AIPM
CODE OF PRACTICE

based on the Code of Practice approved by the EFPIA General Assembly on 27 June 2019

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2020

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DEFINITIONS

The definition of commonly used, capitalised terms and abbreviations are included in the order of their appearance in the text to ensure consistent interpretation, in accordance with the provisions of (i) Act XCV of 2005 on Medicinal Products for Human Use and Amendments to Other Regulations on Medicinal Products, and (ii) Act XCVIII of 2006 on the General Provisions Relating to the Reliable and Economically Feasible Supply of Medicinal Products and Medical Aids and on the Distribution of Medicinal Products.

Applicable Codes:

a) (i) in the case of promotion or interaction that is undertaken, sponsored or organised by or on behalf of, or with, a Member Company located within Europe, the Member Association National Code of the European country in which such Member Company is located; 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 of Europe, the EFPIA Code; and

b) 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 Member Company sponsors the attendance of a Healthcare Professional, if any funding is provided to such Healthcare Professional in accordance with the provisions of Article 13, such funding is subject to the rules of the National Code where such Healthcare Professional 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(s) set in the country where the Event takes place (i.e. the "host country") must prevail.

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

Donations and Grants: collectively, mean the provision of funds, assets or services to organisations free of charge for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the Beneficiary to provide goods or services to the benefit of the donor in return.

AIPM – Association of Innovative Pharmaceutical Manufacturers: professional and advocacy association of innovative pharmaceutical companies operating in Hungary.

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

EFPIA Code: The EFPIA Code of Practice including the annexes.

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

Events: All professional, promotional, scientific, educational events, 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 Member Company.

Gift: Gifts for the personal benefit (such as sporting or entertainment tickets, electronic items, social courtesy gifts, etc.) of Healthcare Professionals, Healthcare Organisations' members or Patient Organisations' Representatives (either directly or indirectly through a Healthcare Organisation or Patient Organisation) are prohibited, not including Informational or Educational Materials, and Items of Medical Utility.
Providing or offering cash, cash equivalents or personal services is also prohibited. For these purposes, personal services are any type of service unrelated to the Healthcare Professional's profession and that confer a personal benefit to the Healthcare Professional.

Healthcare Organisation/Provider (HCO): any legal person, entity, individual entrepreneur (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 Patient Organisations within the scope of Article 21) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more Healthcare Professionals provide services.

Healthcare Professional (HCP): natural persons having medical qualifications, participating in the recommendation, prescription, procurement, selling, distribution or administering of medicinal products and in the provision of health services, including, in particular, physicians, pharmacists, healthcare professionals, members of healthcare service provider staff or any other specialist working in health care. In the application of this Code, the definition of healthcare professionals includes the following: (i) any official or employee of a government, agency or other organisation (whether in the public or private sector) that may prescribe, purchase, recommend or administer Medicinal Products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) wholesalers or distributors of Medicinal Products, and their employees.

Host country principle: The monetary threshold set for one meal (food and beverages) in the National Code of the country where the Event takes place shall prevail against the thresholds set in other national codes.

Informational or Educational Material: constitutes inexpensive document directly relevant to the practice of medicine or pharmacy and directly serving the interests of patient care.

Item of Medical Utility: constitutes inexpensive item aimed directly at the education of Healthcare Professionals enhancing the provision of medical services and patient care and that does not offset routine business practices of the Healthcare Professionals.

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.

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

Medical Sales Representative: a natural person employed by a Member Company or under contract by Third Parties, in employment relationship or under other contractual agreement to work, who meets the qualification requirements laid down in a decree of the minister responsible for healthcare and has a medical sales representative licence.

Medical Sample: as free samples of Medicinal Products, no more than two packaging units per year per medicine may be provided to each person authorised to prescribe, instruct on the use of, and distribute medicines, following the start of sales of the medicine in Hungary, with the mention that in the case of medical aids, the two packaging units must not exceed the quantity necessary for one month. No free samples may be given of medicines in a subsidy category higher than 0% subsequent to the end of the year following the start of sales of the medicine in Hungary.

Medicinal Product: any substance or combination of substances presented as having properties for preventing or treating human diseases, or any substance or combination of substances which may be used in or on the human body by exerting pharmacological, immunological or metabolic effects, either with a view to restoring, correcting or modifying physiological functions or to making a medical diagnosis.

Member Association: means an organisation representing pharmaceutical manufacturers at national level whose members include, among others, research-based companies. Collectively, the national Member Associations or their constituent members, as the context may require, and bound by the EFPIA Code.

Member Company: EFPIA and AIPM members – research-based companies, developing and manufacturing Medicinal Products for human use in relation to the requirements set out in this Code of Practice.

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

National Code: The code of practice of a Member Association.

Non-Interventional Study (NIS): is a study where the Medicinal Product is prescribed in the usual manner in accordance with the terms of the marketing authorisation and 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): non-profit organisation – including the umbrella organisation to which it belongs –, which is a legal person or business organisation mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers (including the umbrella organisation to which it belongs) and whose 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 Patient Organisation 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].

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[2] Article 2 of the 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.

Prescription-Only Medicines (POM): is a Medicinal Product that requires a medical prescription issued by a professional person qualified to prescribe.

Commercial practice: any information, activity, practice of presentation, marketing or other kinds of commercial communication intending to increase prescription, procurement, sale or consumption of a medicinal product.

Promotion or Medicinal Product: A commercial practice dealing with the composition, effect, and administration of a medicinal product, and performed exclusively for or by Healthcare Professionals qualified to prescribe and distribute medicinal products.

Beneficiary: any Healthcare Professional or Healthcare Organisation or Patient Organisation as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Europe.

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

Research and Development Benefit: Benefits to Healthcare Professionals or Healthcare Organisations 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[5] 536/2014); 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, Healthcare Professionals specifically for the study.

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

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

Benefit: Direct and indirect benefit, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of Prescription-Only Medicine exclusively for human use. Direct Benefits are those made directly by a Member Company for the benefit of the Beneficiary. Indirect Benefits are those made on behalf of a Member Company for the benefit of a Beneficiary, or those made through a Third Party and where the Member Company knows or can identify the Beneficiary that will benefit from the Benefit.

Professional Congress Organiser (PCO): is a company/individual specialised in organising and conducting Events. For the application of this Code, commercial companies involved in organisation of travel (travel agencies) or accommodation (hotels, event venues, banqueting functions in hotels, etc.) are not considered PCOs.

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

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[5] In the EFPIA HCP/HCO Disclosure Code, the definition of Research and development Benefits 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.

PREAMBLE

The present Code of Practice constitutes the set of ethical rules agreed by the member companies of the AIPM for the Promotion of Medicinal Products to HCPs and the interactions with HCPs, HCOs and POs, so that these activities are conducted while respecting the most stringent ethical principles of professionalism and responsibility.
This Code of Practice applies to all types of communication and interaction (traditional and digital).

ETHICAL PRINCIPLES

As pharmaceutical companies, we work in collaboration with various stakeholders including Healthcare Professionals, Healthcare Organisations/Providers, Patient Organisations and their Representatives, regulatory authorities, governments and the public with the aim of increasing and improving health and quality of life, as well as the quality of patient care.

We continuously invest 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.

We believe in what we do and know that there is somewhere a patient whose health and well-being is, directly or indirectly, dependent on our work.
We aim at creating an environment where our stakeholders and the public, consider pharmaceutical companies as trusted partners.

In addition to complying with extensive legal requirements (i.e. laws and regulations applicable to our industry such as pharmaceutical, 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 position statements.

For EFPIA, its Member Organisations – including the AIPM – and its Member Companies, self-regulation means being fully committed to define, implement, comply with and enforce the highest ethical standards through EFPIA and National Codes, where breaches are not tolerated.
Self-regulation includes the concept of continuous challenge for us to exceed society's expectations and openness regarding suggestions from others on how we might further strengthen confidence in our industry and our behaviour.
Stakeholders who share the values and principles enshrined in this self-regulation are invited to adhere to these rules and guidance[6].

[6] EFPIA Leadership statement on ethical practices – June 2010

This demonstrates our commitment to the following ethical principles:

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

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

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

All members of EFPIA and the AIPM[7] are aware 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 Healthcare Professionals, Healthcare Organisations and Patient Organisations, 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 Healthcare Professionals, Healthcare Organisations and Patient Organisations.

Chapters 1, 2, and 3 reflect the requirements of Directive 2001/83/EC, on the Community code relating to medicinal products for human use and its subsequent amendments, 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.

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

The EFPIA Code and the present Code of Practice thereby aim 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 management 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 compensated for the legitimate expertise and services they provide to the industry.

The EFPIA and the AIPM believe that interactions between Member Companies 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 a HCP to prescribe a Medicinal Product is one of the pillars of the healthcare system. The EFPIA and the AIPM recognise that interactions between the industry and HCPs/HCOs can create the potential for conflicts of interest. Consequently, professional and industry associations, including EFPIA and its Member Associations, have adopted codes and guidelines to ensure that these interactions meet the high standards of integrity that patients, governments and other stakeholders expect.

In order to continue to be successful, self-regulation needs to meet to the evolving expectations of society. In particular, the EFPIA and the AIPM recognise the growing expectation that interactions with society are not only conducted with integrity but are also transparent.

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.

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[7] The updated list of EFPIA members is available at www.efpia.eu, and the list of AIPM members is available at the https://aipm.hu/en/who-we-are/member-companies website.

POs have a key role in helping to shape, develop and define the outcomes that make the most difference to patients. Member Companies disclose the amounts provided to POs in the framework of these interactions.

The EFPIA and the AIPM strongly support 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, since the introduction of the EFPIA Disclosure Code, EFPIA has worked hard to encourage Member Companies to always look to disclose and to encourage HCPs (and HCOs where relevant) to agree to individual disclosure.

SCOPE OF THE CODE OF PRACTICE

This Code of Practice shall enter into force on the 1st of January 2021.

The Code of Practice covers the following:

- the commercial practice of AIPM Member Companies related to prescription-only medicines;
- the promotion of prescription-only medicines by AIPM Member Companies to HCPs;
- interactions between AIPM Member Companies and HCPs and HCOs including, but not limited to, interactions in the context of research or contractual arrangements (including certain aspects of clinical trials, non-interventional studies as well as consultancy and advisory board), and POs;
- disclosure of Benefits from AIPM Member Companies to HCPs, HCOs and POs; and
- procedural requirements of the present Code of Practice.

The Code of Ethics for Pharmaceutical Marketing Communication is only applicable in accordance with the provisions of this AIPM Code of Practice. In case of any inconsistency, AIPM Member Companies are required to apply the provisions of this Code of Practice to each other.

Member Companies shall be responsible for the compliance with the obligations imposed under the present Code of Practice even if they commission a Third Party to design, implement or engage in activities covered by this Code on their behalf. Furthermore, Member Companies must take reasonable steps to ensure that Third Parties commissioned to engage in activities covered by the present Code of Practice comply with the present Code of Practice, if they do not perform such activities on behalf of the Member Company (e.g. joint ventures, licensees).

The present Code of Practice covers all types of Promotion 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 communication forms and channels, such as websites and social media, the use of audio-visual systems such as films, video recordings, data storage services etc. It also covers the provision of Informational or Educational Materials, Items of Medical Utility, hospitality in relation to Events and Medical Samples.

The present Code of Practice does not regulate the activities directed towards the general public which relate solely to non-prescription Medicinal Products.

Furthermore, the present Code of Practice does not cover the following:

- the labelling of Medicinal Products and accompanying package leaflets, which are subject to the provisions of Title V of the Directive 2001/83/EC;
- answering a specific question about a particular Medicinal Product, possibly accompanied by professional-scientific material that does not fall within the definition of promotion and its content does not qualify as promotion;
- factual, informative announcements and reference material relating to pack changes, adverse-reaction warnings as part of general precautions, trade catalogues and commercial price lists, provided they include no promotional claims related to products;
- activities which relate solely to non-prescription Medicinal Products; or
- non-promotional, general information about Member Companies (such as information directed to investors or to current/prospective employees), including financial data, descriptions of research and development programmes, and regulatory developments affecting a Member Company and its Medicinal Products.

CHAPTER 1

PROMOTION OF PRESCRIPTION-ONLY MEDICINES TO HEALTHCARE PROFESSIONALS

ARTICLE 1 MARKETING AUTHORISATION

Section 1.01. The promotion of prescription-only medicines is prohibited in Hungary before the issuance of a valid marketing authorisation permitting its sale, or outside the approved indication.

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

Section 1.03. New scientific knowledge relating to pharmaceutical research may be disclosed at professional-scientific conferences or in professional publications if the provision of such information does not qualify as commercial practice according to existing legislation. Even in communicating such information it must be clearly pointed out that the provided information is not part of the marketing authorisation of any specific medicinal product.

ARTICLE 2 INFORMATION TO BE MADE AVAILABLE

Section 2.01. Subject to applicable national laws and regulations, in the interest of providing detailed and balanced information on medicinal products, all written promotional materials presented to HCPs must include the following information, in a clear and easily legible form:

a) essential information consistent with the summary of product characteristics, specifying the date on which such essential information was generated or last revised;
   including the strength and pharmaceutical form, active ingredient (international non-proprietary name), dosage and method of administration, authorised indication(s), contraindications and most important side effects of the medicinal product;
b) the following warning: "For more information, please read the summary of product characteristics";
c) name and address of the marketing authorisation holder's agent in Hungary, who is available to provide more information on the application of the medicinal product;
d) name and supply classification of the Medicinal Product; and
e) when appropriate, the selling price or indicative price of the various presentations and the conditions for reimbursement by social security bodies.
f) the internal ID of the material;
g) date on which the document was finalised or last updated;

Instead of the information presented in subparagraph a) (except for its authorised name, including strength and pharmaceutical form, active ingredient (international non-proprietary name), the website address link that leads to the entry in the medicine database of the pharmaceutical public authority or the competent EU authority that refers to the medicine presented can be indicated on the promotional material. In addition to the website address, a QR code pointing to the same web address can also be displayed.

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

Section 2.03. The logo of the medicinal product shall not include any information that is not present in the summary of product characteristics relative to the name, qualitative and quantitative composition or dosage form of the medicinal product.

Section 2.04. If information qualifying as promotion is presented on the item referred to in subsection 2.02. of this Chapter, the rules set out in subsection 2.01. of this Chapter shall be applied as appropriate.

ARTICLE 3 PROMOTION AND ITS SUBSTANTIATION

Section 3.01. Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the HCP to form his/her own opinion of the therapeutic value of the Medicinal Product concerned. The information provided must be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. The information provided must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.

Section 3.02. The information provided must be capable of substantiation and to the reasonable request of Healthcare Professionals, competitors, competent authorities or the Member Company literature used for this purpose must be provided within ten (10) days from such request. In particular, the information provided about side effects must reflect available evidence or be capable of substantiation by clinical practice. However, no substantiation is required in relation to the validity of product characteristics approved in the summary of product characteristics.

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

Section 3.04. Only scientific findings that have been communicated in literature should be used for substantiation, including, as a minimum requirement, written abstracts of lectures delivered or posters presented at local or international conferences. Further substantiation in relation to the contents of the summary of product characteristics is not needed.

Section 3.05. Any comparison made between different Medicinal Products must be based on relevant and comparable aspects of the Medicinal Products. Only comparable aspects are permitted to be compared. Comparative commercial communication must not be misleading or degrading, competitors' products must not be discredited; no unfair advantage must be obtained by misuse of the reputation of a competitor's product or trademark; promotional materials or other materials containing information of other Companies must not be disclosed, even in imitation, or published as own work; price comparison in any promotional material shall also qualify as pharmaceutical advertisement, and therefore such comparisons should use specific data and precise references to the source.

Section 3.06. All artwork, including graphs, illustrations, photographs and tables taken from published studies included in information provided must comply with the following: (a) the precise source(s) of the artwork must be clearly indicated; (b) they must be faithfully reproduced.
Particular care must be taken to ensure that artwork included in the information provided 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). Data published in the referenced publication(s) in tabular or textual form may be displayed graphically under the following conditions:

a) all data being relevant for the substantiation of the claim must be displayed;
b) if only part of the data included in a table is displayed, this fact must be clearly indicated;
c) scales must be displayed accurately and non-continuous scales must be marked as such;
e) "n" values (number of items) and significance values must be provided;
d) the text of the graph must legibly and clearly indicate that it is based on data which were used in the publication with the indication of page number and/or figure number.

Generalisations shall not be used. Comparatives or superlatives shall only be used to describe specific and sufficiently substantiated facts.

Section 3.07. The word **"safe"** or any of its derivatives must never be used to describe a Medicinal Product without proper indication of source. It can only be used with the accurate definition of its meaning (e.g. "its plasma concentration will not be higher even in patients with renal insufficiency"), referring to the proper source and avoiding any exaggerated generalisations (such as "proven safety").

Section 3.08. The word **"new"** must not be used to describe any Medicinal Product or presentation which (i) has generally been commercially available in Hungary, this period runs from the first delivery to the wholesaler, or (ii) any therapeutic indication which has been generally promoted, for more than one year.

Section 3.09. It must not be stated that a Medicinal Product has no side effects, toxic hazards, or its use is not associated with the risks of addiction or dependency.

ARTICLE 4 USE OF QUOTATIONS IN COMMERCIAL PRACTICE

Quotations from medical and scientific literature, specialist reports or personal communications must be faithfully reproduced, and the author, as well as the place and time of publication must be specified.

ARTICLE 5 ACCEPTABILITY OF COMMERCIAL PRACTICE

Member Companies must maintain high ethical standards at all times. COMMERCIAL PRACTICE SHALL: (a) never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry; (b) be of a nature which recognises the special nature of Medicinal Products and the professional standing of the intended audience; and (c) not be likely to constitute infringement, not be abusive, misleading or aggressive; (d) reflect in its texts precision and they shall be consistent with the grammatical rules and orthography of the language used, and with the rules of proper style; (e) be easily understandable for patients and/or for consumers to whom the advertisements and publicities are addressed; (f) be subject to reasonable self-control and moderation.

ARTICLE 6 RECIPIENTS OF PROMOTION

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

Section 6.02. Distribution lists of recipients of the Promotion must be maintained and updated in full compliance with the data protection regulations. Requests to be removed from mailing lists must be complied with.

Section 6.03. Subject to applicable national laws and regulations, the use of faxes, e-mails, automated calling systems, text messages and other electronic data digital communications for Promotion is prohibited except with the prior permission, or upon the request, of those who receive it.

ARTICLE 7 TRANSPARENCY OF COMMERCIAL PRACTICE

Section 7.01. Commercial practice must not be covert.

Section 7.02. Clinical assessments, post-marketing surveillance programmes, and post-authorisation studies (including those that are retrospective in nature) must not be the subject of surreptitious commercial practice. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose.

Section 7.03. Where a Member Company pays for or otherwise secures or arranges the publication of the commercial communication in a journal, such commercial communication must not resemble independent professional or scientific publication, or editorial material.

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

Section 7.05. The use of pre-made, pre-printed, stamped or otherwise reproduced prescription forms containing the name of a medicinal product, or the use of promotional materials that are confusingly similar to prescription forms, shall not be allowed in commercial practice. The use of pre-made, pre-printed, stamped or otherwise reproduced other forms (e.g. referrals, recommendations) containing the name of a prescription-only medicinal product or a medicinal product which can be ordered under social security subsidy, shall be prohibited in commercial practice.

ARTICLE 8 PROMOTIONAL INFORMATION PROVIDED DURING INTERNATIONAL EVENTS

Promotional information which appears on exhibition stands or is communicated to participants at international Events may, unless prohibited or otherwise regulated by local laws and regulations, refer to Medicinal Products (or uses) which are not registered in the country where the Event takes place, or which are registered under different conditions, as long as: (i) any such promotional material is accompanied by a suitable statement indicating the countries in which the Medicinal Product is registered and makes clear that the Medicinal Product or indication is not registered locally, and (ii) any such promotional material which refers to the prescribing information (indications, warnings etc.) 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 ISSUES AND CAMPAIGNS FOR HEALTH EDUCATION (DISEASE AWARENESS)

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

Campaigns organised and/or sponsored by Member Companies with the aim of health education and raising health awareness that convey messages relating to human health or diseases, shall not qualify as advertisements of medicinal products, provided they neither directly nor indirectly qualify as commercial practice pertaining to a given medicinal product.

Health education campaigns raising health awareness shall be aimed primarily at enabling patients and laypersons to learn more about diseases, their prevention and symptoms and possible treatment. Such campaigns must provide precise and certifiable information for patients and for laypersons. The information must be balanced and must convey useful knowledge for patients and laypersons that they can actually use. Attention must be drawn in the campaign to the fact that decision on the suitable treatment must be taken by the HCP after consultation with the patient.

CHAPTER 2

INTERACTIONS WITH HEALTHCARE PROFESSIONALS, HEALTHCARE ORGANISATIONS AND PATIENT ORGANISATIONS

ARTICLE 10 EVENTS AND HOSPITALITY

Section 10.01. All Events must be held in "appropriate" Locations and Venues that are conducive to the main purpose of the Event, and Venues that are renowned for their entertainment facilities or are extravagant should be avoided.
In connection with the Events, "appropriate" Venues, therefore not extravagant, are those that have the necessary conditions for the transfer of information for scientific or educational purposes, and which do not serve exclusively as tourist destinations and are not linked exclusively to leisure/sports activities.

Section 10.02. No Member Company may organise or sponsor an Event that takes place outside its home country unless:

- most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the Event in another country; or
- given the location of the relevant resource or expertise that is the object or subject matter of the Event, it makes greater logistical sense to hold the Event in another country.

Section 10.03. Member Companies may only offer hospitality to HCPs, HCOs' members or POs' Representatives, if such hospitality is secondary to the purpose of the Event and the amount of hospitality is in accordance with the maximum amount prescribed by the Medicinal Products Act and the AIPM Board. The amount of the hospitality offered during foreign Events is governed by the rules of the country where the Event takes place - "Host Country Principle".

Section 10.04. Support in connection with Events must be limited to travel, meals, accommodation, and genuine registration fees.

Section 10.05. Hospitality shall only be extended to those persons who attend the Event in their own right. In exceptional cases of established health needs of a PO representative (e.g. disability or injury), the travel, meals, accommodation and genuine registration fee costs of an accompanying person may be paid.

Section 10.06. In accordance with Section 10.03., 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 on reasonableness, the hospitality provided must not exceed the amount that those individuals would normally be prepared to pay for themselves.

Section 10.07. Hospitality must not include sponsoring or organising entertainment events (e.g. sporting or leisure).

ARTICLE 11 PROHIBITION OF GIFTS

Section 11.01. Gifts for the personal benefit (such as sporting or entertainment tickets, social courtesy gifts) of HCPs, HCOs' members or POs' Representatives (either directly or indirectly) are prohibited, not including Informational or Educational Materials, and Items of Medical Utility. Providing or offering cash, cash equivalents or personal services is also prohibited. For these purposes, personal services are any type of service unrelated to professional activity and that confer a personal benefit to the Beneficiary.

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

ARTICLE 12 DONATIONS AND GRANTS TO HEALTHCARE PROFESSIONALS AND PATIENT ORGANISATIONS

Section 12.01 Donations and Grants provided (in cash, in kind or otherwise) 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 (iii) they do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.

Section 12.02. Donations and Grants to private individuals and to those specified by the national laws and regulations are not permitted. Rules on Contribution to the Costs of HCPs' participation in Events are specified in Article 13.

ARTICLE 13 CONTRIBUTION TO COST OF EVENTS AND SPONSORSHIP

Section 13.01. Member Companies must comply with the criteria governing the selection and support of HCPs or POs' Representatives to attend Events as provided in, or in connection with the present Code of Practice and local regulatory requirements. No payment must be offered to compensate merely for the time spent by the HCP or PO's Representative in attending Events.

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

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

ARTICLE 14 MEMBER COMPANY FUNDING AND SPONSORSHIP

No Member Company may require that it be the sole funder or sponsor of a PO or HCO or any of its programmes.
Member Companies welcome broad support and sponsorship of POs and HCOs from multiple sources.

ARTICLE 15 CONTRACTED SERVICES

Section 15.01. Contracts between Member Companies and HCPs, HCOs, POs or POs' Representatives under which the professional or organisation in question provides any type of service to that Member Company (not otherwise covered by the present Code of Practice) are only allowed if such service (i) is provided for the purpose of supporting healthcare, research or education; and (ii) does not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.

Section 15.02. It is permitted to use HCPs or POs' Representatives both 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, and for such participation they may receive remuneration, and reimbursement for travel, accommodation, and hospitality. The arrangements that cover these 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 subparagraph (g) below, the basis for payment of those services;
b) a legitimate need for the services has been clearly identified and documented in advance of requesting the services and entering into arrangements;
c) the criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular consultant meets those criteria;
d) the number of consultants retained and the extent of the service are not greater than are reasonably necessary to achieve the identified need;
e) the contracting Member Company maintains records concerning, and makes appropriate use of, the services provided by consultants;
f) the hiring 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 compensation for the services is reasonable and reflects the fair market value of the services provided. In this regard, token consultancy arrangements should not be used to justify compensating the HCPs or PO Representatives.

Section 15.03. In their written contracts with consultants, Member Companies are strongly encouraged by EFPIA and the AIPM to include provisions regarding the obligation of the HCPs to declare that they act upon the request of the given Member Company whenever they write or speak in public about a matter that is the subject of the agreement or any other matter relating to that Member Company.
The provisions of this Section 15.03. apply even though the present Code of Practice does not otherwise cover non-promotional, general information about Member Companies (as discussed in the "Scope of the Code of Practice" section).

Section 15.04. Limited market research, such as one-off phone interviews or mail/e-mail/internet questionnaires are excluded from the scope of this Article 15, provided that the HCP, HCO's member or PO's Representative is not consulted in a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) and that the remuneration is in accordance with the Fair Market Value.

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

CHAPTER 3

SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

ARTICLE 16 MEDICAL EDUCATION

Medical Education is aimed at increasing the scientific knowledge and competence of HCPs in order to enhance medical practice and improve patient outcome.
Member Companies may implement different types of Medical Education but such activities must not result in Promotion.
When supporting and/or sponsoring independent Medical Education or organising Medical Education activities either directly or in collaboration with Third Parties, Member Companies must ensure that their participation and role is clearly acknowledged at all times and apparent from the outset. When Member 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 elaborated to allow the expression of diverse theories and recognised opinions.

When supporting Medical Education, the Member Companies are obliged to comply with the legislative provisions in effect, with particular regard to mandatory refresher courses.

ARTICLE 17 INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

Section 17.01. The provision of Informational or Educational Materials is permitted provided it is: (i) "inexpensive"; (ii) directly relevant to the practice of medicine or pharmacy; and (iii) directly contributes to the improvement of patient care. With regard to "inexpensive", the provisions of the Medicinal Products Act shall apply.

Section 17.02. Items of Medical Utility aimed directly at the education of HCPs and patient care are permitted only if they are "inexpensive" and do not offset routine business practices of the receiving party. With regard to "inexpensive", the provisions of the Medicinal Products Act shall apply.

Section 17.03. The scope 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, prescribe, purchase, supply, sell or administer a Medicinal Product.

Section 17.04. Informational or Educational Materials and Items of Medical Utility can include the Member Company name, but must not contain the product name, 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

Section 18.01. Non-Interventional Studies must be conducted with a primarily scientific purpose and must not be disguised Promotion.

Section 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) There is a written study plan (observational plan/protocol) and (ii) there are written contracts between healthcare professionals and/or the institutes at which the study will take place, on the one hand, and the company sponsoring the study, on the other hand, which specify the nature of the services to be provided and, subject to clause (c) immediately below, the basis for payment of those services; Any remuneration provided is reasonable and reflects the fair market value of the service performed;
b) In countries where ethics committees are prepared to review such studies, the study plan must be submitted to the ethics committee for review; Local laws, rules and regulation on personal data privacy (including the collection and use of personal data) must be respected; The study must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product;
c) The study plan must be approved by the Member Company's medical department and the conduct of the study must be supervised by the Member Company's scientific service as described in Section 20.01.a;
d) The study results must be analysed by or on behalf of the contracting Member Company and summaries thereof must be made available within a reasonable period of time to the Member Company's medical department (as described in Section 20.01.a), and the medical department must maintain records of such reports for a reasonable period of time. The Member Company must send the summary report to all HCPs that participated in the study and must make the summary report available to industry self-regulatory bodies and/or committees that are in charge of supervising or enforcing Applicable Codes upon their 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;[8] and
e) Medical Sales Representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the Member Company's medical department that will also ensure that the Medical Sales Representatives are adequately trained. The involvement of Medical Sales Representatives must not be linked to the intention of Promoting any Medicinal Product.

Section 18.03. Member Companies are advised to comply with the provisions of Section 18.02. for all other types of NIS as well, including epidemiological studies and registries and other studies that are retrospective in nature. In any case, such studies are subject to Section 15.01.

ARTICLE 19 MEDICAL SAMPLES

Section 19.01. In principle, no Medical Samples should be given, except on an exceptional basis.
Medical Samples must not be given as an inducement to recommend, prescribe, purchase, supply, sell or administer specific Medicinal Products, and should 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.

As free samples of Medicinal Products, no more than two packaging units per year per medicine may be provided to each person authorised to prescribe, instruct on the use and distribute medicines, following the start

[8] Member 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.

of sales of the medicine in Hungary, with the mention that in the case of medical aids, the two packaging units must not exceed the quantity necessary for one month. No free samples may be given of medicines in a subsidy category higher than 0% subsequent to the end of the year following the start of sales of the medicine in Hungary.

Section 19.02. Member Companies must have adequate systems of control and accountability for all Medical Samples which they distribute and for all Medicinal Products handled by their Medical Sales Representatives. This system must also clearly establish, for each HCP, the number of Medical Samples supplied in application of the provisions in Section 19.01.

Section 19.03. Each Medical Sample must be no larger than the smallest presentation of that particular Medicinal Product in the relevant country.
Each Medical Sample must be marked "free medical sample – not for sale" or words to that effect and must be accompanied by a copy of the summary of product characteristics.

ARTICLE 20 MEMBER COMPANY STAFF

Section 20.01. All Member Company staff must be fully conversant with the relevant requirements of the present Code of Practice, and the laws and regulations.

a) Each Member Company must establish a medical department in charge of information about its Medicinal Products and the approval and supervision of NIS. Member Companies are free to decide how best to establish the medical department in accordance with this Section 20.01. (i.e. whether there is one department in charge of both duties or separate departments with clearly delineated duties), taking into account their own resources and organisation. The medical department must include a medical doctor or, where appropriate, a pharmacist who will be responsible for approving any promotional material before release. Such person must certify that he or she has examined the final form of the promotional material and that in his or her belief it is in accordance with the requirements of the present Code of Practice and any relevant laws and regulations, is consistent with the summary of product characteristics and is a fair and truthful presentation of the facts about the Medicinal Product. In addition, company staff 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). Such person must certify 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 present Code of Practice and any relevant laws and regulations.
b) Each Member Company must appoint at least one senior employee who must be responsible for supervising the Member Company and its subsidiaries to ensure that the standards of the present Code of Practice are met.

Section 20.02. Each Member Company must ensure that its Medical Sales Representatives are familiar with the relevant requirements of the present Code of Practice, 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 present Code of Practice, and all applicable laws and regulations, and Member Companies are responsible for ensuring their compliance.
b) Medical Sales Representatives must approach their duties responsibly and ethically.

c. 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.
d. Medical Sales Representatives must transmit to the medical department of their companies forthwith any information they receive in relation to the use of their company's Medicinal Products, particularly reports of side effects.
e. Medical Sales Representatives must ensure that the frequency, timing and duration of visits to HCPs, pharmacies, hospitals or other healthcare facilities, together with the manner in which they are made, do not cause inconvenience.
f. Medical Sales Representatives must not use any inducement or subterfuge to gain an interview. 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 Member Company they represent.

CHAPTER 4

SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH PATIENT ORGANISATIONS

ARTICLE 21 INTERACTIONS WITH PATIENT ORGANISATIONS

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

1. The independence of POs, in terms of their political judgement, policies and activities, must be assured.
2. All partnerships between POs and Member Companies must be based on mutual respect, with the views and decisions of each partner having equal value.
3. Member Companies must not request, nor shall POs undertake, the Promotion of a particular POM.
4. The objectives and scope of any collaboration must be transparent. Financial and non-financial support provided by Member Companies shall always be clearly documented.

Section 21.02. The promotion of POMs to the general public is prohibited by EU and national legislation.

Section 21.03. When Member 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 and also the purpose (e.g. unrestricted grant, specific meeting or publication, etc.). It must also include a description of significant indirect support (e.g. the sponsorship of public relations agency´s time and the nature of its involvement) and significant non-financial support.

Section 21.04. Member Companies must not influence the text of PO's material they sponsor in a manner favourable to their own commercial interests. This does not preclude Member Companies from correcting factual inaccuracies. In addition, at the request of POs, Member Companies may contribute to the drafting of the text from a fair and balanced scientific perspective.

CHAPTER 5

DISCLOSURE OF BENEFITS FROM MEMBER COMPANIES

ARTICLE 22 DISCLOSURE OF BENEFITS TO HEALTHCARE PROFESSIONALS & HEALTHCARE ORGANISATIONS AND PATIENT ORGANISATIONS – GENERAL RULES

Section 22.01. Time of Disclosure

Disclosures must be made by each Member Company within 6 (six) months after the end of the relevant Reporting Period, and the information disclosed must be made available for the public for a minimum of 3 (three) years after the time such information is first disclosed unless, in each case, the relevant data protection legal basis (e.g. the legitimate interest grounds, a legal duty or the Beneficiary's consent relating to a specific disclosure) is no longer applicable.

The common reporting period for publication of Benefits to Beneficiaries is set during the time interval from 20th to 30th June each year at the latest.

ARTICLE 23 DISCLOSURE OF BENEFITS TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

Section 23.01. Rationale

The following article provides for disclosures of Benefits to HCPs and HCOs, whether directly or indirectly. When deciding how a Benefit must be disclosed, Member 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 law and regulations.

Section 23.02. Implementation and deviations

If any of the following provisions conflict with domestic law or official requirements, it shall not apply.

Section 23.03. Disclosure obligation

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

Excluded Disclosures Without limitation, Benefits that (i) are solely related to over-the-counter medicines; (ii) are not listed in Section 23.05. of this article, such as Items of Medical Utility (governed by Article 17), meals (governed by Article 10, especially Section 10.05.), Medical Samples (governed by Article 19); or (iii) are part of ordinary course purchases and sales of Medicinal Products by and between a Member Company and a HCP (such as a pharmacist) or a HCO do not fall within the scope of the disclosure obligation described above in *"General Obligation"*.

Section 23.04. Form of Disclosure

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

Template. Subject to "Platform of Disclosure", for consistency purposes, disclosures pursuant to this article will be made using a structure set forth in Annex A for reference, reflecting the requirements of this article. Deviations from this template are only acceptable where legal requirements justify that this article is not transposed in full – therefore, within a given country, only one template shall apply.

Platform of Disclosure. Disclosures can be made in either of the following ways, provided that they are unrestricted and publicly available:
(i) on the relevant Member Company's website in accordance with the section "Applicable National Code"; or
(ii) on a central platform, such as one provided by the relevant government, regulatory or professional authority or body or a Member Association, provided that disclosures made on a central platform developed at the initiative of Member Associations must be made, so far as possible, using a structure set forth in Annex A for reference.

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

Language of Disclosure. Disclosure must be made in Hungarian. Member Companies can make disclosures in English as well in addition to the mandatory disclosures in the local language.

Documentation and Retention of Records. Each Member Company must document all Benefits required to be disclosed pursuant to Section 23.03. and maintain the relevant records of the disclosures made under this article for a minimum of 5 (five) years after the end of the relevant Reporting Period, unless a shorter period is required under applicable national laws or regulations.

Section 23.05. Individual and Aggregate Disclosure

Individual Disclosure. Except as expressly provided by this article, Benefits must be disclosed on an individual basis. Each Member Company must disclose, on an individual basis for each clearly identifiable Beneficiary, the amounts attributable to Benefits to such Beneficiary in each Reporting Period which can be reasonably allocated to one of the categories set out below. Such Benefits may be aggregated on a category-by-category basis, provided that itemised disclosure shall be made available upon request to (i) the relevant Beneficiary, and/or (ii) the relevant authorities.

1. For Benefits to HCOs, 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, including sponsorship 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 (must not be excessive/luxurious and must be in line with the objectives of the event) in accordance with the provisions of Article 10.

    For the purpose of this chapter, the definition of Events excludes investigator meetings for clinical trial purposes.

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

2. For Benefits to a HCP:

a) Contribution to costs related to Events. Contribution to costs related to Events, such as:
i. Registration fees; and
ii. Travel and accommodation (must not be excessive/luxurious and must be in line with the objectives of the event).

Contribution to costs related to Events, through HCOs or Third Parties, including sponsorship to HCPs to attend Events, shall be disclosed individually under the name of the Beneficiary. Such costs may include:
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.

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

Reporting of Indirect Benefits provided through PCOs

Contributions provided to Events through PCOs – that would therefore be the Beneficiaries of the Benefits – must be considered as Indirect Benefits.

In consideration of legal issues that may arise in the reporting of Benefits through Distributors on behalf of a Member Company, reporting of such Benefits are not within scope of this Code.

Contribution to costs related to Events paid through Third Parties to the benefit of individual HCPs that the Member Company knows, must be reported on an individually named basis, as Indirect Benefits to HCPs.

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

- All Benefits to an HCO (either as Receiving Party or as Beneficiary) are reported in the relevant category under the name of the HCO
- Benefits through PCOs must be reported as follows:
  - either in the name of benefiting HCO (through *the name of Beneficiary PCO*), if not included in direct Benefits to the HCO;
  - or in the name of Beneficiary PCO (to the benefit of *the name of benefiting HCO*).

Member Companies shall include support / sponsorship to Events through PCOs in written contracts, and these contracts shall include provisions which oblige the PCOs to communicate certain information to the Member Company allowing appropriate reporting of Benefits in accordance with this Code.

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

Examples of possible scenarios in support of Events:

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

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

Aggregate Disclosure. For Benefits where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Section 23.05., cannot be disclosed on an individual basis for legal reasons, a Member Company must disclose the amounts attributable to such Benefits in each Reporting Period on an aggregate basis. Such aggregate disclosure must identify, for each category, (i) the number of Beneficiaries covered by such disclosure, on an absolute basis and as a percentage of all Beneficiaries, and (ii) the aggregate amount attributable to Benefits to such Beneficiaries.

Non duplication. Where a Benefit required to be disclosed pursuant to Section 23.05. is made to an individual HCP indirectly via a HCO, such Benefit 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 Section 23.05.

Research and Development Benefit Member Companies must disclose Research and Development Benefits in each Reporting Period on an aggregate basis, except in the cases provided below in the section "Disclosure of non-interventional studies". 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 Benefit" category.

Disclosure of non-interventional studies. The application of the exemption on individual reporting of Benefits relating to non-interventional studies (NIS) is limited to NIS that are prospective in nature. Retrospective NIS must be reported on an individual names basis, in line with this Code of Practice.

Benefits relating to NISs that are not within the definition of Research and Development Benefits under the Disclosure Code must be reported on an individually named basis. In this regard, prospective versus retrospective NIS will be considered following classification in the table below:

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

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

Methodology. Each Member Company must publish a note summarising the methodologies used by it in preparing the disclosures and identifying Benefits for each category described in Section 23.05. 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 Benefits for purposes of this article, as applicable.

ARTICLE 24 DISCLOSURE OF SUPPORT AND SERVICES PROVIDED TO PATIENT ORGANISATIONS

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

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

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

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

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

CHAPTER 6

PUBLIC RELATIONS ACTIVITY

Member Companies, at their own initiative or upon request, may issue press releases, background information or other press materials, or give verbal briefings to members of the press on news or information relating to their products and activities (hereinafter: PR).

During their PR activities Member Companies shall respect editorial freedom to the maximum extent and shall not, in any way whatsoever, attempt to influence the contents of any article, interview or broadcast. They however may seek the possibility for peer review to correct factual inaccuracies.
Member Companies shall not be allowed to pay journalists or media organisations for any articles, interviews or broadcasts that are based on information supplied by the Member Company if such news items are presented as editorial matter, or indicating the name of the journalist or the phrase "from our correspondent".

In the case of paid PR articles, it must be ensured that such articles are not mistaken for independent editorial matter. To this end, such articles should be followed by the mark "(X)" or published in a frame.

When preparing press releases or organising press events Member Companies must take it into account who is the "target group" for the press release or the event. To this end:

a) exclusively when briefing journalists and editors of restricted-circulation publications that are intended for Healthcare Professionals and unavailable to the general public, Member Companies may act as if they were briefing the audience of scientific events or symposia, therefore in the course of such briefing may name prescription-only medicinal products;

b) when providing written or verbal briefing to commercial or lay media, any information suitable for identifying a specific medicinal product according to subsection 8.1 of this Chapter, shall be qualified as advertisement. When providing such briefings, Companies must pay particular attention to observe the legal and ethical rules of advertising prescription-only medicinal products that are named in, or can be identified from an indirect reference to them. No briefing, either written or verbal, that names or otherwise identifies a prescription-only medicinal product shall be provided to the correspondent or employee of the lay media. Any representative of the lay media requesting specific therapeutic information about a medicinal product may be refused to be given such information with reference to the applicable legislation, or be reminded, in a documented form, of the relevant legislation thereof.

For Member Companies listed on the stock exchange, company statements shall include the name of any prescription-only medicinal product. Cases when following stock exchange statements, a prescription-only medicinal product or an active ingredient is named in the media or in other official papers that are a source of relevant information for investors and analysts, shall not fall under the scope of this Code of Practice.

CHAPTER 7

PROCEDURAL REQUIREMENTS

ARTICLE 25 AIPM ETHICS COMMITTEE (AEC)

In order to identify cases of violation of this Code of Practice, Member Companies shall set up a body functioning in the form of a committee, called AIPM Ethics Committee (hereinafter: "AEC") and lay down its procedural regime as part of this Code, providing that the AEC evaluates ethics complaints filed with the AEC by applying the provisions of this Code of Practice.

For conducts conflicting with current legislation any proceeding initiated and/or conducted pursuant to the provisions of this Code shall be without prejudice to the right to open market or advertising pre-vetting procedures, other administrative or court actions under current legislation. The AEC shall only be entitled to act in cases of violation of the provisions of this Code.

Section 25.01. Bylaws of the AEC:

Composition of the AEC and the election of its members:
The AEC shall consist of 8 (eight) members and a Chairman. Members of the AEC shall participate in the work of the AEC as representatives of the Member Companies; they shall have equal rights and obligations, and they shall perform their activities in order to enforce the principle of self-regulation. Members of the AEC shall not be instructed or held accountable in relation to their duties associated with specific issues of ethics.

The AEC members comprise of persons delegated by the Member Companies. Among the candidates of the Member Companies, not more than one (1) member can be elected from each member company.

Candidates to be delegated to the AEC are selected biannually by the AIPM General Assembly within their own competence from among the persons nominated by the General Managers (GM) of the Member Companies. The AIPM General Assembly elects new AEC members from the candidates by secret ballot. The AIPM General Assembly shall have the right to recall the elected members provided that a new member is delegated immediately to replace the recalled member in accordance with the rules on the election of members. The same applies to cases in which a person's membership in the AEC is terminated for any other reason. The AEC members shall be mandated for two years, from 1 January each year and they may be re-elected once.

Members delegated to the AEC

a) may request that their opinion concerning a specific issue be specifically entered in the minutes, and such request shall be carried out on a mandatory basis;
b) may propose that the AEC should discuss a case not qualifying as an issue of ethics but falling in the scope of its competence, which must be submitted to the next AEC meeting;
c) are obliged to participate in the work of the AEC;

The AIPM Board appoints and dismisses the **AEC Chairman** based on the recommendation of the AIPM Compliance Working Group. Any person that has no employment relationship with any pharmaceutical company under or outside the scope of the AIPM Code of Practice may be appointed AEC chairman. AEC members can propose the revoking of the AEC Chairman's mandate based on simple majority. The Chairman's mandate is for 2 (two) years and the Chairman can be re-elected on two occasions. The detailed bylaws of the AEC is approved by the AIPM Board.

If an AEC Chairman is incapacitated in attending to their duties, the AEC members shall elect an interim Chairman from among themselves. The interim Chairman shall attend to the duties of the AEC Chairman for the duration of the incapacitation. If such incapacitation continuously persists for over three (3) months, a new AEC Chairman shall be appointed.

The following shall fall within the scope of duties and powers of the Chairman:

a) convening and chairing the meetings of the AEC;
b) documenting, transmitting to the parties concerned, and disclosing AEC resolutions;
c) monitoring the implementation of AEC resolution(s);
d) representation of the AEC in AIPM's internal communication.

Any AEC member, who is making the complaint (complainant), or affected by the notification, or an employee of a Member Company included in the procedure ex officio, or is biased for any other reason, therefore an objective assessment of the case cannot be expected from them, shall not participate in the adjudication of that case being heard by the AEC. Adjudication of a case is understood to mean participation in making decision on the starting of the proceeding and in the proceeding itself, actual decision-making and any appeals procedure. Cases of affection are to be reported to the AEC by any affected member or Chairman and by any person that has knowledge of such interest or affection. The AEC decides about cases of affection by simple majority. If the AEC does not have a quorum as a result of an exclusion, the quorum must be established on the basis of the number of AEC members without the excluded ones.

Section 25.02. Meetings and procedure of the AEC

A Member Companies shall endeavour to resolve their disputes amicably between themselves before submitting them to the AEC. The reporting Member Company shall contact the party named in the complaint before initiating the AEC procedure in writing by way of registered mail, mail with acknowledgement of receipt or hand delivery, and request such other party to present their standpoint on the objected conduct to the reporting Member Company within fifteen (15) days of the receipt of the letter.

The AEC procedure is initiated upon request/report (hereinafter: report). Requests may be submitted by any natural or legal person that has information on any conduct or action violating the provisions of this Code.

Complainants may ask for confidential handling of their data by the AEC. In such cases the AEC shall handle the data of the complainant confidentially in the course of the procedure and following its termination. If it is requested by the complainant, their identity shall not be revealed by the Chairman even to the members of the AEC. In such cases the identity of the complainant may only be revealed by the Chairman with the prior consent of the complainant and without such consent the investigation could not be carried out. If the complainant dissents to the revealing of his/her identity, the AEC Chairman shall regard that the complainant has decided to withdraw the complaint. The complainant must be notified about this.

If the complainant seeks a ruling from another authority before, or simultaneously with filing a complaint with the AEC or if the AEC initiates a procedure by the competent authority before making its decision on the issue, the AEC shall not commence its proceedings until the other authority's final ruling is issued or shall suspend proceedings already in progress. The proceedings shall be initiated or continued if the requested authority itself requests that the AEC should conduct the proceedings.

Reports filed with the AEC anonymously shall not be investigated by the AEC.

The Chairman of the AEC shall send the complaint received to the party named in the complaint by way of

registered mail, mail with acknowledgement of receipt or hand delivery within fifteen (15) days of the receipt of the complaint and request such other party to present their standpoint on the matter to the AEC within fifteen (15) days of the receipt of the letter. The AEC may only hear the case on the merits after the above deadline has expired, regardless of whether the responding party has communicated their standpoint within the deadline.

The Procedure may be initiated within (1) year of detecting the non-compliance with this Code. If the conduct in conflict with this Code is manifested in an act of omission, the proceedings can be initiated during the existence of the infringement or within one year of its termination.

Complaints submitted to the AEC must include all data and evidence necessary for the evaluation of a case. If the complaint fails to include these data and evidence, the AEC shall call upon the complainant to have the missing information submitted by a specified deadline only once in the course of the proceedings. In such cases, procedural deadlines shall start on the date on which the missing information is received by the AEC. If the requested party does not supply the missing information by the deadline, the AEC shall

a) terminate the proceedings or
b) make its decision on the merits of the submission on the basis of the information and data at its disposal.

The Chairman and the members of the AEC shall treat strictly confidential any data, information and documents that they accessed or otherwise became aware of in connection with a AEC proceeding and that are not in the public domain, and shall retain them and ensure that they are not disclosed to any third party during or after the proceeding. Members of the AEC and its Chairman shall sign a declaration of confidentiality approved by the AEC, which shall be preserved among the AEC's documents for a period of five (5) years from the discontinuation of membership or the mandate.

Ad hoc meetings are held by the AEC based on the reports received. The AEC meets once a year on a mandatory basis and prepares a report on its annual operation for the General Assembly. The Chairman shall convene the meetings of the AEC by a written invitation sent at least five (5) days in advance of the meeting. In the case of a new complaint the Chairman shall convene the AEC meeting within thirty (30) days of the deadline specified in the communication sent by the party involved in the complaint.

An AEC meeting has a quorum if at least five (5) members are present. If an orderly convened AEC meeting does not have a quorum, the Chairman shall convene a new meeting again within seven (7) days and repeat this as long as the AEC meeting has a quorum.

The AEC shall hold closed meetings which shall be attended by the AEC members, the Chairman, the person performing administrative tasks, and the invited persons only.

The AEC shall pass its resolutions by the simple majority of the votes of the members present. The Chairman may attend AEC meetings with consultation right. If the Chairman is incapacitated, an interim chairman chairs the AEC meeting. In the event of a tied vote of the AEC members, the vote of the Chairman or the interim Chairman shall be decisive. The absence of the person concerned shall not prevent the resolution from being adopted.

In cases received by the AEC, it shall pass its resolutions within sixty (60) days of the initiation of the proceeding. The chairman of the AEC may extend this deadline once for another thirty (30) days and at the same time inform all parties concerned.

During its proceedings, the AEC shall examine the documents and other materials necessary for the adjudica-

tion before deciding on a case, and shall hear the parties concerned. The AEC does not rely on the assistance of legal experts in its meetings, it hears only the representative of the member company in question. Legal representatives of the member companies are not allowed to participate in the hearing. The AEC will pass its resolutions regardless of any failure or delay by any party to reply letters, answer an inquiry or failure to attend a hearing.

When adopting its decisions, the AEC is obliged to take into account the decisions, arguments and correlations elaborated in its previous resolutions adopted regarding this Code, in order to comply with the spirit of this Code and ensure its uniform application.

Section 25.03. Decisions of the AEC

The AEC shall pass a resolution or ruling at the end of every proceeding initiated and send it to the parties concerned in writing within fifteen (15) days from the date of the adoption of the decision, via registered mail with acknowledgement of receipt or by hand delivery.

The AEC shall immediately make its decision even if:

a) the complaint shall be rejected without material investigation in the following cases:
   aa) the AEC is not competent to conduct a proceeding;
   ab) the complaint calls for the investigation of an obviously impossible matter;
   ac) the complaint was filed late;
   ad) the AEC has already adjudicated the complaint on the merits;
   ae) the proceeding does not fall under the scope of this Code;
   af) the Member Company making the complaint failed to provide advance written notification to the reported Member Company.
b) the proceeding is terminated in the following cases:
   ba) the complaint could have been refused without investigation but the reason for refusal came to the knowledge of the AEC after the proceeding was launched;
   bb) the proceeding has become devoid;
   bc) the proceeding had initiated upon request and the complainant had withdrawn the request, except if the case had several complainants but not all of them withdrew the complaint;
   bd) the proceeding has become devoid due to the fact that any of the parties concerned had ceased without legal successor;
   be) if the parties concerned conclude an agreement in the course of the proceeding, which is not contrary to the provisions of this Code.

The AEC shall pass its resolutions on the merits of the case after examining all relevant circumstances of a case. In its written decisions the AEC shall:

a) give a brief description of the investigated case;
b) establish whether or not an ethical violation has taken place;
c) provide reasoning for its decision;
d) if it has established that an ethical violation had taken place, communicate the sanctions;
e) provide information on whether an appeal may be submitted against the resolution, as well as where such appeal may be filed and within what deadline.

In the event of a breach of this Code, the AEC may impose the following sanctions (multiple sanctions, even in combination):

a) warn the offender in writing;
b) calls for termination of the conduct that violates this Code, or by setting a deadline, calls for the conduct to be brought into conformity with the provisions of this Code in a specific manner, and to notify the AEC of this in writing within the specified time limit;

c) in the event of conduct in breach of this Code, publication of the decision on the AIPM's protected website;
d) in the case of an ethical violation of communicational nature where the deceptive communication may lead to the inappropriate use of a medicinal product or pose any other risk to patients, consumers, it may order the offender to distribute a circular letter for the rectification to the HCPs involved in commercial communication. The AEC shall approve the draft circular submitted by the Member Company committing the offence before sending it.

Section 25.04. Review of the AEC Decisions

A resolution of the AEC may be appealed by requesting a review from the AEC Chairman within fifteen (15) days of receipt of the resolution ("Appeal"). The AEC Chairman shall convene a three-member ad hoc review committee within ten (10) days.

The members of the ad hoc committee are nominated by the leaders of the Member Companies. From the proposed persons, the Chairman of the AEC shall elect the three (3) members of the committee. The ad hoc committee shall appoint a presiding Chairman from among its members, who shall record the committee's resolution in writing. Full members of the AEC may not participate in the ad hoc committee meeting. The ad hoc committee shall decide on the basis of the files in the main proceedings, but may, if necessary, initiate a hearing of the parties concerned, and it shall hear any party concerned on the party's initiative. The decision of the ad hoc committee is final, and the committee shall inform the parties concerned, the AEC and the Member Companies in writing.
The rules governing the operation of the AEC shall be properly applied to the functioning of the ad-hoc committee, with the ad hoc commission members deciding by a majority on the merits of the appeal (they can uphold, repeal, or alter the AEC's decision).

Section 25.05. The AEC's position statement regarding competences

Issuing an AEC position statement on competence may be requested by any Member Company and any AEC member.

The AEC is entitled to issue a position statement on competences with the following content:
Acts on and issues a position statement based on the report of a Member Company or any member of the AEC in the event that the CEC initiates proceedings in connection with the commercial practice of prescription-only medicine specified in the Code of Ethics for Pharmaceutical Marketing Communication in case of suspicion of an ethical violation only affecting AIPM Member Companies. Pursuant to this Code, the AEC is entitled to act exclusively in these proceedings.

Issue of a position statement on competence and adoption of its full text requires a majority vote of two third of the members present at the AEC meeting, and the position statement shall be sent to the Member Companies concerned and to the CEC.

Section 25.06. Scope of this Code – procedural rules for dispute resolution

AIPM Member Companies shall comply with the rules of procedure set forth in Article 25 of this Code in the event of conduct in violation of the provisions of this Code. AIPM Member Companies shall comply with the rules of procedure set forth in Article 25 of this Code in the event of conduct in violation of the provisions of this Code. In the event that the CEC initiates proceedings in connection with the commercial practice of

prescription-only medicine specified in case of suspicion of an ethical violation only affecting AIPM Member Companies, the AIPM Member Companies are entitled to request the AEC's position statement specified under Section 25.5 in connection with the presumed ethical violation.

The CEC rules of procedure set out in the Code of Ethics for Pharmaceutical Marketing Communication apply to AIPM Member Companies in the following cases:

a) in the event of suspicion of ethical violation of the commercial practice related to a non-prescription medicine, where a party concerned is an AIPM Member Company;
b) in the event of suspicion of ethical violation of the commercial practice related to a prescription-only medicine, where a party concerned is not an AIPM Member Company;
c) in the event of suspicion of ethical violation of the commercial practice related to a prescription-only medicine, where the parties concerned include both AIPM Member Companies and non-Member Companies.

In the event that the CEC initiates proceedings in case of suspicion of an ethical violation in connection with such commercial practice of a prescription-only medicine specified in the Code of Ethics for Pharmaceutical Marketing Communication in which the parties concerned are AIPM Member Companies, any AIPM Member Company may initiate the issuance of the AEC's position statement on competence.

ARTICLE 26 AWARENESS AND EDUCATION

The AIPM must, within current applicable laws and regulations facilitate companies' awareness of and education about the present Code of Practice, including by providing guidance to companies in order to prevent breaches of the National Codes. The AIPM is entitled to share its experience concerning this Code of Practice through regular meetings or through the IFPMA Association.

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 aggreate 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 aggreate disclosure in the total number, by category, of Recipients disclosed					%	%	%	%	%	%		N/A

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

latest update: 27 June 2019

ANNEX B

DISCLOSURE "GATEWAY" ON MEMBER ASSOCIATIONS WEBSITES

Background

In application of the EFPIA Disclosure Code, Benefits to HCPs / HCOs are published (in line with applicable laws and regulations) in one of the following forms:

- on individual Member Companies websites;
- through an Associations platform operating as a "gateway" to individual companies websites;
- on a multi-stakeholder platform;
- on a government platform.

In Hungary, member company disclosure reports are primarily displayed via the **www.transzparencia.org** website.

Following disclosure in 2016, media have criticised poor access to the data, denouncing lack of transparency. On the 14th of July 2016 (i.e. only 2 weeks following public disclosure), Der Spiegel provided access to all data disclosure by Member Companies in Germany, re-organising the data in a full transparent way, using the searchable database constructed by Correctiv (a Research Centre of Public Interest). In the months following, Correctiv provide access to a similar database for Switzerland and Austria.

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

Against this trend, the Board supported the Codes Committee suggestion to take steps leading from disclosure to transparency, as the pharmaceutical industry should take credit for its disclosure initiative.

Relevant EFPIA Disclosure Code provision

Section 2.04. Platform of Disclosure.
Disclosures can be made in either of the following ways, provided that they are unrestricted and publicly available:

(i) on the relevant Member Company's website in accordance with Section 2.05; or

(ii) on a central platform, such as one provided by the relevant government, regulatory or professional authority or body or a Member Association, provided that disclosures made on a central platform developed at the initiative of Member Associations shall be made, so far as possible, using a structure set forth in Schedule 2 for reference.

Recommendation

In countries where there is no central platform in place, Member Associations are encouraged to provide access to individual Member Companies reporting in their country through a "Gateway" on the Association's website as a way to improve access to information disclosed.

Each Member Association will frame the "Gateway" in consideration of the national context and in line with application law and regulations, and in consideration of the EFPIA HCP Code "Guidelines for Internet Web-

sites Available to Healthcare Professionals, Patients and the Public in Europe". In this context, it is recommended to include a pop-up on the relevant Member Association website indicating that the visitor is being redirected to a website that is not under the Member Association's responsibility.

Each Member Association is expected to ask its member companies to provide the links to their disclosure reports.

It is expected that Member Associations take steps to operationalise the "Gateways" in time for the upcoming disclosure period (June 2018).

Follow-up

The Codes Committee will check the follow-up that Member Associations will have given to this recommendation – a status report will be included in the 2018 Codes Report.

Based on learning, the Codes Committee may issue recommendation aiming at improving transparency.

ANNEX C
Examples of the ethical principles

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

- Continue to improve existing treatments and deliver new, innovative 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 judgement, 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 Benefits 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)