ASSOCIATION OF THE RESEARCH-BASED PHARMACEUTICAL MANUFACTURERS IN BULGARIA

ARPharM Innovative Solutions for the Bulgarian Patient

Code of Ethics of the Research-Based Pharmaceutical Industry in Bulgaria

Adopted on 10 June 2020, effective from 1 January 2021.

Amended on 18 October 2021, immediate effect;

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

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DEFINITIONS

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

Applicable codes:

(i) in the case of Promotion or interaction that is undertaken, sponsored or organised by or on behalf of, or with a Company located within Europe, this Code shall apply; or (ii) in the case of Promotion or interaction that is undertaken, sponsored or organised by or on behalf of or with a Company located outside Europe, the EFPIA Code shall apply; and

The Member Association's National Code of the country in which the Promotion or the interaction takes place.

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

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

Association of Research-Based Pharmaceutical Manufacturers in Bulgaria (ARPharM or the Association): is a representative body of the research-based pharmaceutical industry in Bulgaria. It brings together the multinational manufacturers and marketing authorization holders, operating on the Bulgarian market which have signed this Code and invest in the development of the pharmaceutical industry through synthesis and formulation of medicinal products containing innovative active pharmaceutical substances.

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

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

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

ARPharM Code: The ARPharM Code of Ethics, including annexes thereto that are specifically mentioned as binding and which are an integral part of this Code.

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

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

Events: All professional, promotional, scientific, educational meetings, congresses, conferences, symposia, and other similar Events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) organised or sponsored by or on behalf of a Company.

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

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

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

Informational or Educational Material: constitutes inexpensive material worth up to BGN 40 with VAT directly relevant to the practice of medicine or pharmacy and directly beneficial to the care of patients.

Item of Medical Utility: constitutes an item worth up to BGN 100 with VAT aimed at the education of HCPs enhancing the provision of medical services and patient care by supporting the activities of HCPs and overcoming the consequences of insufficient public funding of healthcare in Bulgaria. Items of Medical Utility should not be part of the necessary/mandatory equipment for medical practice and may include medical and scientific literature.

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

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

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

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

Medicinal Product: has the meaning set forth in Article 3 of the Law for Medicinal Products in Human Medicine and Article 1 of Directive 2001/83/EC, namely: (a) any substance or combination of substances

presented as having properties for treating or preventing disease in human beings; or (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Company: any company that is an ARPharM member, as well as any company that manufactures or holds a marketing authorisation for Medicinal Products for human use in Europe, which has undertaken to abide by this Code. Separate legal entities belonging to the same multinational company, whether that multinational company is a parent company, a subsidiary or any other form of enterprise or organisation - must be considered as one company and as such are bound by the Code.

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

National Code: the Association's Code of Ethics.

Non-Interventional Study (NIS): is a study where the Medicinal Product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorization. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the Medicinal Product is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures must be applied to the patients and epidemiological methods must be used for the analysis of collected data[2]

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

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

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

Prescription-Only Medicines (POM): is a Medicinal Product that requires a medical prescription issued by a professional person qualified to prescribe under Article 171(1)(1) of the Law for Medicinal Products in Human Medicine (Drug Act).

Promotion and Advertising: includes any activity undertaken, organised or sponsored by a Company, or on its behalf or at its expenses, which promotes the prescription, supply, sale, administration, recommendation or consumption of its Medicinal Product(s).

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

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[2] Article 2 of Directive 2001/20/EC

[3] EUPATI definition

[4] Definition based on the definitions of "personal data'" "genetic data" and "data concerning health" in Article 4 of GDPR

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

Research and Development Transfers of Value: Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) medical research within the meaning of the Health Act; (ii) clinical trials (as defined in Regulation 536/2014 and Drug Act); or (iii) NIS that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study.

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

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

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

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

PREAMBLE

This document replaces previous ARPharM codes, namely:

- The Code of Ethics of the Research-Based Pharmaceutical Industry in Bulgaria, in force since 15.06.2006;

- The Code of the Relations Between the Research-Based Pharmaceutical Industry and Patient Organisations in Bulgaria, in force since 31.07.2008; And

- The Code on Disclosure of the Transfers of Value from Pharmaceutical Companies to HCPs and HCOs, in force since 01.01.2014.

ETHICAL PRINCIPLES

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

The pharmaceutical industry continuously invests in research and development to deliver new treatments for medical needs and improving the quality of treatment.

As commercial organisations, we encourage competition and economic development, to sustain investment and foster innovation.

The pharmaceutical industry believes in what it does and knows that there is somewhere a patient whose health and wellbeing is, directly or indirectly, dependent on its work.

We aim at creating an environment where our stakeholders and the general public consider pharmaceutical companies as trusted partners.

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

For the Association and its members self-regulation means being fully committed to defining, implementing, observing and imposing the highest ethical standards through the codes of EFPIA and ARPharM, where breaches are not tolerated.

Self-regulation includes the concept of continuous challenge for the industry to exceed society's expectations and openness regarding suggestions from others on how we might further strengthen confidence in the industry.

Stakeholders who share the values and principles enshrined in this self-regulation are invited to adhere to these rules and guidance[5].

This demonstrates the commitment of the industry to the following ethical principles:

[5] EFPIA Leadership statement on ethical practices - June 2010

First and foremost, the **PATIENTS ARE AT THE HEART OF WHAT WE DO.** We aspire to ensure that everything we do will ultimately benefit patients. Our primary contribution to society is to make high quality Medicinal Products and to encourage their appropriate and rational use.

We act with **INTEGRITY**, interact in a responsible manner with our partners and aim to ensure that our communications with stakeholders are accurate, legitimate and balanced. We are accountable for our decisions, actions and interactions and we encourage others to follow the same high ethical standards.

We interact with all our stakeholders with **RESPECT**. We commit to approach our stakeholders in an open manner, with a responsive, constructive and learning attitude and mutual respect. We value the importance of independent decision-making by stakeholders, based on evidence and including patient interest. With respect to society, we listen to what is expected from us and adapt our way of working accordingly. We follow applicable laws and make ethical judgments when processing Personal Health Data.

We are committed to ensure that **TRANSPARENCY** is respected. We are open about our activities and interactions and encourage stakeholders to act with the same openness.

INTRODUCTION

The main priority of the Association and its members is to contribute to the provision and protection of health and human life, ensuring access for Bulgarian patients to quality, safe and effective medicinal products for prevention, diagnostic testing, and treatment of diseases.

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

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

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

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

HCPs and HCOs provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and scientific experience. This expertise makes an important contribution to the industry's efforts to improve the quality of patient care, with benefits for individuals and society at large. HCPs and HCOs should be fairly remunerated for the legitimate expertise and services they provide to the industry.

The Association believes that interactions between the pharmaceutical industry and HCPs have a profound and positive influence on the quality of patient treatment and the value of future research. At the same time, the integrity of the decision of an HCP to prescribe a Medicinal Product is one of the pillars of the healthcare system. The Association recognises that interactions between the industry and HCPs/HCOs can create the potential for conflicts of interest. Consequently, the Association has adopted codes and guidelines to ensure that these interactions meet the high standards of integrity that patients, governments and other stakeholders expect.

In the same way, the pharmaceutical industry works with POs to learn from their knowledge and experience of patient's condition that is able to provide a true picture of what it is like to live with a specific condition, how care is delivered, how that impacts on them, their careers and families and how medicines and other treatments can change their quality of life and meet their needs.

Companies disclose the amounts provided to POs in the framework of these interactions.

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

In relation to working with HCPs and HCOs, ARPharM encourages Companies to always look to disclose and to encourage HCPs (and HCOs where relevant) to agree to individual disclosure.

In order to provide for accurate, objective and fair information which ensures rational prescription and reasonable use of Medicinal Products, Companies interact with representatives of the healthcare profession and distribute among them specialized information about the products, collected in research and development, as well as from the experience obtained during the treatment of diseases. The aim of this promotional activity is raising awareness as to the merits and characteristics of the specific Medicinal Product through appropriate educational and marketing means.

Pharmaceutical manufacturers and marketing authorization holders organise their advertising and promotional activities regarding prescription-only Medicinal Products, as well as regarding their interactions with the HCPs, in compliance with the regulations of the Bulgarian legislation in effect. While the trial, manufacturing, marketing and control on pharmaceuticals are subject of extensive regulation, the advertising and promotion of Medicinal Products cannot be extensively arranged through legal regulations. Therefore, pharmaceutical companies are brought together around this Code of Ethics (**the Code**) and commit to conduct their activity relating to the promotion and advertising of prescription-only Medicinal Products, as well as regarding their interactions with HCPs, in compliance with the provisions of this Code.

The Member Companies of the Association are bound not to perform or encourage activities directed towards inducement of HCPs to prescribe particular Medicinal Products for material benefits (items, money or services). Items, subsidies, financial support, scholarships, grants, invitations to participate in conferences, cannot be offered or provided to HCPs against prescription or undertaking of engagement to prescribe certain Medicinal Products.

SCOPE OF THE ARPHARM CODE

The ARPharM Code covers:

- Regulation of Promotion and Advertising of POMs to HCPs,

- Interactions between Companies and HCPs, HCOs and POs ;

- Minimum standards for documentation and disclosure of ToV by Companies to or for the benefit of HCPs, HCOs and POs; and

- Procedural requirements.

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

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

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

The ARPharM Code is not intended to restrain or regulate activities directed towards the general public which relate solely to non-prescription Medicinal Products.

The ARPharM Code does not cover the following:

- the labelling of Medicinal Products and accompanying package leaflets, which are subject to the provisions of Title V of Directive 2001/83/EC;

- correspondence, possibly accompanied by materials of a non-promotional nature, needed to answer a specific question about a particular Medicinal Product;

- factual, informative announcements and reference materials relating, for example, to pack changes, adverse-reaction warnings as part of general precautions, trade catalogues and price lists, provided they include no advertising of the Medicinal Products;

- statements relating to human health and diseases, unless the use of the Medicinal Product has been mentioned directly or indirectly;

- activities relating exclusively to non-prescription Medicinal Products; or

- non-promotional, general information about Companies (such as information a to investors or to current/prospective employees), including financial data, descriptions of research and development programmes, and regulatory developments affecting a Company and its Medicinal Products.

The following documents are attached to the EFPIA Code, to this Code and are binding on EFPIA members:

- Annex A Standardised Disclosure template;

- Annex B EFPIA guidance;

- Annex C Guidance obligations for Member Associations under the EFPIA Code; and

- Annex D EFPIA Standard Operating Procedure related to processing of complaints and questions submitted to EFPIA.

- Annex E EFPIA e4ethics rules and procedure

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

- Examples of ethical principles.

APPLICABILITY OF THE EFPIA CODE

The EFPIA Code sets out the minimum standards which EFPIA considers must apply.

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

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

Companies must be bound by the relevant National Code in each country in Europe in which they operate (whether directly or through its relevant subsidiary).

The ARPharM Code can be applied voluntarily by companies that are not members of the Association.

SECTION 1. PROMOTION OF POMs TO HCPs

ARTICLE 1 RESPONSIBILITY AND MARKETING AUTHORIZATION

Article 1.01. Companies conducting promotion and advertising or interaction with HCPs bear the responsibility for their actions and for the content of the promotional and advertising materials which is expected to be accurate, objective and compliant with the SPC, as well as with the published scientific information. The Company bears the responsibility for the activity of its employees and third parties conducting promotion and advertising of its Medicinal Products or interaction with HCPs. The activity of the employees and the third parties representing the Companies in the promotion and advertising of their Medicinal Products or in the interaction with HCPs, must not breach the provisions of this Code.

Article 1.02. This responsibility is not limited only to the Medicinal Product subject of promotional and advertising activity, but also to the information provided or to the statements made with respect to other Medicinal Products that should also be in line with the SPC, regardless of the information/statement source.

Article 1.03. Promotion and advertising of a Medicinal Product or therapeutic indication of a Medicinal Product is prohibited before the issuance of the marketing authorization, allowing its sale or delivery. This prohibition is not intended to prejudice the right of the scientific community and the public to be fully informed of scientific and medical progress. It does not aim to restrict the full and accurate exchange of scientific information concerning a Medicinal Product, including the presentation of relevant scientific facts in specialized or mass media and at scientific conferences. It should also not restrict the communication to shareholders and others of information about a Medicinal Product in accordance with the requirements or recommendations of the law, rules or regulations.

ARTICLE 2 INFORMATION TO BE MADE AVAILABLE

Article 2.01. Each promotional and advertising material, including advertisements in specialized medical journals, must be accompanied by the SPC or by information consistent with the data available in the SPC, specifying:

- classification of the Medicinal Product according to Article 171(1) of Drug Act; and

- advertising may include the price and conditions for full or partial reimbursement by the National Health Insurance Fund (NHIF) of the Medicinal Product.

Article 2.02. When the purpose of the advertisement is only to remind about a well-known Medicinal Product, the requirement stipulated in Article 2.01 above do not apply, provided that the advertisement includes no more that the trade name of the Medicinal Product, the international non-proprietary name of the active ingredient, the name of the Company or a picture of the package. The advertisement serving as a reminder must not contain any promotional claims.

ARTICLE 3 STANDARDS OF PROMOTIONAL AND ADVERTISING ACTIVITY

Article 3.01. Promotion and advertising must be accurate, balanced, fair, objective and sufficiently complete to enable the HCP to form his/her own opinion of the therapeutic value of the Medicinal Product concerned. The information in promotional and advertising materials must be based on up-to-date analysis of data for which scientifically valid evidence is available and must not be deceptive or

misleading. Promotion must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.

Article 3.02. Additional information and scientific evidence supporting the claims set out in promotion and advertising must be provided by the Company upon request from HCPs. The data quoted in the promotional and advertising materials, including publications in specialized editions, must be provided to the persons requesting them within one month of receiving the request. In particular, advertising claims for side effects must reflect the available evidence or be able to be substantiated by clinical experience. However, it is not necessary to provide evidence regarding the validity of the elements approved in the marketing authorization.

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

Article 3.04. When the Promotion refers to any published studies[6], they must be clearly indicated, with the respective cross-references.

Article 3.05. Any comparison made between different Medicinal Products must be based on relevant and comparable aspects of the Medicinal Products. Comparative advertising must not be misleading or disparaging. and must meet the requirements of Article 5.03 et seq. of this Code.

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

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

Article 3.08. The word "**new**" must not be used to describe any Medicinal Product, pharmaceutical form or therapeutic indication which have been available on the Bulgarian market for more than one year since their launch.

Article 3.09. The promotion and advertisement must not contain claims that the product has no side effects, risk of poisoning or risk of addiction or dependence.

Article 3.10. Companies must maintain high ethical standards at all times. The promotion must: (a) never be presented in a way that discredits or undermines the credibility of the pharmaceutical industry; (b) be of a nature that takes into account the special nature of the medicinal products and the professional status of the target audience; and (c) not be potentially offensive.

[6] Publications in specialized reviewed medical journals; abstracts of accredited congresses/ scientific conferences involving medical specialists" (Ordinance No. 1, Article 10, (4)).

ARTICLE 4 USE OF QUOTATIONS IN PROMOTION

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

ARTICLE 5 MISLEADING PROMOTION AND ADVERTISING. COMPARATIVE ADVERTISING

Article 5.01. Any promotion and advertising, which contains misleading claims, contradicts the provisions of this Code. Advertisements and promotion are misleading if:

(a) Promotion and advertisement attribute to a medicinal product a therapeutic effect or efficacy which the product does not have.

(b) Promotion and advertisements contain claims that the treatment with this particular product will be surely successful.

(c) Promotion and advertisements contain claims that no damage would occur if the Medicinal Product is administered according to the instructions, or if the Medicinal Product is applied over a long period of time.

Article 5.02. Promotion and advertising must not resemble messages and designs used by other manufacturers in a way that could lead to misleading or confusing.

Article 5.03. Any promotion and advertising, which points out directly or indirectly to a company competitor or to a product of a competitor, is a comparative promotion and advertising.

Article 5.04. The information and claims contained in comparative advertising and promotion must comply with Article 3 of this Code, must correspond to factuality and be proved through reference to the respective source. For cases in which comparative advertising refers to studies that were not designed to compare directly the properties and characteristics of the advertised Medicinal Products and Medicinal Products used for comparison, this must be explicitly stated in the advertisements.

Article 5.05. Comparative advertising and promotion contradicts the provisions of this Code of Ethics if it:

(a) specifies Medicinal Products that have different therapeutic indications in comparison with the Medicinal Product, subject of promotion or advertising;

(b) does not objectively clarify one or several of the main, relevant properties and peculiarities of the Medicinal Products concerned;

(c) creates confusion in respect to the company conducting the promotion and advertising and its competitors, or with respect to the Medicinal Products subject of this promotion and advertising, as well as to the medicinal products used to serve as a comparison, or regarding the trademarks of the medicinal products specified;

(d) contains statements defining the medicinal products used for comparison as "imitation or copy" of the medicinal product, which is subject of promotion or advertising;

(e) contains disparaging or disgraceful statements concerning the products, activity, personal or business standing of a company competitor or its employees;

(f) contains the trade name of the competitor medicinal product or the name of the company competitor.

ARTICLE 6 TRANSPARENCY OF PROMOTION

Article 6.01. Promotion and advertising must not be disguised. They must be presented in a way that allows them to be recognized as advertising and promotion by their recipients.

Article 6.02. Clinical assessments, post-marketing surveillance and experience programmes and post-authorization studies (including those that are retrospective in nature), non-interventional post-authorization studies must not be disguised Promotion and Advertising. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose.

Article 6.03. Where a Company pays for or otherwise secures or arranges the publication of promotional material in specialised medical journals, such promotional material must not resemble independent editorial matter.

Article 6.04. Material relating to Medicinal Products and their uses, whether promotional in nature or not, which is financed or otherwise enabled by a Company must clearly indicate that it has been sponsored by that sponsor Company.

Article 6.05. Independent materials that reflect the holding of symposia/Events are not considered sponsored materials within the meaning of Article 6.04.

ARTICLE 7 DISTRIBUTION OF PROMOTION

Article 7.01. Promotion must only be directed at those HCPs whose need for, or interest in, the particular information can reasonably be assumed.

Article 7.02. Mailing lists must be kept up-to-date. Requests to be removed from mailing lists must be complied with.

Article 7.03. Subject to applicable national laws and regulations, the use of faxes, e-mails, automated calling systems, text messages and other digital communications for Promotion is prohibited except with the prior permission, or upon the request, of those who receive it.

ARTICLE 8 PROMOTIONAL INFORMATION PROVIDED DURING INTERNATIONAL EVENTS

An international Event can be used for presenting and handing out to participants promotional information on Medicinal Products, pharmaceutical forms or therapeutic indications, which are not authorized for use in the country, where the international Event takes place, or these are registered under other conditions as long as: (i) any such promotional material is accompanied by a suitable statement indicating the countries in which the Medicinal Product, pharmaceutical form or therapeutic indication is registered and makes clear that the Medicinal Product, pharmaceutical form or therapeutic indication is not registered locally, and (ii) any such promotional material which refers to the prescribing information (indications, warnings etc.) authorized in a country or countries where

the Medicinal Product is registered must be accompanied by an explanatory statement indicating that registration conditions differ internationally.

ARTICLE 9 PERSONAL MEDICAL MATTERS

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

SECTION 2.

INTERACTIONS WITH HCPs, HCOs AND POs

ARTICLE 10 EVENTS AND HOSPITALITY

Article 10.01. All Events must be held in "appropriate" Locations and Venues that are conducive to the main purpose of the Event, avoiding those that are "renowned" for their entertainment facilities or are "extravagant". The fact of sponsorship by the Company must be clearly announced in advance, at the meeting and in all activities. Hospitality, in which the participants in the event are accommodated in extravagant and luxury hotels, which are associated mainly with entertainment activities is considered inappropriate.

a. Extravagant and luxury hotels for the purposes of this Code are all 5 star hotels, located in year-round[7] resort destinations, as well as all hotels, regardless of the class, located in seasonal[8] resort destinations during the summer or winter tourist season respectively; wine tourism complexes, regardless of their class and location.

b. Other than those listed in item "a", venues are not considered extravagant or luxury hotels if they have the necessary conditions to hold scientific events - the required number of halls, sound equipment and others.

Article 10.02 When sponsoring an event organised by a third party (a company or organisation that is not a member of the Association and has not undertaken to comply with the Code), the members of the Association may not impose conditions on third parties organising the event preventing them from accepting sponsorship by other companies, if they so wish.

Article 10.03. No Company may organise or sponsor an Event that takes place outside Bulgaria ("international Event") unless:

- most of the invitees are from other countries and, it makes greater logistical sense to hold the Event in another country; or

- given the location of the relevant resource or expertise that is the object or subject matter of the Event, it makes greater logistical sense to hold the Event in another country.

Article 10.04. Companies may only offer hospitality when such hospitality is "appropriate" and in every way complies with the provisions of any Applicable Code(s).

Article 10.05. Hospitality extended in connection with Events must be limited to travel, meals, accommodation and genuine registration fees.

Article 10.06. Companies must not provide or offer any meal (food and beverages) to HCPs, HCOs' members or POs' Representatives, unless, in each case, the value of such meal provided in a one-

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[7] For the purposes of Article 10.01 of the Code, year-round resort destinations on the territory of the Republic of Bulgaria are considered Sandanski, Velingrad and Hissarya.

[8] Within the meaning of Article 10 of the Code, seasonal resort destinations in Bulgaria are be considered to be: (a) for the summer season (from 15 June to 15 September) - located at the seaside with the exception of Varna and Burgas; (b) for the winter ski season (from 15 December to 30 March) - Bansko, Borovets and Pamporovo.

off way to an HCP, HCO member or PO Representative does not exceed BGN 100 with VAT. Outside the territory of Bulgaria, a value threshold set for the country where the Event takes place shall apply.

Article 10.07. Hospitality may only be extended to persons who qualify as participants in an Event in their own right. In exceptional cases of established health needs (e.g. disability or injury), the travel, meals, accommodation and genuine registration fee costs of an accompanying person can be reimbursed within the same parameters.

Article 10. 08. All forms of hospitality offered to HCPs, HCOs' members or POs' Representatives must be "reasonable" in level and strictly limited to the main purpose of the Event. As a general rule, the hospitality provided must not exceed what those individuals would normally be prepared to pay for themselves. The hospitality provided must not cover a stay exceeding the officially declared duration of the event, unless the arrival on the previous day or the departure on the next is necessary for the effective planning of the trip. If the participant/participants wish to arrive earlier or to leave later, all expenses connected with their extra stay, may not be paid or reimbursed by the sponsoring company.

Article 10.0 9. Hospitality must not include sponsoring or organising entertainment events (sports games and other entertainment events in the free time from the scientific/work programme).

Article 10.10. Organisation and sponsorship of an Event by a Company:

a. Companies organise and sponsor Events for HCPs in compliance with the provisions of this Code.

b. Events, on the territory of the Republic of Bulgaria, organised or sponsored by a Company, cannot have duration of above three twenty-four hour periods. No less than 6 hours of each full day of the Event shall be arranged for effective[9] working/scientific programme. No less than 3 hours of each half-day[10] of the event shall be effectively committed to the working/scientific programme, when the remainder of the day facilitates the arrival or departure of participants.

c. International Events organised or sponsored by a Company cannot continue more than five twenty-four hour periods. No less than 6 hours of each full day of the Event shall be arranged for the working/scientific programme. This provision shall not be applied to Events organised by the head office of the Company.

Article 10.11. The expenses of HCPs, HCOs' members or POs' representatives, related to the Event organised or sponsored by the Company, are covered by bank transfer, by cheque or promissory note, supported by primary documents for the expenses incurred. Per diems within the meaning of the Bulgarian legislation are not provided. Except for the cases under Article 10.06, when organising international Events where the costs are covered or otherwise sponsorship is available to HCPs or HCOs' members or POs' Representatives for participation in the event, when it comes to covering costs/sponsorship this Code applies along with the relevant regulations of the place where the HCP exercises his/her profession or activity or HCOs or POs operate, rather than the norms set out in the country hosting the international Event.

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[9] The effective working/scientific programme does not include the time set for registrations, coffee breaks, lunches, dinners, and other events that have no scientific or educational purpose.

[10] Half-day is each day of the programme in which registration begins before 6 p.m. or the check-out is after 10 a.m.

Article 10.12. The maximum allowable hospitality limits are:

a. Flight tickets (in Bulgaria and international) - economy (tourist) class. Business class is allowed only as an exception for non-stop flight of over 6 hours.

b. Stay in a hotel - hospitality is limited to the value of an accommodation and breakfast package. All additional expenses are on the account of the participant.

Article 10.13. Hospitality may not be tied to an obligation for the HCO to prescribe or to encourage prescription of a specific Medicinal Product.

Article 10.14. The provisions of this Section shall apply to cases when the Event is organised by a third party but completely or partially financed by a Company.

Article 10.15. When facing a decision as to whether to sponsor a national Event, to participate in such an Event or to sponsor HCPs to participate in the Event, ARPharM Member Companies shall consult the database for a preliminarily assessment of such an Event, available on the ARPharM website www.arpharm-e4ethics.org. The database of national events under Article 10.1 above, based on the system for preliminary assessment and monitoring of events in respect of this Code, is designed under a procedure set out by the Managing Board of the Association.

Article 10.16. When facing a decision as to whether to sponsor an international Event, to participate in such an Event or to sponsor HCPs to participate in the Event, ARPharM Member Companies shall consult the database for a preliminarily assessment of such an Event, available on the website www.efpia-e4ethics.eu.

Article 10.17. A preliminary assessment of a national or international event cannot be used to assess the quality or content of the scientific programme or the quality of speakers. Each Company autonomously decides whether to sponsor or participate in an event or to sponsor the participation of HCPs in this event. ARPharM Member Companies should consider the rules and regulations of this Code of Ethics when facing a decision as to whether to participate or sponsor the Event, and whether to sponsor the participation of HCPs in this Event.

ARTICLE 11 PROHIBITION OF GIFTS

Article 11.01. Gifts for the personal benefit (such as but not limited to sporting or entertainment tickets, social courtesy gifts) of HCPs, HCOs' members or POs' Representatives (either directly or indirectly) are prohibited. Providing or offering cash, cash equivalents or personal services is also prohibited. For these purposes, personal services are any type of services unrelated to the profession and that confer a personal benefit to the Recipient.

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

ARTICLE 12 DONATIONS AND GRANTS TO HCOs AND POs

Article 12.01. Donations and Grants (in cash or in kind) to HCOs and/or POs are only allowed if: (i) they are made for the purpose of supporting healthcare, research or education; (ii) they are documented and kept on record by the donor/grantor and can be made available upon request via the executive director of the Association, of another Company, or the Committee; and (iii) they do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.

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

Article 12.03. Donations in the form of repair works, technical equipment and furniture may be provided only to medical institutions for inpatient care, outpatient and diagnostic consultative centres.

Article 12.04. Donations of Medicinal Products can be provided only to medical institutions for inpatient care.

ARTICLE 13 CONTRIBUTION TO COSTS RELATED TO EVENTS AND SPONSORSHIP

Article 13.01. Companies must comply with criteria governing the selection and support of HCPs or POs' Representatives to attend Events as provided in, or in connection with, any Applicable Code(s). No payment must be offered to compensate merely for the time spent by the HCP or PO's Representative in attending Events. In cases of sponsorship of an HCP for participation in an international Event, the provisions of the national code of the country in which the HCP practices/exercises his/her activity are applicable.

Article 13.02. The public use of an HCO or PO´s logo and/or proprietary/copyright material by a Company requires written permission from that organisation. In seeking such permission, the specific purpose and the way the logo and/or proprietary material will be used must be clearly stated.

Article 13.03. Companies must ensure that their Sponsorship and/or support to HCOs and POs is always clearly acknowledged and apparent from the outset.

ARTICLE 14 COMPANY FUNDING

No Company may require that it be the sole funder or sponsor of a PO or HCO or any of its programmes.

Companies welcome broad funding and sponsorship of POs and HCOs from multiple sources.

ARTICLE 15 CONTRACTED SERVICES/CONSULTANCY

Article 15.01. Contracts between Companies and HCPs, HCOs, POs or POs' Representatives under which those provide any type of services to Companies (not otherwise covered by the Code) are only allowed if such services: (i) are provided for the purpose of supporting healthcare, research or education; and (ii) do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.

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

a. a written contract is agreed in advance of the commencement of the services which specifies the nature of the services to be provided and, subject to clause (g) below, the basis for payment of those services;

b. a legitimate need for the services has been clearly identified and documented in advance of requesting the services and entering into arrangements (in line with the Company's internal rules) by the Company prior to the enquiry on the provision of consultancy services and signing of a relevant contract;

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

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

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

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

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

Article 15.03. Written contracts for the provision of consultancy services must set out:

- an obligation for HCPs - consultants to declare that they are consultants to the Company whenever they write or speak in public about a matter that is the subject of the agreement or any other matter relating to that Company;
- an obligation for HCPs employed by the Company to declare their employment arrangements with the Company whenever they write or speak in public about a matter that is the subject of the employment or any other matter relating to that Company.

Article 15.04. Article 15 does not cover cases of HCPs, HCOs' members or POs' representatives answering questionnaires for market research, such as one-off phone interviews or mail/e-mail/internet questionnaires; provided that the HCP, HCO member or PO representative is not consulted on a regular basis (in terms of the frequency of discussions as a whole or visits related to the research) and that the remuneration is up to BGN 60, VAT inclusive.

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

Article 15.06. The amount of fees for presentations/lectures, conducting/moderating meetings and events, conducting courses/trainings (for Bulgarian citizens) is determined according to the significance of the Event (regional or national), the academic status of the lecturer and the form and duration of the Event. The fees may not be higher than 1.5 times the average salary for employees in the field of health and social activities, determined by the National Statistical Institute for non-habilitated persons, or 2 times the amount of the average salary for employees hired under an employment contract in the field of healthcare and social activities for habilitated persons.

SECTION 3.

SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH HCPs AND HCOs

ARTICLE 16 MEDICAL EDUCATION

Medical Education is aimed at increasing the scientific knowledge and competence of HCPs to enhance medical practice and improve patient outcome. Companies can be engaged in different types of Medical Education, but such activities must not constitute Promotion.

When funding independent Medical Education or organising Medical Education activities directly or in collaboration with Third Parties, Companies must ensure that their participation and role is clearly acknowledged and apparent from the outset.

When organising Medical Education activities in which Companies have input in the content, they are responsible for what is communicated during the activities. Such content must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognized opinions.

ARTICLE 17 INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

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

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

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

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

ARTICLE 18 NON-INTERVENTIONAL STUDIES

Article 18.01. A non-interventional study with Medicinal Products authorized for use in Bulgaria is conducted with a primarily scientific purpose to obtain additional information about the product prescribed in the usual manner in accordance with the conditions specified in the marketing authorization and cannot constitute disguised Promotion. The Bulgarian legislation shall apply to the regulation of non-interventional studies.

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

a. the study is carried out with a scientific purpose;;

b. there is (i) a written study plan (observational plan/protocol) and (ii) written agreements between HCPs and/or institutions in which the study will be conducted on one hand and on the other - the Company sponsoring the study, identifying the nature of the services to be provided and the remuneration for these services in compliance with Article 18.02 below;

c. Any remuneration provided by the Companies for the HCPs taking part in the non-interventional studies is reasonable and reflects the fair market value of the work performed;

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

e. The results of studies conducted solely in Bulgaria must be analysed by or on behalf of the Company and summaries thereof must be made available to the Company's scientific service (as described in Article 20.01.a) within 180 days from the completion of the study, which service must maintain records of such reports for at least 5 years. The Company must send the summary report to all HCPs that participated in the study and must make the summary report available to the Ethics Committee upon substantiated request. If the study shows results that are important for the assessment of benefit-risk, the summary report must be immediately forwarded to the relevant competent authority[11]; and

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

Article 18.03. The Companies are obliged to observe, when applicable, the provisions of Article 18.02 above in the conduct of medical research, including epidemiological studies, record keeping and other studies that are retrospective in nature. In any case, Article 15.01 applies to the participation of HCPs in such studies.

Article 18.04. Upon a substantiated request by the Ethics Committee, the Company is obliged to submit to it the documents related to a specific non-interventional study. The Company's failure to provide information regarding a non-interventional study or preventing the Ethics Committee from conducting an examination of such a study constitutes an infringement of this Code.

ARTICLE 19 MEDICAL SAMPLES

Article 19.01. Medical Samples can be handed out on an exceptional basis to HCP entitled to prescribe in their practice the relevant Medicinal Product. Medical Samples must not be given as an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products, and must not be given for the sole purpose of treating patients.

Medical Samples are provided to HCPs so that they may familiarise themselves with the Medicinal Product and acquire experience in dealing with them.

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

In accordance with national and/or EU laws and regulations, a limited number of Medical Samples may be supplied on an exceptional basis and for a limited period. A reasonable interpretation of this provision is that each HCP should receive, per year, not more than 2 packs of Medical Samples of a particular Medicinal Product he/she is qualified to prescribe for 4 years after the HCP first requested samples of a particular new Medicinal Product (i.e. the "2x4" standard).

In this context, a "new" Medicinal Product is a product for which a new marketing authorisation has been granted, either following an initial marketing authorisation application or following an extension application for a new indication.

Extensions of the marketing authorisation to additional strengths/dosage forms for existing indications or pack sizes (number of units in the pack) without any change in the therapeutic indications cannot be considered as new Medicinal Product.

Medical Samples containing psychotropic or narcotic substances subject to control under the Control of Narcotic Substances and Precursors Act must not be provided.

Medical Samples can only be given in response to a written request from HCPs qualified to prescribe that particular Medicinal Product. Written requests must be signed and dated by those who ask for the Medical Samples

Article 19.02. Companies must have adequate systems of control and accountability for Medical Samples. This system must also clearly establish at least: the requesting HCP, resp. who received the sample, type, quantity and time during which samples of a given Medicinal Product have been provided, in compliance with the conditions of Article 19.01. above. The company is obliged to keep the information on the reporting of the samples for at least 5 years, as well as to present it at the request of the Ethics Committee.

Article 19.03. Each Medical Sample must be no larger than the smallest presentation of that particular Medicinal Product registered in Bulgaria. Each Medical Sample must be marked "free medical sample - not for sale" or words to that effect and must be provided to the HCP accompanied by a copy of the summary of product characteristics.

ARTICLE 20 COMPANY STAFF. MEDICAL SALES REPRESENTATIVES

Article 20.01. Companies in cooperation with the Association are obliged to continuously provide training and education to the medical sales representatives in respect of this Code. The provisions of this Article 20 shall apply to medical sales representatives of the Company, to employees hired through a contract with third parties who act as medical sales representatives, and all other employees of the Company who are not medical sales representatives in charge of the preparation or approval of promotional and advertising materials and/or activities, must be fully aware of the provisions of this Code and the EFPIA Code and relevant Bulgarian laws and regulations.

a. Each Company must establish a scientific service in charge of information about its Medicinal Products and the approval and supervision of NIS. Companies are free to decide how best to establish such service(s) in accordance with this Article 20.01 (i.e. whether there is one service in charge of both duties or separate services with clearly delineated duties), taking into account their own resources and organisation. The scientific service must include a medical doctor or, where appropriate, a pharmacist who will be responsible for approving any promotional and advertising material before release. Such a person must certify that he or she has examined the final form of the promotional and advertising

material and that in his or her belief it is in accordance with the requirements of the Applicable Code(s) and any relevant laws and regulations in place in Bulgaria, is consistent with the summary of product characteristics and is a fair and truthful presentation of the facts about the advertised Medicinal Product. In addition, the scientific service must include a medical doctor or, where appropriate, a pharmacist, who will be responsible for the oversight of any NIS (including the review of any responsibilities relating to such studies, particularly with respect to any responsibilities assumed by Medical Sales Representatives and other Company staff/ third party staff involved in the NIS). Such person must certify (by signing) that he or she has examined the protocol relating to the NIS and that in his or her belief it is in accordance with the requirements of the Applicable Code(s) and any relevant laws and regulations in place in Bulgaria.

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

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

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

b. Medical Sales Representatives must use only promotional and advertising materials drawn up in line with the Code requirements.

c. Oral statements of Medical Sales Representatives must not violate the provisions of the Code. Medical Sales Representatives must approach their duties responsibly and ethically.

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

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

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

g. Medical Sales Representatives must not pay a fee, pledge provide any material benefit, inducement or subterfuge to get an appointment at an HCP or HCO. In an interview, or when seeking an appointment for an interview, Medical Sales Representatives must, from the outset, take reasonable steps to ensure that they do not mislead as to their identity or that of the Company they represent.

Article 20.03. One of the main principles of this Code is that any promotional or advertising claim(s) must be accompanied by the SPC or by information consistent with the data available in the SPC, at

the same time specifying the date of its latest approval by BDA/EMA. When the intention is to provide for several forms of promotional materials, the SPC or the information consistent with the data available in the SPC must be included at least once.

Article 20.04. Audio-visual materials must be accompanied by a document containing the information under Article 20.03.

Article 20.05 Advertising and promotion materials for POMs may be supplied only to HCPs, with the exception of the cases, acceptable according to the Bulgarian legislation. Distribution of such materials at places accessible to the general public, such as pharmacies, waiting rooms and corridors in healthcare facilities and etc. is prohibited.

SECTION 4.

SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH POs

ARTICLE 21 INTERACTIONS WITH POs

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

- The independence of POs, in terms of their political judgment, policies and activities, must be assured.

- All interactions between POs and Companies must be based on mutual respect, with the views and decisions of each partner having equal value.

- The pharmaceutical industry and Companies must not request, nor shall POs undertake, the Promotion and Advertising of a particular POM.

- The objectives and scope of any collaboration between the pharmaceutical industry and PO must be transparent and clearly defined. Financial and non- financial support provided by Companies must always be clearly and adequately acknowledged.

- The pharmaceutical industry welcomes broad funding of POs from multiple sources.

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

Article 21.03. When Companies provide financial support, significant indirect support and/or significant non-financial support to POs, they must have in place a written agreement. This must state the amount of funding/ the value of non-financial support and also the purpose (e.g. unrestricted grant, specific Event or publication, etc). In cases where direct or indirect non-financial support is provided, its nature must be described in detail in the agreement (e.g. a donation in the form of a public relations agency and the nature of its engagement). Each Company should have a process in place for approving these contracts.

Article 21.04. Companies must not influence the text of materials drawn up by POs they sponsor in a manner favourable to their own commercial interests. This does not preclude Companies from correcting factual inaccuracies in materials. In addition, at the request of POs, Companies may contribute to the drafting of the text from a fair and balanced scientific perspective.

SECTION 5.

DISCLOSURE OF ToVs FROM COMPANIES

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

Article 22.01. Time of disclosure

Disclosures must be made by each Company within 6 months after the end of the relevant Reporting Period and the information disclosed must be required to remain in the public domain for a minimum of 3 years after the time such information is first disclosed unless, in each case, (i) a shorter period is required under applicable national laws or regulations, or (ii) the relevant data protection legal basis (e.g. the Recipient's consent relating to a specific disclosure if required by law) is no longer applicable.

(ii). The common reporting period for publication of ToVs to Recipients is set during the time interval from 20th to 30th June each year at the latest.

ARTICLE 23. DISCLOSURE OF ToVs TO HCPs AND HCOs

Article 23.01. Rationale

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

Article 23. 02. Disclosure Obligation

General Obligation. Subject to the terms of this Article, each Company must document and disclose ToVs it makes, directly or indirectly, to or for the benefit of a Recipient, as described in more detail in Article 23.04.

Excluded Disclosures. Without limitation, ToVs that (i) are solely related to over-the-counter medicines; (ii) are not listed in Section 23.04 of this Article, such as Items of Medical Utility (governed by Article 17), meals (governed by Article 10, especially Article 10.06), Medical Samples (governed by Article 19); or (iii) are part of ordinary course purchases and sales of Medicinal Products by and between a Company and an HCP (such as a pharmacist) or an HCO do not fall within the scope of the disclosure obligation described above in *"General Obligation".*

Article 23.03. Form of Disclosure

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

Template. For the sake of consistency, disclosures under this Code shall be made in the template set out in Annex A for reference, reflecting the requirements of this Article.

Platform of Disclosure. Disclosures are made in the following way:

- on the relevant Company's website, a link to which is published on a dedicated information website in Bulgarian http://transparencybg.org, access to which is free of restrictions and public, using the template set out in Annex A.

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

Language of disclosure. Disclosure shall be made in Bulgarian. Companies are encouraged to make disclosures in English in addition to the mandatory disclosures in Bulgarian.

Documentation and Retention of Records. Each Company must document all ToVs required to be disclosed pursuant to Article 17.2 above and maintain the relevant records of the disclosures made under this article for a minimum of 5 years after the end of the relevant Reporting Period, unless a shorter period is required under applicable national laws or regulations.

Article 23.04. Individual and Aggregate Disclosure

Individual Disclosure. Except as expressly provided by this Article, ToVs must be disclosed on an individual basis. Each Company must disclose, on an individual basis for each clearly identifiable Recipient, the amounts attributable to ToVs to such Recipient in each Reporting Period which can be reasonably allocated to one of the categories set out below. Such ToVs may be aggregated on a category-by-category basis, provided that itemised disclosure must be made available upon request to the relevant Recipient.

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

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

b. Contribution to costs related to Events. Contribution to costs related to Events, through HCOs or Third Parties[12], including support to HCPs to attend Events, such as:

i. Registration fees;

ii. Sponsorship agreements with HCOs or with Third Parties appointed by an HCO to manage an Event; and

iii. Travel and accommodation (to the extent governed by Article 10).

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

2. For ToVs to an HCP:

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

i. Registration fees; and

ii. Travel and accommodation (to the extent governed by Article 10).

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

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

Aggregate Disclosure. For ToVs where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Article 23.04, cannot be disclosed on an individual basis for legal reasons, a Company must disclose the amounts attributable to such ToVs in each Reporting Period on an aggregate basis. Such aggregate disclosure must identify, for each category, (i) the number of Recipients covered by such disclosure, on an absolute basis and as a percentage of all Recipients, and (ii) the aggregate amount attributable to ToVs to such Recipients.

Non-duplication. Where a ToV required to be disclosed pursuant to Section 23.04 is made to an individual HCP indirectly via an HCO, such ToV must only be required to be disclosed once. To the extent possible, such disclosure must be made on an individual HCP named basis pursuant to Article 23.04.

Research and Development ToV. Research and Development ToVs in each Reporting Period must be disclosed by each Company on an aggregate basis. Costs related to Events that are clearly related to activities covered in this section can be included in the aggregate amount under the "Research and Development Transfers of Value" category.

Methodology. Each Company must publish a note summarising the methodologies used by it in preparing the disclosures and identifying ToVs for each category described in Article 23.04. The note, including a general summary and/or country specific considerations, must describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amounts of ToVs for purposes of this article, as applicable.

ARTICLE 24. DISCLOSURE OF SUPPORT AND SERVICES PROVIDED TO POs

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

This disclosure must include a description of the nature of the support or services provided that is sufficiently complete to enable the average reader to form an understanding of the nature of the support or the arrangement without the necessity to divulge confidential information.

In addition to the name of the PO, the following elements must be included:

- For support:

  - the monetary value of financial support and of invoiced costs.

  - the non-monetary benefit that the PO receives when the non-financial support cannot be assigned to a meaningful monetary value.

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

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

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

SECTION 6.

PROCEDURAL REQUIREMENTS

ARTICLE 25. ENFORCEMENT

Article 25.01. Enforcement through Member Associations

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

The Association shall adopt Implementation and Procedure Rules (as set forth in more detail in Article 27), which will be binding upon its members, and set forth the framework for the implementation of this Code, the processing of complaints and the enforcement of sanctions in a manner consistent with applicable data protection, competition and other laws and regulations.

ARTICLE 26. AWARENESS AND EDUCATION

The Association, must, within current applicable laws and regulations facilitate companies' awareness of and education about this Code, including by providing guidance to companies in order to prevent breaches of the Code.

ARTICLE 27. IMPLEMENTATION AND PROCEDURE RULES

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

Article 27.01. General provisions

The implementation and observance of the Code is monitored by the Ethics Committee of ARPharM.

All complaints concerning possible breaches of the Code should be submitted to the Committee. The Committee may issue decisions interpreting the provisions of the Code when referred to it or when the need arises. Interpretative decisions shall be binding on the meaning of the interpreted provision from the time of notification to the Companies or from the date specified therein.

The Association shall be obliged to:

a. put in place procedures and to set up the Ethics Committee as a structure to receive and process complaints, to determine sanctions and to publish appropriate details regarding the same with the Ethics Committee consisting of: a non-industry chairperson and, besides any industry members, membership from other stakeholders;

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

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

Article 2 7.02. Ethics Committee of ARPharM

1. The Committee consists of 10 members and a legal adviser. The legal adviser advises the Committee and has no right to vote.

2. The Chairperson and the Deputy Chairperson of the Ethics Committee are elected after its establishment among its members through simple majority. The Deputy Chairperson of the Ethics Committee shall perform the functions of the Chairperson on his/her unavailability. In case both heads of the Committee are not available, the Committee shall appoint an ad hoc chairperson for the respective action or period.

3. Seven members of the Ethics Committee are from the Association's Member Companies and are elected by the General Assembly of the Association.

4. Three members of Ethics Committee are not from the Association's Member Companies and are nominated by the Managing Board of the Association by proposals by the Association members.

5. The mandate of the Ethics Committee members is for two years and cannot coincide with the Managing Board mandate. In time of change of the Ethics Committee members, all pending cases are reviewed anew by the new Committee members.

6. The Committee shall meet in regular and extended panel. The regular panel shall include the Committee members under item 3 and one of the members under item 4, appointed as chairperson. The extended panel includes the members under item 3 and the members under item 4.

7. All Committee members shall be duly notified in writing of the Committee meetings at least 7 days before the meeting in question, indicating its agenda and enclosing the materials thereto. The Committee shall hold meetings with a quorum of 6 members when convening in a regular panel and 7 members, one of which is at least a member under item 4, when convening in an extended panel. Where, for objective reasons regular members cannot gather a quorum of two consecutive sessions allowed him to participate and member under item 4.

8. Each Committee member shall be required to withdraw when the Company he/she represents is the complainant or respondent in the relevant proceedings or where there are any circumstances which may give rise to reasonable doubts as to his/her impartiality. Provided that the person who may be interested is not removed, the Committee shall, of its own motion or at the request of one of the parties, issue a ruling, the person whose withdrawal is requested not taking part in the vote.

9. The Committee shall issue decisions when resolving disputes on the merits and rulings when settling procedural matters. The chairperson shall issue orders in the cases provided for in this Code.

10. Each of the members has one vote, and the Committee decisions are taken by a majority of the members present.

Article 27.03. Reception of Complaints

Complaints may be lodged either with the Association or the EFPIA. The adjudication of complaints and decision-making thereon must be a matter solely for the Ethics Committee of ARPharM.

Complaints received from EFPIA must be handled as follows:

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

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

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

Article 27.04. Lodging and processing of complaints

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

b. Complaints must be processed at national level by the Ethics Committee in line with the procedures and structures set out in this Code. The Ethics Committee must take decisions and pronounce any sanctions on the basis of this Code.

c. Sanctions set out in this Code are proportionate to the nature of the infringement, have a deterrent effect and take account of repeated offences of a similar nature or patterns of different offences. A combination of publication and fines is generally considered to be the most effective sanction; however, any other appropriate sanction may be enforced under this Code. The Association takes note of any applicable legal, regulatory or fiscal requirements which would affect the nature or extent of sanctions which may be imposed. Where publication or fines are not permitted due to applicable legal, regulatory or fiscal requirements, the Ethics Committee should impose the most effective alternative sanction.

d. The Association establishes effective procedures for appeals against the initial decisions made by the Ethics Committee.

e. The Ethics Committee shall ensure that any final decision taken in an individual case shall be published in its entirety or, where only selected details are published, in a level of detail that reflects the seriousness and/or recurrence of the breach as follows:

- in cases of a serious/repeated breach, the Company name(s) should be published together with details of the case;

- in cases of a minor breach, or where there is no breach, publication of the details of the case may exclude the Company name(s).

<u>Procedure for filing and reviewing complaints by the ARPharM Ethics Committee</u>

1. Any legal entity, natural person or trade representative office may submit a complaint in line with this Code, hereinafter referred to for the purposes of this procedure - COMPLAINANT[13]. A complaint filed through EFPIA is handled by the ARPharM Ethics Committee under this procedure.

2. The company against which the complaint has been submitted shall be hereinafter referred to for the purposes of this procedure - RESPONDENT.

3. Each complaint must be lodged in writing in Bulgarian and must contain the following:

3.1. Complainant - name and registered address as per the court registration or the registration at the BCIC when the complainant is a legal entity or a representation office; name and address of residence when the complainant is a natural person.

3.2. Respondent - name and registered address as per the court registration or the registration at the BCIC when the respondent is a legal entity or a representative office.

3.3. The complaint must contain the name of the medicinal product(s) and a description of actions and circumstances considered an infringement of this Code.

3.4 The complaint must be accompanied by materials supporting the claims for infringement of this Code[14].

3.5 The date on which the alleged infringement was detected by the complainant.

3.6 The date on which the alleged infringement was performed.

3.7 Date of lodging the complaint.

3.8 The specific provisions of this Code which the complainant claims to have been breached - article, paragraph.

3.9 Receipt for payment of inclusive charge, where applicable.

3.10 Signature of the complainant

3a. Special cases:

3a.1.The Ethics Committee may on its own initiative commence proceedings against a Company for infringements of the Code, if the Ethics Committee has received sufficient data about a breach of Section Two and Article 17 of this Code. In this case, the Ethics Committee may conduct its own investigation to establish if there are sufficient facts and circumstances to prove the infringement of this Code; the investigation will be conducted by a specifically hired person. After the investigation, the contractor shall prepare a written report[15] of his/her findings and submit it to the Ethics Committee and the Company, suspected of committing an offence. In the event that, the report has found the complaint to be substantiated, the Ethics Committee shall initiate proceedings and Article 6.5 and the subsequent provisions of the procedure to file and review complaints shall apply accordingly.

[13] The complaint should not contain names or other personal information of particular medical professionals. In cases where these details attend they will be deleted in the adoption of the complaint in the records of the Association.

[14] The materials should not contain names or other personal information of particular medical professionals. In cases where these details attend they will be deleted in the adoption of the complaint in the records of the Association.

[15] The report should not contain names or other personal information of particular medical professionals.

3 a.2. For cases where the complainant sets out the allegations of infringement of Article 10, 11 and 12 of this Code, the complaint may not contain materials in support of the complainant's claims, but shall contain evidence that such materials can be collected. In such cases, during the proceedings to review the complaint, the Ethics Committee may (a) decide on its own initiative or at the request of a party in the proceedings, that the procedure for collection of evidence applies pursuant to Article 6.9.2. below and/or (b) assign the collection of evidence to a specially hired person.

4. Each complaint and the documents attached thereto must be lodged at the following address:
To the attention of ARPharM Ethics Committee
1113Sofia, Iztok district,
19 Fr. J. Curie Str, bl. 1, fl. 14, apt 26

5. The complainant pays a charge in the amount of BGN 900 (nine hundred leva) for the review of every complaint. At the Committee's discretion, when the complainant is a patient, a PO, HCP, as well as in other cases, it may be exempted from the payment of a charge.

6. Processing of complaints:

6.1. The chairperson of the Ethics Committee checks the complaint for availability of the obligatory requisites specified under Article 3 above, within 7 working days. Should the complaint lack one or more of the requisites, the complaint is returned to the complainant to be completed with the order of the chairperson of the Ethics Committee.

6.2. The complainant fills in the missing requisites in the complaint within 7 working days from the receipt of the order under Article 6.1 above, which puts on halt the period counted for setting a date for a session under Article 6.8 below. If the complainant does not fill in the missing requisites in the stated term, the complaint will not be examined.

6.3. The complaints are inadmissible if:

6.3.1. complaints are lodged in more than one month as of the date, on which the infringement has been established by the complainant, or in more than three months of the date, on which this infringement has been made.

6.3.2. they are based on facts and/or activities which are beyond the scope of the Code of Ethics.

6.3.3. they are in pursuit only of the corporate interests of the complainant.

6.3.4. a prima facie case of infringement of this Code is not established for the complaint.

6.4. Should the chairperson establish evident reasons for the complaint to be inadmissible he/she leaves it with no access and brings it back to the complainant with reasoned order, which is subject to appeal within 14 calendar days from its receipt by the complainant in front of the regular panel of the Ethics Committee. The regular panel of the Ethics Committee passes a ruling on the admissibility of the complaint, which is final.

6.5. When issuing an order or ruling on the admissibility of the appeal, the chairperson shall send a copy of the appeal and all supporting documents to the respondent within 7 working days from the issuance of the order/ruling.

6.6. The respondent may submit a written position within 15 calendar days as of the receipt of the copy of the complaint[16]. The chairperson sends, with no delay, a copy of the position of the respondent to the complainant.

6.7. The chairperson of Ethics Committee shall appoint a rapporteur on the matters concerning the complaint, upon setting the date of the Ethics Committee first session, who shall acquaint with the materials available and shall report at the first session of Ethics Committee[17].

6.8. The chairperson of Ethics Committee shall schedule a session for consideration of admissible complaints within 30 calendar days from the date of their lodging or the date of correcting the omissions in the complaints. Both parties are summoned in writing by the chairperson of Ethics Committee at least 7 calendar days prior to the date of the session.

6.9. At the first session on the complaint, after hearing the parties, the Committee comes up with an opinion on the evidence submitted by both parties.

6.9.1. At this session both the complainant and the respondent may bring up new claims for collecting of evidence with a view to the position in writing of the other party under Article 6.6.

6.9.2. If the complaint is based on statements or materials provided by or related to an HCP whose identity must not be disclosed to the parties in the proceedings, including the members of the Ethics Committee, the designated rapporteur for the proceedings should be allowed by the party which would benefit from such materials or statements, to meet with the HCP and examine the materials in their entirety. The outcome of the meeting with the HCP shall be announced to the parties and to the other members of the Ethics Committee at the next session of the complaint, without revealing the identity of the HCP. Documents prepared by the Ethics Committee in connection with the hearing of the complaint, which was held under such proceedings/ orders, rulings and decisions shall not contain data identifying the HCP.

6.9.3. If there are no claims for collecting additional evidence or the Committee does not uphold such claims, the end of the evidence collecting procedure is called and the consideration on the merits follows, where both parties state their arguments and accordingly are entitled to reply and rejoinder.

6.10. Both parties should be equal in rights in the proceedings. This principal includes as well the right of equal time for pleading.

6.11. The Committee members can ask questions both parties, any time, as to clarify the disputable facts and positions.

6.12. The Committee reviews the complaint on the grounds of the claimed infringements of the Code of Ethics alone. The Committee cannot extend officio the subject or the parties of the complaint.

6.13. The Ethics Committee shall notify both parties about its decision/ruling within 14 days from the date of rendering it and shall enclose a copy thereof[18]. The decision/ruling shall explicitly state the body to which it may be appealed, as well as the time limit to do so.

[16] The written statement of the defendant should not contain names or other personal information of particular medical professionals.

[17] The report should not contain names or other personal information of particular medical professionals.

[18] The decision / ruling of the Ethics Committee must not contain names or other personal information of particular HCPs.

6.14. Within 7 days as of the receipt of Ethics Committee's decision establishing infringement of this Code, the respondent is expected to submit a list of particular measures to discontinue activities found to have infringed on this Code, made in writing, signed by the person representing the company and a declaration pledging to prevent similar actions in future.

7. Should the respondent admit, in writing, the claimed infringement within 15 days from the receipt of the copy of the complaint, it must inform the Ethics Committee about the measures undertaken to eliminate harmful consequences / to restore the condition as existed prior to the infringement, before the first session has been held. In these cases, the Ethics Committee may cease the proceedings.

8. Should the respondent express objection against the claimed infringement, it must indicate specific reasons for this objection, and if applicable, submit reasoning (for example scientific publications) supporting the objection before the Ethics Committee.

Appeal against the decision of the regular panel of the Ethics Committee

1. The respondent and the complainant may appeal against the decision of the Ethics Committee in its regular panel before the extended panel of Ethics Committee within 15 days as of the decision receipt.

2. With regard to the submission and the handling of the complaint against the decision of the regular panel of the Ethics Committee, the relevant provisions listed above apply.

3. The chairperson of Ethics Committee schedules a session of the extended panel of the Ethics Committee within 30 days from lodging the complaint under item 1. Both parties shall be summoned, in writing, by the chairperson of the Ethics Committee at least 7 calendar days prior to the scheduled session.

4. The decision taken by the extended panel of the Ethics Committee shall be considered final and shall not be subject to appeal[19]

Sanctions

1. Upon establishing an infringement of the Code of Ethics, the Committee shall impose a fine in the amount of BGN 2,000 to BGN 7,000, depending on the nature and gravity of the infringement.

a. In cases of relapse (two or more offences within 12 months), the Committee imposes a penalty of twice the maximum penalty.

b. The monetary sanction is due within 30 days of receipt of the Committee's decision by the respondent.

c. Monetary sanctions imposed are payable to the Association pursuant to Article 37 of the Association's Statute as an additional voluntary contribution.

2. When a breach of the Code of Ethics is established, the decision of the Ethics Committee shall be announced to the remaining companies that have signed this Code. Depending on the nature

[19] The decision of the extended panel of the Ethics Committee cannot contain names or other personal information of particular HCPs.

and gravity of the offence, the Committee may decide to announce the decision to the parent company.

3. In cases of a recurrent offence, the decision of the Ethics Committee may be announced to the competent authorities and professional organisations including international ones.

4. The Ethics Committee may prescribe mandatory corrective actions to address the harmful consequences. In this case, the Committee approves and monitors the implementation of the corrective actions.

5. Where the Ethics Committee considers it necessary, it may propose to the Managing Board of the Association to expel the respective Company. The expulsion is governed by the procedure provided in the Association's Statute.

ANNEX A (binding)

TABLE

ANNEX A - STANDARDISED DISCLOSURE TEMPLATE

Date of publication: .....

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

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

latest update: 27 June 2019

June 2020

*HCP – healthcare professional

*HCO – healthcare organisation

ANNEX B (binding)

EFPIA guidance

GUIDELINES FOR DISCLOSURE OF NON-INTERVENTIONAL STUDIES

Background

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

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

The Ethics & Compliance Committee (E&CC) had considered that definitions in the new EU Clinical Trials Regulation 536/2014[20] could be used for reference when implementing the Disclosure requirements, thus anticipating and align with the regulatory change that will eventually take place.

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

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

Relevant EFPIA Disclosure Code provision

Schedule 1: Definition of Terms

Research and Development Transfers of Value - Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Regulation N° 536/2014[21]); or (iii) non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (Section 15.01 of the HCP Code).

Guidance

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

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

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

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

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

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

This Guidance will apply at the latest to 2021's ToVs, the (reported in 2022).

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

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

RECIPIENT **PCO RECEIVING THE TOVS**	BENEFICIARY **HCP/HCO BENEFITTING**	DISCLOSURE
PCO on behalf of / in collaboration with HCO	where the Member Company knows the HCP/ HCO benefitting	Individual disclosure following guidance

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

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

ANNEX C (binding)

Guidance obligations for Member Associations under the EFPIA Code

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

Article 10 Events and hospitality

For the purposes of this Code, ARPharM has set monetary thresholds and has defined the meaning of the term "reasonable", "appropriate", " renowned for their entertainment facilities" and "extravagant" Venues, as used in the Article 10.

Article 15 Contracted services

Article 21.03

Any support that can find financial expression and whose value is over BGN 100, including VAT, is significant.

ANNEX D (binding)

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

IMPLEMENTATION & ENFORCEMENT OF CODES

PROCESSING OF COMPLAINTS

QUESTIONS SUBMITTED TO EFPIA

Background

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

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

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

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

- EFPIA's "Code of Practice on the Promotion of Medicines and Relationships with Healthcare Professionals" (HCP Code);

- EFPIA’s Code on Relationships between the Pharmaceutical Industry and Patient Organisations" (PO Code); and

- EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (Disclosure Code).

Under these Rules each member association is required to:

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

- Ensure that its national code, together with its administrative procedures and other relevant information, are easily accessible through, at a minimum, publication of its national code on its website; and

- Prepare, and provide to the EFPIA Codes Committee, an annual report summarizing the work undertaken by it in connection with the implementation, development and enforcement of its national code during the year.

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

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

Relevant EFPIA Code Provision

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

ANNEX A to the EFPIA Codes is attached for reference.

STANDARD OPERATING PROCEDURES (SOP)

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

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

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

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

Common procedure rules

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

A. Complaints[22] RECEIVED BY EFPIA

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

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

- EFPIA will forward any complaints it receives (without considering their admissibility or commenting upon them) to the relevant member association(s)

- EFPIA will send an acknowledgement of receipt to the complainant, indicating the relevant national association(s) to which the complaint has been sent for processing and decision.

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

Procedural Steps

- When a complaint is received by EFPIA, the Compliance Officer forwards it, within 10 working days, to the relevant Member Association(s) for action under the Member Association(s)'s procedure for dealing with complaints, and the complainant will be informed of which Member Association(s) are responsible for dealing with the complaint

- Simultaneously, the Compliance Officer will inform, in writing, the responsible senior employee[23] of the company(ies) against which the complaint is made. If the complaint involves a number of countries, EFPIA will forward the complaint to the Member Association of the parent company and to the relevant company's subsidiary(ies)

- The Member Association(s) must acknowledge receipt of the complaint from EFPIA within 30 days following EFPIA's communication

- The Member Association(s) should consider the complaint under its usual procedure, including timelines. During the adjudication period, EFPIA will not intervene, neither will it answer questions neither from the complainant nor from the Member Company(ies) involved in the case

- When the Member Association(s) has(ve) completed its(their) consideration of the matter, EFPIA must be so informed of the decision(s) made by the adjudication bodies, including, where appropriate, the sanction imposed. The Member Association(s) should provide updates to EFPIA as the matter proceeds no later than 6 months after it receipt of the complaint, and subsequently within each following quarter until a final decision is made on the compliant (within a reasonable timeframe)

- A summary of decisions made on cases submitted to EFPIA will be published in EFPIA's Codes Activity Report - once the complaint has been concluded, the learnings might lead to further discussion by the Codes Committee including enhancing code consistent implementation, where relevant.

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

[23] Each Member Company must appoint at least one senior employee who shall be responsible for supervising the company and its subsidiaries to ensure that the standards of the Applicable Code(s) are met. *See EFPIA Charter and Section 18.02 of the EFPIA HCP Code.*

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

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

- either be a member of ARPharM (either directly or through the relevant subsidiary);

- Or agree in writing with ARPharM that the company (or its relevant subsidiary) is bound by this Code (including any applicable sanctions that may be imposed thereafter).

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

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

Procedural Steps

- When the Ethics Committee of ARPharM, following completion of the adjudication of a complaint is unable to achieve resolution of a complaint concerning an EFPIA Member Company, the Association will inform EFPIA, indicating the reasons[24] why it cannot achieve resolution of the complaint;

- Within 10 working days of notification of the issue, EFPIA's Compliance Officer will inform, in writing, the responsible senior employee[25] of the Member Company concerned with ARPharM's request for EFPIA's intervention;

- Based on the respondent Member Company's comments (that should be provided to EFPIA within 30 days of EFPIA's request), EFPIA's Compliance Officer will consult with the Codes Committee Chairs to agree on follow-up actions that could be recommended. These actions could be to report to the Codes Committee and/or to EFPIA Board. The Codes Committee Chairs should agree on these actions within 60 days;

- No later than 120 days following ARPharM's initial information, EFPIA will inform the Member Company of steps that it is expected to take in accordance with its EFPIA membership obligations;

- Within 30 days, the Member Company should inform EFPIA of follow-up actions put in place, and ARPharM will confirm with EFPIA that the issue has been settled;

[24] For example: The Member Company concerned might not be a member of the Member Association in that country; or it might not accept a decision of that Member Association.

[25] Each Member Company must appoint at least one senior employee who shall be responsible for supervising the company and its subsidiaries to ensure that the standards of the Applicable Code(s) are met. *See EFPIA Charter and Section 18.02 of the EFPIA HCP Code.*

- If no response is received from the Member Company or the response is not adequate, EFPIA will take the opinion of the Codes Committee on next steps to be taken. The Codes Committee could decide on further action, such as reporting the matter to the EFPIA Board that will decide on the recommended action that should be agreed.

C. MEMBER COMPANY NOT SUBMITTED TO APPLICABLE CODES

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

Scope and Applicability of EFPIA Codes

The EFPIA Codes apply to activities relating to prescription-only medicines (POM) (whether patented or off-patent, branded or generics). This is similar to the scope of the EU Pharma Regulation[26]. The Codes are **applicable to all activities relating to POM and relationships with Healthcare Professionals, Healthcare Organisations and Patient Organisations** (as defined in the Codes, and excluding commercial activities).

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

Implement high and transparent standards of conduct in dealings with external stakeholders, including:

- **Abiding by the rules of EFPIA including rules laid down in the EFPIA Codes**:

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

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

For application of the EFPIA Codes, the term "Company" shall mean any legal entity that organises or sponsors promotion, or engages in interactions with healthcare professionals covered by an Applicable Code, which takes place within Europe, whether such entity be a parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation[27].

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

Procedural Steps

[26] DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use.
[27] See Section "Applicability of the Code" in the EFPIA Codes.

- When actions undertaken by a Member Association aiming at ensuring that an EFPIA Member Company is subject to that Member Association's national code are unsuccessful, the Member Association will inform EFPIA, in writing, providing details of its actions and the Member Company's response;

- EFPIA will intervene directly when an EFPIA Member Company does not submit to the national applicable codes and require that the Member Company formalises its adherence to national applicable codes including their adjudication arrangements within 2 months of EFPIA's request;

- If the EFPIA Member Company still does not agree to respond to EFPIA's request to confirm its adherence to applicable national codes (including submission to the national sanction system), the Board will be informed;

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

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

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

Procedural Steps

- When EFPIA establishes that a Member Association does not have the required national procedures and body in place to receive and process complaints, it shared the elements on which its assessment is based with the Member Association, with a request to provide a written explanation within 30 days.

- If EFPIA maintains its view that the Member Association's arrangements for implementation of its code are inconsistent with those required by the EFPIA Codes, EFPIA will refer to the Codes Committee that will hear the Member Association at its next upcoming meeting.

- Within 30 days of the Codes Committee meeting, the Compliance Officer will submit a remediation plan (approved by the Codes Committee Chairs) to the Member Association with the deadline for implementation of proposed measures (which should not exceed 3 months).

- Where the Member Association fails to confirm the establishment of appropriate implementation and procedure rules within the 3-month deadline, the Codes Committee will escalate the case to the Board with a request for intervention.

E. QUESTIONS SUBMITTED TO EFPIA FOR CLARIFICATION OF CODE PROVISIONS

The EFPIA Codes set out the minimum standards which EFPIA considers must apply to all EFPIA Member Companies in the countries where they operate. Member Associations will transpose the

EFPIA Codes' provisions into their national codes, in line with applicable law or regulation. Member Associations may adopt stricter standards.

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

Deviations and Variations

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

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

Clarification and interpretation of Code provisions

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

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

Procedural steps

- EFPIA will acknowledge receipt of a question submitted by a Member (either a company or an association) within 10 days;

- When an EFPIA Member submits a question that goes beyond factual clarification of an EFPIA Code provision, EFPIA's Compliance Officer will draft an answer for review by the Codes Committee Chairs and the Member Association of the country(ies) involved, who may want to complement. It is expected that input from Codes Committee Chairs and Member Associations will not delay EFPIA's response beyond 1 month following the date of the question;

- Where the Codes Committee Chairs would consider that the question must be submitted to the full Codes Committee, EFPIA's Compliance Officer will inform the author of the question. In such case, the final response should however be sent no later than 3 months following the date of the question;

- Answers that pertain to Codes interpretation with a broader scope will be summarized in the yearly Codes Activities Report, and may be submitted as a Recommendation for Guidance to the Board approval, enhancing consistent implementation of the EFPIA Codes.

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

ANNEX D

Examples of ethical principles

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

- Continue to improve existing treatments and deliver innovative new medicines.

- Support the common objective of timely access to medicines.

- Maintain a dialogue to better understand the needs of patients.

- Work with stakeholders including research communities to tackle healthcare challenges.

- Continue appropriate collaboration with HCPs and others to support their role in treating patients.

2. We act with INTEGRITY, therefore we:

- Engage with HCPs/HCOs/POs only when there is a legitimate need.

- Take into consideration the role and responsibility of stakeholders with whom we interact to avoid conflicts of interest or improper influence.

- Consider the values, standards, procedures and decision-making processes of other stakeholders.

- Support evidence-based decision making.

- Facilitate access to medical education and help rapid dissemination of scientific information.

3. We act with RESPECT, therefore we:

- Are conscious of the importance of providing accurate, fair and objective information about medicinal products so that rational decisions can be made about their appropriate use.

- Support the independence of the prescribing decisions of HCPs.

- Assure mutual respect and independence, in terms of political judgment, policies and activities, in all partnerships with patient organisations.

- Promote an attitude and environment of mutual regard for other stakeholders, taking into account differences such as cultures, views and ways of working.

4. We are TRANSPARENT about our actions, therefore we:

- Share clinical trial data in a responsible way.

- Publish details of the Transfers of Value made to HCPs and HCOs.

- Publish details of financial support and significant non-financial support to patient organisations.

- Clearly indicate pharmaceutical company sponsorship of any material relating to medicinal products and their uses.

- Disclose activities through other relevant registers (such as the European Institutions' Transparency Register)

ANNEX E (binding)

EFPIA e4ethics rules and procedure

1. Background

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

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

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

2. e4ethics decisions binding and mandatory assessments

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

3. Collaboration with MedTech Europe

In 2012, MedTech Europe, the European Association for Medical Devices, set up the Conference Vetting System (CVS) as an independently managed system that checks the compliance of third-party

educational events with MedTech Europe's Code of Ethical Business Practice and Mecomed's Code of Business Practice. The outcome of the assessment determines the appropriateness for MedTech Europe and Mecomed member companies to provide financial support to the events. The decisions rendered by the Compliance Officer are binding on MedTech Europe and Mecomed members. This means that these members cannot provide support to an event which is found to be non-compliant.

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

a. Key elements

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

Common back end[28]: In the back end, all assessment requests will be received by MedTech Europe Compliance Officers, which will become the Compliance Officers also for Pharma Events.

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

b. Alignment of criteria

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

- **The submission for events assessment must be done proactively and online by the EFPIA member companies or the congress organisers.**
- The travel arrangements and meals & drinks threshold will no longer be part of the criteria assessed. Therefore, the EFPIA Member Associations will not be consulted.

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

- **Submission in e4ethics will be mandatory, i.e. EFPIA Member Companies need to verify that a e4ethics positive assessment is available for the Event prior to being able to provide any kind of support, from the first day of the pilot phase. This submission can be made by the Member Company or the Congress Organiser (HCO/PCO).**
- **Binding nature of all decisions rendered by e4ethics on the EFPIA members during and after the pilot phase, meaning that an Event assessed as non-compliant cannot receive any form of support from EFPIA members.**
- Full MedTech Europe/EFPIA alignment on the approach and interpretation of the six assessment criteria, which means that there will not be a difference on how Pharma and MedTech Events will be assessed.

c. Important considerations

The following considerations are important:

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

4. Procedure applicable to e4ethics

a. Appeal

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

An appeal may be filed by the congress Organiser with the Compliance Panel provided that the following requirements are respected:

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

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

b. Complaint related to an Event

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

"A. Complaints[29] received by EFPIA

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

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

Procedural Steps

1 *When a complaint is received by EFPIA, the Compliance Officer forwards it, within 10 working days, to the relevant Member Association(s) for action under the Member Association(s)'s procedure for dealing with complaints, and the complainant will be informed of which Member Association(s) are responsible for dealing with the complaint;*
2 *Simultaneously, the Compliance Officer will inform, in writing, the responsible senior employee[30] of the company(ies) against which the complaint is made. If the complaint involves a number of countries, EFPIA will forward the complaint to the Member Association of the parent company and to the relevant company's subsidiary(ies);*
3 *The Member Association(s) must acknowledge receipt of the complaint from EFPIA within 30 days following EFPIA's communication;*

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

[30] Each Member Company must appoint at least one senior employee who shall be responsible for supervising the company and its subsidiaries to ensure that the standards of the Applicable Code(s) are met. *See EFPIA Charter and Section 18.02 of the EFPIA HCP Code*

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

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