Association must, within 8 days from the expiration of 120 days, notify in writing the President of the Ethics Council in the specific case to return the entire case file to the Director of the Association.

The Director of the Association undertakes to inform the Members of the Association accordingly so that making a decision on the case would be put on the agenda of the first to come session of the Association, which is to decide on accountability of the reported member (the reported member and the member submitting the report are excluded from voting on that item on the agenda at that session).

### **31. Decisions of the Ethics Council on the report**

- 31.1. The Ethics Council may render the following decisions:
- a) a decision to dismiss the report as ungrounded if the action being the subject matter of the report does not constitute a violation of the Code or if there exist the circumstances which exclude responsibility of the reported member of the Association or if there is no evidence to prove that the reported member committed the violation or if it is established that the reported member did not commit the violation,
  - b) a decision to find the reported Member of the Association guilty for the violation of the Code,
  - c) a decision on cancellation of the procedure if it is established that there is no sufficient evidence to prove that the reported Member of the Association is reasonably suspected of having committed the violation of the Code which is the subject matter of the report.
- 31.2. A decision of the Ethics Council shall be rendered by majority vote of all members.
- 31.3. A reasoned written decision of the Ethics Council shall be delivered to the report submitting party and the reported Member of the Association, and it shall mandatorily include a legal remedy – the right to appeal.

### **32. Right to appeal**

- 32.1. Against a decision of the Ethics Council rendered in the first instance procedure, an appeal may be filed by the following:
- a) a report submitting party only in the case of a decision dismissing the report as ungrounded, however, an appeal of the report submitting party against the pronounced sanctions ( type and scope) is inadmissible, and
  - b) the accused member of the Association.
- 32.2. An appeal shall be filed within 15 days, counting from the date of receipt of a written copy of the Ethics Council's decision.
- 32.3. An appeal shall be filed with the Director of the Association who shall, having verified if the appeal was filed by the appellant in a timely manner, prepare the case file for the session of the Assembly of the Association and notify the Members of the Association accordingly.
- 32.4. If the appeal has not been filed in a timely manner, the Director of the Association shall forward the appeal to the President of the Ethics Council to render a decision on dismissal of the appeal.

### **33. Second instance procedure – deciding on the appeal**

- 33.1. If the appeal is filed within a set deadline, the Director of the Association shall forward the entire case file to the President of the Association Assembly to put the case on the agenda of the first to come session of the Assembly of the Association. At that session of the Association Assembly, the President of the Ethics Council or one of the members shall be a case reporting member, thereafter a discussion and voting about the appeal shall be held.
- 33.2. Assembly of the Association may render the following decisions:
- a) dismiss the appeal as ungrounded and confirm a decision of the Ethics Council;
  - b) cancel and modify, in its entirety or in part, a decision of the Ethics Council relative to the decision itself or the sanctions imposed.
- 33.2.1. The Assembly shall render decisions with simple majority vote of all present voting members of the Assembly.
- 33.3. A decision of the Assembly on the appeal is final and no appeal lies from it.

### **34. Sanctions**

- 34.1. The Ethics Council and the Assembly of the Association shall impose the following sanctions in their decisions by which they pronounce a reported Member of the Association guilty:
- a) warning;**
  - b) notification** to the company founding the Member of the Association of the Association's binding decision finding that Member of the Association guilty of violation of the Code;
  - c) publication of a decision** of the Ethics Council and the Assembly of the Association on the website of the Association in local language and its summary in English language;
  - d) exclusion the Member** from the Association.
- 34.2. Sanctions foreseen in this Code may also cumulate.
- 34.3. When establishing and weighing sanctions, the following aspects should be taken into account:
- a) violation gravity,
  - b) potential effect of violation to the public perception of integrity of Members of the Association,
  - c) is it onetime or a repeated violation of the Code by the Member of the Association,
  - d) consequence of the imposed sanction for the Member of the Association,
  - e) to which extend the accused member of the Association attempted to fight against the Code violations in his organisation,

- f) internal sanctions and organisational measures taken and implemented by the accused Member of the Association, or he had them on his mind as a reaction to violation the report refers to, in general and in this specific case
- g) overall behaviour and cooperation of the accused Member of the Association during the procedure before the Association.

1. **35. Obligation to keep the current procedures secret**

35.1 All those involved in the procedure, members of the Ethics Council, members of the Working Group for Legal Affairs and Compliance and the Regulatory Group, Management Board and persons who are familiar with the procedure in any way possible and connected with the work of the Association, shall be obliged to keep data on all activities and information they reach secret.

**36. Reporting to the relevant authorities**

36.1 Depending on the nature of the committed violation, especially in the case of the existence of grounded doubt that, by violating the Code, the applicable regulations on medicinal products and medicine devices and their advertising, and other regulations, has also been violated, the Ethics Council may report to the relevant authorities accordingly: the Agency for Medicinal Products and Medical Devices of BiH, Ministry of Health of FBiH and RS, Health Department of the Brčko District of Bosnia and Herzegovina, that is investigation authorities, about the acts for which minor offence, that is, criminal accountability is foreseen.

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**PART SEVEN: FINAL PROVISIONS**

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**37. Final provisions**

- 23.1. 37.1 Coming into effect of this Code shall repeal the Code of Conduct of Research-based Medicine Producers, No.: 02/19 of 9 September 2016.
- 23.2. 37.2 This Code shall take effect on the date of issue and, as of that date, it shall become binding on all Members of the Association.

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Reference: 012/18  
Done in Sarajevo, on 22 June 2018

President of the Assembly  
Jasmin Šarić





**ANNEX 1**

**Disclosure Template  
(in accordance with Article 20 (3) of the Code)**

<b>Date of publication:</b>											
Full Name (Ar. 19.1.)	HCPs: City of Principal practice HCOs: city where registered (Ar. 20.6)	Country of Principal Practice (Ar. 20.6. in conjunction to Ar. 21.)	Principal Practice Address (Ar. 20.6.)	Unique country identifier (optional) (Ar. 20.6.)	Donations to HCOs (Ar. 21.1.A. (i))	Contribution to costs of Events (Ar. 21.1.A.(ii) i 21.1.B(i))			Fee for service and consultancy (Ar. 21.1.A.(iii) i 21.1.B(ii))		TOTAL OPTIONAL
						Sponsorship agreements with HCOs//third parties appointed by HCOs to manage and Event	Registration Fees	Travel and Accommodation	Fees	Related expense agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract	
<b>INDIVIDUAL NAMED DISCLOSURE – one line per HCP</b> (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	Annual amount	Annual amount	Annual amount	Annual amount	
Dr. B					N/A	N/A	Annual amount	Annual amount	Annual amount	Annual amount	
etc.					N/A	N/A	Annual amount	Annual amount	Annual amount	Annual amount	
<b>OTHER, NOT INCLUDED ABOVE – where information cannot be disclosed on an individual basis due to legal reasons</b>											
Aggregate amount attributable to Transfers of Value to such Recipients Ar. 21.2.					N/A	N/A	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs	Optional
Number of Recipients in aggregate disclosure – Ar. 21.2.					N/A	N/A	Number	Number	Number	Number	Optional
% of the number of Recipients included in the aggregate disclosure in the total number of Recipients – Ar. 21.2.					N/A	N/A	%	%	%	%	N/A
<b>INDIVIDUAL NAMED DISCLOSURE – one line per HCO</b> (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)											
HCO1					Annual amount	Annual amount	Annual amount	Annual amount	Annual amount	Annual amount	Optional
HCO2					Annual amount	Annual amount	Annual amount	Annual amount	Annual amount	Annual amount	Optional
etc.					Annual amount	Annual amount	Annual amount	Annual amount	Annual amount	Annual amount	Optional
<b>OTHER, NOT INCLUDED ABOVE- where information cannot be disclosed on an individual basis due to legal reasons</b>											
Aggregate amount attributable to Transfers of Value to such Recipients Ar. 21.2.					Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Optional
Number of Recipients in aggregate disclosure – Ar. 21.2.					Number	Number	Number	Number	Number	Number	Optional
% of the number of Recipients included in the aggregate disclosure in the total number of Recipients – Ar. 21.2.					%	%	%	%	%	%	N/A
<b>AGGREGATE DISCLOSURE</b>											

<b>Research and Developmen t</b>	Transfer of Values for Research and Development as defined in Article 21.2.2.	TOTAL AMOUN T	Optional
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