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Asociace inovativního farmaceutického průmyslu

AIFP CODE OF PRACTICE

Adopted by the AIFP Board on 21st August 2023,

and ratified by the AIFP General Assembly of 14th September 2023

CONSOLIDATED VERSION 2023

APPROVED BY THE GENERAL ASSEMBLY OF 14th SEPTEMBER 2023

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

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DEFINITIONS

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

A **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 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 Member 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 an HCP, if any contribution is provided to such HCP in accordance with the provisions of Article 13 of the AIFP Code, such contribution is subject to the rules of the National Code where such HCP primarily carries out his/her profession, as opposed to those in which the international Event takes place.

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

AIFP Code: The AIFP Code of Practice, including those Annexes which are expressly mentioned as binding and which form part of this Code.

Association of Innovative Pharmaceutical Industry (AIFP): is the representative body of the innovative pharmaceutical industry in the Czech Republic and a member of EFPIA.

B **Breach:**

- **Lesser breach:** a breach of AIFP Code that has no safety implications to the patients' wellbeing and/or will have no major effect on how the HCPs will prescribe purchase, supply, recommend, dispense or administer the Medicinal Product.
- **Minor Breach:** a breach of AIFP Code that has no safety implications to the patients' wellbeing but may have effect on how the HCPs will prescribe the Medicinal Product or repeated Lesser breach of the same nature.
- **Major breach:** a breach of AIFP Code that will have safety implications to the patients' wellbeing and/or will have a major effect on how the HCPs will prescribe purchase, supply, recommend, dispense or administer the Medicinal Product or repeated minor breach of the same nature.
- **Repeated Major breach:** when a Member Company repeats Major breach within a period of 24 months in the Promotion of any of the Member Company's Medicinal Products.

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

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

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

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EFPIA Code: The EFPIA Code of Practice, including those Annexes which are expressly mentioned as binding and which form part of the EFPIA Code of Practice.

Ethics Committee (EC): The Ethics Committee is a body of the AIFP defined in the AIFP Statutes which supervises the compliance with the AIFP Code.

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

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

H

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

Healthcare Professional (HCP): any natural person that is a member of the medical, dental, pharmacy, or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a Medicinal Product and whose primary practice, principal professional address or place of incorporation is in Europe.
For the purpose of AIFP Code, the definition of HCPs includes: (i) any official or state employee, agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply, recommend or administer Medicinal Products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of Medicinal Products.

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

I

Informational or Educational Material: constitutes inexpensive material directly relevant to the practice of medicine or pharmacy and directly beneficial to the care of patients.

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

L

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

M

Market research: collecting of data on the scope or dimensions of the market and its components, including the needs of the customers in that market. Market research is a project which does not include any individual patient data.

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

Medical Sales Representative: personnel employed (whether by employment agreement or otherwise) by a Member Company or retained by way of contract with Third Parties, who interact with HCPs and HCOs, in connection with the Promotion of Medicinal Products.

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

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

Member Association: as defined in the EFPIA Statutes, 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, are bound by the EFPIA Code.

Member Company: has the meaning set forth in the AIFP Statutes. Separate entities belonging to the same multinational company – which could be the parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation – are deemed to constitute a single company, and are as such committed to comply with the AIFP Code.

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

N

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

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

P

Patient Organisation (PO): non-for-profit legal person/entity (including the umbrella organisation to which it belongs and including patient organizations as defined by Czech law), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in the Czech republic.

Patient Organisation Representative: is a person who is mandated to represent and express the collective views of a PO on a specific issue or disease area.[1]

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.

Product Information: full or abridged product information according to the summary of product characteristics which contains information essential for the proper use of a Medicinal Product.

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

Promotion: includes any activity undertaken, organised or sponsored by a Member Company, or with its authority, which promotes the prescription, supply, sale, administration, recommendation or consumption of its Medicinal Product(s), including advertising activities defined in the applicable legislation.

[1] EUPATI definition

DEFINITIONS

R

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

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

Research and Development Transfers of Value: Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in the applicable legislation); or (iii) NIS that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study.

S

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 an HCO, a PO or a Third Party.

SÚKL: State Institute for Drug Control (Státní ústav pro kontrolu léčiv).

T

Third Party: is a legal person/entity or individual 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.

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

V

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

PREAMBLE

This document replaces previous codes issued by AIFP, namely:

- AIFP Code on Conduct, adopted in January 1993, as lastly amended on 28. 4. 2017;
- AIFP Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations; and
- AIFP Code on Disclosure of Transfers of Value from Pharmaceutical Companies to HCPs and Healthcare Organisations, approved by the AIFP General Meeting on 21. 11. 2013, as amended on 23. 5. 2014.

ETHICAL PRINCIPLES

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

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 wellbeing is, directly or indirectly, dependent on our work.

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

In addition to complying with extensive legal requirements (i.e. laws and regulations applicable to 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 positions.

For AIFP and its members, self-regulation means being fully committed to define, implement, comply with and enforce the highest ethical standards through AIFP Code, 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.

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 encourage their appropriate and rational use in the care pathway.

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

PREAMBLE

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 judgements when processing Personal Health Data.

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

INTRODUCTION

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

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

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

AIFP believes 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 an HCP to prescribe a Medicinal Product is one of the pillars of the healthcare system. AIFP recognises 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 respond to the evolving demands of society. In particular, AIFP recognises 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. 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.

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

In relation to working with HCPs and HCOs, since the introduction of the AIFP Disclosure Code, AIFP 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. Member Companies will not be criticized for over-disclosure.

SCOPE OF THE AIFP CODE

The AIFP Code covers:

- Promotion of POMs to HCPs,
- interactions between Member Companies and HCPs, HCOs and POs;
- disclosure of ToVs from Member Companies to HCPs, HCOs and POs; and
- procedural requirements of the AIFP Code.

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

The AIFP Code covers all methods 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 communications and channels, such as websites and social media, the use of audio-visual systems such as films, video recordings, data storage services and the like. It also covers the provision of Informational or Educational Materials, Items of Medical Utility, hospitality in relation to Events and Medical Samples.

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

The AIFP Code is not intended to restrain or regulate the provision of non-promotional medical, scientific and factual information; nor is it intended to restrain or regulate activities directed towards the general public which relate solely to non-prescription Medicinal Products.

The AIFP Code does not cover the following:

- the labelling of Medicinal Products and accompanying package leaflets, which are subject to the provisions of the applicable legislation;
- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular Medicinal Product;
- factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general precautions, trade catalogues and price lists, provided they include no product claims;
- non-promotional information relating to human health or diseases;
- activities which relate solely to non-prescription Medicinal Products; 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.

APPLICABILITY OF THE AIFP CODE

The AIFP Code sets out the minimum binding standards which AIFP Member Companies must apply. Promotion and interactions which take place within the Czech Republic must comply with applicable laws and regulations. In addition, Promotion and interactions which take place within Europe must also comply with Applicable Codes.

The spirit, as well as the provisions of the AIFP Code must be complied with. AIFP also encourages compliance with the letter and spirit of the provisions of the EFPIA Code and International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practice, where applicable.

CHAPTER 1

PROMOTION OF POM TO HCPs

ARTICLE 1

MARKETING AUTHORIZATION

Section 1.01. A Medicinal Product must not be promoted (i) prior to the grant of the marketing authorization under the national rules (i.e. with SÚKL) or via the centralized EU authorization procedure (i.e. with EMA) allowing its sale or supply or (ii) outside of its approved indications.

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

ARTICLE 2

INFORMATION TO BE MADE AVAILABLE

Section 2.01. Subject to applicable laws and regulations, all promotional materials must include the following information clearly and legibly:

a. Product Information consistent with the summary of product characteristics, specifying the date on which such information was generated or last revised;

b. the dispensing classification of the Medicinal Product under a marketing authorization; and

c. the conditions for reimbursement from public health insurance funds.

Section 2.02. Subject to applicable laws and regulations, where an advertisement is intended only as a reminder, the requirements of Sections 2.01, 6.04 and 6.06 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, or the trademark.

CZ specific:
Section 2.03. A reminder is designed to remind a prescriber of a Medicinal Product's existence and must not contain any promotional claims. The sole use of a reminder within any one issue of a publication is not permitted before 12 months from the first advertising of a new Medicinal Product. Reminder must comply with Section 2.02 of the AIFP Code and must not represent a Promotional Aid the distribution of which is prohibited according to Section 11.02 of the AIFP Code.

ARTICLE 3

PROMOTION AND ITS SUBSTANTIATION

Section 3.01. Promotion must be valid, 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. It must be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It must not mislead either directly, by implication, distortion, exaggeration, undue emphasis, omission or in any other way and must not be able to cause deceptive imagination of an addressee.

Section 3.02. Promotion must be capable of substantiation which must be provided within 10 working days in response to reasonable requests from HCPs or another Member Company. In particular, promotional claims about side-effects must reflect available evidence or be capable of substantiation by clinical experience. Substantiation need not be provided, however, in relation to the validity of elements approved in the marketing authorization.

CZ specific:
Substantiating information should be based mostly on publications in scientific journals or oral presentations at an international scientific congress and must not rely solely on data on file. A statement that the data requested for substantiation is "confidential" will not be accepted.

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.

CZ specific:
Unqualified superlatives must not be used.

Section 3.04. When Promotion refers to published studies, clear references must be given.

Section 3.05. Any comparison made between different Medicinal Products must be based on relevant and comparable aspects of the Medicinal Products. Comparative advertising must not be misleading or disparaging.

CZ specific:
Comparative advertising must be fair, factual, capable of substantiation, referenced to its source, and must compare only relevant, substantial, verifiable and representative elements and compare in more than one element. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by used scale, by used doses, by undue emphasis or in any other way. "Hanging" comparatives - those which merely claim that a product is better, stronger, more widely prescribed etc. must not be used. "Data on file" when used to substantiate comparative statements must comply with the requirement of Section 3.02 of the AIFP Code.

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

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

Section 3.08. The word **"new"** must not be used to describe any Medicinal Product or presentation which has been generally available or 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 risks of addiction or dependency.

ARTICLE 4

USE OF QUOTATIONS IN PROMOTION

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

ARTICLE 5

ACCEPTABILITY OF PROMOTION

Member Companies must maintain high ethical standards at all times. Promotion must: (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 cause offence.

CZ specific:
Promotion must not be discriminatory, deceptive or disparaging.

ARTICLE 6

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

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

CZ specific:
Exposed mailings including postcards, envelopes or wrappers must not carry matter which might be regarded as advertising to the general public or which could be considered unsuitable for public view. Items suggesting a requirement for urgent attention are not acceptable for promotional purposes. Envelopes implying urgent attention should be restricted to matters relating to product recalls or important safety information. Envelopes must not be used for dispatch of promotional material if they bear words implying that the contents are non-promotional. Unsolicited reprints of journal articles must be consistent with the Product Information, and any covering letter should comply with Article 6 of the AIFP Code.

CZ specific:

Section 6.04. All promotional materials relating to Medicinal Products must be accompanied by either full or abridged Product Information according to the summary of product characteristics. Wherever required, Product Information must appear in a type size of small fonts not less than 2 mm (for format A4 for the lowercase letter "o") on a background sufficiently contrasting for legibility. For smaller format of promotional material, it is possible to decrease the size of fonts of Product Information accordingly with maintaining of good readability. Major headings should be easily identifiable. The date on which the last version of summary of product characteristics was approved by SÚKL or for centrally registered products by EMA must be included. Product Information must not be overprinted or interspersed with promotional phrases or graphics and must clearly identify any recent change of clinical significance.

Section 6.05. Under the heading "Abridged Product Information", the following must appear:

(a) Brand name of the Medicinal Product
(b) The INN of the active ingredient(s)
(c) Approved indications for use
(d) Contra-indications
(e) Clinically significant warnings
(f) Clinically significant precautions for use
(g) Clinically significant adverse events and interactions
(h) Available dosage forms
(i) Dosage regimens and routes of administration
(j) Dependence potential of clinical significance
(k) Reference to special groups of patients
(l) Name and address of the registration holder
(m) Registration number
(n) Storage conditions
(o) Latest revision of summary of product characteristics.

Section 6.06. All promotional materials relating to Medicinal Products, including journal advertisement, printed promotional materials, mailings, and all forms of digital promotion must contain the following within the body of the advertisement:

(a) The brand name of the Medicinal Product
(b) The INN of the active ingredient(s)
(c) The name of the registration holder and its mailing address in the Czech Republic
(d) Full or abridged Product Information
(e) Reimbursement status and dispensing classification of the Medicinal Product
(f) Other data required by applicable laws.

All audiovisual promotional materials must be accompanied by a document which contains the above. Where an individual Medicinal Product is being promoted in the form of an audiovisual item, the appropriate Product Information must be given to every individual viewing the promotional material, made readily accessible, or offered to an audience in a group situation on completion of the presentation.

Where the Product Information is included in interactive data system, instructions for accessing it must be clearly displayed.

DISTRIBUTION OF PROMOTION

Section 6.07. Promotion of Medicinal Products aimed at HCPs may not be carried out through information channels and communication means other than those dedicated mainly to HCPs (e.g. professional magazines and journals, professional audiovisual documents etc.). The Product Information should be placed adjacent to the body of the advertisement. Where it is not practicable to do so, the promotional materials must carry a statement in type size of small fonts not less than 2 mm (for format A4) to the effect of the following statement: "Please review product information before prescribing. In this publication, product information can be found …." At the point …, insert the page number in the publication where the information can be found or reference to an adequately referenced Product Information section or advertisers index. Product Information must form a fixed part of the journal. Loose leaf inserts will not satisfy the requirements of this section.

Section 6.08. Promotional competitions must fulfill all of the following criteria:

(a) The competition is based on medical knowledge or the acquisition of medical knowledge. Medical knowledge must correspond to background of HCPs.

(b) The prize is directly relevant to the practice of HCPs.

(c) Individual prizes offered must be in accordance with the Article 17 of the AIFP Code.

Entry into a competition must not be dependent upon prescribing, purchasing, suppling, recommending, dispensing or administering of a product and no such condition shall be made or implied. The conduct of competitions shall comply in all respects with relevant applicable legislation.

Section 6.09. Promotion must not imitate the items, designs, slogans or general layout used by other Member Companies in a way that is likely to mislead or confuse. Promotion must not infringe or be able to infringe intellectual property rights, trademarks, patents or similar rights of another person or entity.

Section 6.10. Member Companies commissioned articles must be identified as such in a type size of the small fonts not less than 2 mm (for format A4). The Member Company which is responsible for the insertion of the commissioned article must be clearly identified at either the top or the bottom of the article in a type size of the small font not less than 2 mm (for format A4). Member Company commissioned articles must conform to all relevant provisions of the AIFP Code.

Section 6.11. Where multiple forms of Promotion items are intended to be distributed at one time, the Product Information must appear at least once.

ARTICLE 7
TRANSPARENCY OF PROMOTION

Section 7.01. Promotion must not be disguised.

Section 7.02. Clinical assessments, post-marketing surveillance and experience programmes and post-authorization studies (including those that are retrospective in nature) must not be disguised Promotion. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose and not by Member Companies Staff in marketing and sales functions.

Section 7.03. Where a Member Company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial matter.

Section 7.04. Material relating to Medicinal Products and their uses, whether promotional in nature or not, which is sponsored by a Member Company must clearly indicate that it has been sponsored by that Member Company.

ARTICLE 8

PROMOTIONAL INFORMATION PROVIDED DURING INTERNATIONAL EVENTS

Promotional information which appears on exhibition stands or is communicated to participants at international Events organized in the Czech Republic must not, i.e. it is prohibited by local laws and regulations, refer to Medicinal Products (or uses) which are not registered in the Czech Republic, or which are registered under different conditions. This applies even if: (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 is accompanied by an explanatory statement indicating that registration conditions differ internationally.

ARTICLE 9

PERSONAL MEDICAL MATTERS

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

CHAPTER 2

INTERACTIONS WITH HCPs, HCOs AND POs

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, avoiding those that are "renowned" for their entertainment facilities or are "extravagant".

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 when such hospitality is "appropriate" and otherwise complies with the provisions of any Applicable Code(s).

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

Section 10.05. Member Companies must not provide or offer any meal (food and beverages) to HCPs, HCOs' members or POs' Representatives, unless, in each case, the value of such meal does not exceed the monetary threshold set by the relevant Member Association in its National Code (following the "Host Country Principle").

CZ specific:
If no limits are set by relevant Member Association in its National Code, hospitality offered or provided to HCPs and PO Representatives in connection with Promotion and Events are stipulated in the AIFP implementing guideline.

Section 10.06. Hospitality may only be extended to persons who qualify as participants in their own right. In exceptional cases of established health needs (e.g. disability or injury), and unless prohibited by Czech law, the travel, meals, accommodation and genuine registration fee costs of an accompanying person can be reimbursed within the same parameters.

Section 10.07. All forms of hospitality offered to HCPs, HCOs' members or POs' Representatives must be "reasonable" in level, secondary to the professional content, in proportion to the occasion and strictly limited to the main purpose of the Event. As a general rule, the hospitality provided must not exceed what those individuals would normally be prepared to pay for themselves.

Section 10.08. Hospitality must not include sponsoring or organising entertainment events (e.g. sporting or leisure).

CZ specific:
Section 10.09. The Event must be directly related to the HCP's area of expertise or HCO´s member´s or PO´s Representative´s area of professional interest.

Section 10.10. Arrival at the venue of the Event must occur within 24 hours before start of the Event and departure must occur within 24 hours after the Event finishes. If attendees elect to arrive earlier or stay longer, any expenses associated with the additional time must be paid by the attendee and may not be reimbursed by the Member Company.

Section 10.11. At least 75% of usual working hours must be allocated to the scientific/educational program of any Event.

Section 10.12. Contribution cannot be linked to prescribing behavior or volume of sales. Invitation to the Event cannot be linked to an agreed level of prescriptions.

Section 10.13. Reimbursement for expenses associated with contributions to the Event must be made by bank transfer or money order and not by cash or other cash equivalent, and must be associated with itemized receipts for all reimbursed expenses. Member Companies are encouraged to pay for the expenses directly to the providers of hospitality (travel, accommodation, meals) and to pay registration fees directly to the congress organizer.

Section 10.14. Sponsorship cannot be undertaken by any Member Company to the exclusion of any other Member Company willing to sponsor any particular Event.

Section 10.15. Investigator meetings can be held only for participants in clinical trials which are conducted consistent with good clinical practice and which were either approved by or notified to SÚKL.

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.
Providing, offering or promising cash, cash equivalents or personal services is also prohibited. For these purposes, personal services are any type of service unrelated to the profession and that confer a personal benefit to the recipient.

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

ARTICLE 12
DONATIONS AND GRANTS TO HCOs AND POs

Section 12.01. Donations and Grants (in cash or 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 individuals, even indirectly, are not permitted. The Contribution to Costs related to Events for HCPs to attend international Events is covered by Article 13 of the AIFP Code.

CZ specific
Section 12.03. Donations and Grants must be able to withstand public and professional scrutiny and conform to professional standards of ethics and of good morals and taste. Each Member Company should establish internal procedures to review Donations and Grants for appropriateness.

DONATIONS AND GRANTS TO HCOs AND POs

Section 12.04. All Donations and Grants to HCOs must be based on unsolicited, written request by the recipient HCO. In the case of equipment or other tangible items, such equipment must always remain in the possession and within the site of the HCO and must not be used for personal use of individual HCP at any time.

ARTICLE 13
CONTRIBUTION TO COSTS RELATED TO EVENTS AND SPONSORSHIP

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

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.

CZ Specific
Section 13.04. Member Companies must report every Sponsorship and Contribution to Costs related to Events of Third Parties in the applicable database of AIFP according to the terms stipulated in the AIFP implementing guideline.

Section 13.05. Member Companies support Events for purely professional, scientific and educational purposes. Sponsorship of or Contribution to Costs related to Events, that do not satisfy this principle, is not allowed.

Section 13.06. Trade displays are important for the dissemination of knowledge and experience to the HCPs. The prime objective in organizing such displays must be the enhancement of medical knowledge.
Trade displays must comply with applicable laws with a special consideration to promoted Medicinal Products. A trade display must include, in a prominent position, the name of the sponsoring Member Company. Product Information for Medicinal Products being promoted must be available from the display stand. No alcohol and game of chance are allowed at trade displays.

ARTICLE 14
MEMBER COMPANY FUNDING

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 funding 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 those provide any type of services to Member Companies (not otherwise covered by the AIFP Code) are only allowed if such services: (i) are provided for the purpose of supporting healthcare, research or education; and (ii) do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.

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

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

b. a legitimate need for the services has been clearly identified and documented in advance of requesting the services and entering into arrangements;

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

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

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

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

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

Section 15.03. In their written contracts with consultants, Member Companies are strongly encouraged to include provisions regarding the obligation of the consultants to declare that they are consultants to the 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.

Similarly, Member Companies that employ, on a part-time basis, HCPs that are still practising their profession are strongly encouraged to ensure that such persons have an obligation to declare their employment arrangements with the Member Company whenever they write or speak in public about a matter that is the subject of the employment or any other matter relating to that Member Company. The provisions of this Section 15.03 apply even though the AIFP Code does not otherwise cover non-promotional, general information about Member Companies (as discussed in the "Scope of the AIFP Code" section).[2]

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 of the AIFP Code, 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 minimal.

[2] Companies are strongly encouraged to include such provisions in any contracts covered by this Section 15.03.

CONTRACTED SERVICES

CZ specific:
Market research must be clearly identified as such when the initial approach is made. Promotion must not be presented as market research or research of any type. Market research is not to be carried out be Medical Sales Representatives or any other position involved in sales activities, unless there is no payment to the HCP who is taking part in the research. Member Companies carrying out market research must practically utilize its results.

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

CHAPTER 3

SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH HCPs AND HCOs

ARTICLE 16

MEDICAL EDUCATION

Medical Education is aimed at increasing the scientific knowledge and competence of HCPs to enhance medical practice and improve patient outcome. Member Companies can be engaged in different types of Medical Education, but such activities must not constitute off-label or otherwise prohibited Promotion. When funding independent Medical Education or organizing Medical Education activities directly or in collaboration with Third Parties, Member Companies must ensure that their participation and role is clearly acknowledged and apparent from the outset. 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 designed to allow the expression of diverse theories and recognized opinions.

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 beneficial to the care of patients.

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

Section 17.03. The nature of Informational or Educational Materials and Items of Medical Utility considered may not constitute a circumvention of the prohibition on gifts defined under Article 11 of the AIFP Code. The transmission of such materials or items must not constitute an inducement to recommend, prescribe, purchase, supply, sell, dispense 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 be product branded, unless the Medicinal Product's name is essential for the correct use of the material or item by the patient.

CZ specific

Section 17.05. The total value of all Informational or Educational Materials and Items of Medical Utility provided to a single HCP cannot exceed 1,500 CZK per year (this does not apply to Member Companies' own marketing/educational materials).

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.

NON-INTERVENTIONAL STUDIES

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);

b. If applicable law or a particular site requires ethics committee approval, the study protocol must be submitted to the ethics committee for review;

c. The study protocol must be approved by the Member Company's scientific service 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 scientific service (as described in Section 20.01.a), which service 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;[3] 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 scientific service that will also ensure that the Medical Sales Representatives are adequately trained. Such involvement must not be linked to the Promotion of any Medicinal Product.

Section 18.03. To the extent applicable, Member Companies are encouraged to comply with Section 18.02 for all other types of NIS, including epidemiological studies and registries and other studies that are retrospective in nature. In any case, such studies are subject to Article 15.01 of the AIFP Code.

CZ specific

Section 18.04. NIS must concern Medicinal Products with valid marketing authorisation, used in approved indications.

Section 18.05. The objective of the NIS must be to obtain real clinical evaluation of the use of the Medicinal Product studied. The information collected must include clinical data, safety data and/or QoL data to sufficiently describe clinical experience with the Medicinal Product studied.

Section 18.06. Every NIS has to be notified to AIFP Executive Director before its start. Member Companies have to submit the protocol of the NIS and template study report form, template written agreement with the HCP, including information about method and amount of remuneration in the NIS. These documents are filed in NIS AIFP Database. The following information from the submitted studies will be made available to all Member Companies on the AIFP intranet: study sponsor, study product, name of the study and duration. AIFP Executive Director ensures confidentiality of the submitted documentation.

In case of complaint by a Member Company regarding NIS performed by another Member Company, the Executive Director makes available all study documentation to the Ethics Committee. The Ethics Committee may randomly review up to 20% of the submitted NIS whether they fulfil criteria described in the AIFP Code. If a particular NIS is selected for review, the sponsoring Member Company is invited to the review meeting. The Member Company should be represented by its Medical Director. The Ethics Committee decides whether the NIS is compliant with the AIFP Code. In case of breach of the AIFP Code, the Ethics Committee may penalize the Member Company according to rules of this AIFP Code.

[3] 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.

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 must not be given for the sole purpose of treating patients. Medical Samples are provided to HCPs so that they may familiarise themselves with the Medicinal Product and acquire experience in dealing with them. In accordance with Czech and/or EU laws and regulations, a limited number of Medical Samples may be supplied on an exceptional basis and for a limited period.

A reasonable interpretation of this provision is that each HCP should receive, per year, not more than 4 Medical Samples of a particular Medicinal Product he/she is qualified to prescribe for 2 years after the HCP first requested samples of each particular Medicinal Product (i.e. the "4x2" standard). In this context, a new Medicinal Product is a product for which a new marketing authorisation has been granted, either following an initial marketing authorisation application or following an extension application for new strengths/dosage forms that include a new indication as well as a Medicinal Product for which a new group of prescribing HCPs has been authorized. Extensions of the marketing authorisation to additional strengths/dosage forms for existing indications or pack sizes (number of units in the pack) cannot be considered as new Medicinal Product.

Without prejudice to the ban on medical sampling of Medicinal Product containing psychotropic and narcotic substances, Medical Samples can only be given in response to a written request from HCPs qualified to prescribe that particular Medicinal Product. Written requests must be signed and dated by those who ask for the Medical Samples.

Section 19.02. Member Companies must have adequate systems of control and accountability for Medical Samples which they distribute and for all Medicinal Products handled by theirs Medical Sales Representatives. Medical Sales Representatives must take adequate precautions to ensure the security of samples in their possession. Member Companies must develop an appropriate recording system so that, if a Medicinal Product recall is necessary, relevant samples will be included in the recall. This system must also clearly establish, for each HCP, the number of Medical Samples supplied in application of the "4x2" standard.

Section 19.03. Each Medical Sample must be no larger than the smallest package of that particular Medicinal Product authorized under a separate marketing authorization number presented to the market in the Czech Republic. Each Medical Sample must be marked "free sample" or "sample not for sale" 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 Applicable Code(s) and laws and regulations.

a. Each Member Company must establish a scientific service 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 such service(s) in accordance with this Section 20.01 (i.e. whether there is one service in charge of both duties or separate services with clearly delineated duties), taking into account their own resources and organization. The scientific service must include a medical doctor or, where appropriate, a pharmacist or another qualified personnel 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 Applicable Code(s) 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, the scientific service must include a medical doctor or, where appropriate,

a pharmacist or another qualified personnel, 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 AIFP Code 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 Applicable Code(s) are met.

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

a. Medical Sales Representatives must comply with all relevant requirements of the Applicable Code(s), and all applicable laws and regulations, and 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, as well as information on reimbursement, for each Medicinal Product they present.

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

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.

CZ specific

Section 20.03. Each Member Company is required to ensure that its Medical Sales Representatives, including their line managers, undergo certification training in the basics of pharmacology, pharmaceutical law and ethics, which is available on the website at www.certifikat-aifp.cz, and subsequently pass exam verifying the acquired knowledge. Detailed rules for certification of Medical Sales Representatives are determined by the AIFP implementing guideline.

CHAPTER 4

SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH POs

ARTICLE 21

INTERACTIONS WITH POs

Section 21.01. Member Companies must comply with the following principles:

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

2. All interactions 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 must always be clearly acknowledged.

5. Member Companies welcome broad funding of POs from multiple sources.

Section 21.02. EU and Czech laws and regulations prohibit the advertising of POM to the general public.

CZ specific:
Where Members Companies assist or are directly involved in the conduct of public/patient disease awareness programs to meet growing demands of society for more information and enhance public understanding of disease prevention, signs and symptoms of medical conditions, illnesses, and available treatments, such activities must adhere to the highest standards of accuracy and support the role of the healthcare provider.

All such information must be accurate, fair and not misleading and fully complying with the currently valid Czech summary of product characteristics. Communication must not contain any promotional claim.

Communications may include the provision of patient package inserts and other leaflets and booklets, etc., made available to inform patients about Medicinal Products prescribed by HCP.

All materials containing brand or generic names of Medicinal Products must include information at the very beginning that they are intended only for patients using the mentioned Medicinal Product. Such publications can be distributed only by medical persons or pharmacists and only to the patients using the pertinent Medicinal Product. To ensure such way of distribution is the objective and non-transferable responsibility of the Member Company producing such publication. Member Companies must take all precautions to guarantee that such materials will not be found in public rooms.

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 donation 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 ToVs FROM MEMBER COMPANIES

ARTICLE 22

DISCLOSURE OF ToVs TO HCPs, HCOs, AND POs

Section 22.01. Time of Disclosure
Disclosures must be made by each Member Company within 6 months after the end of the relevant Reporting Period and the information disclosed must be required to remain in the public domain for a minimum of 3 years after the time such information is first disclosed unless, in each case, (i) a shorter period is required under applicable laws or regulations, or (ii) the relevant data protection legal basis (e.g. the legitimate interest grounds, a legal duty or the Recipient's consent relating to a specific disclosure) is no longer applicable.

The common reporting period for publication of ToVs to Recipients is set by the AIFP Board of Directors subject to general publication terms applicable to all EFPIA members.

ARTICLE 23

DISCLOSURE OF ToVs TO HCPs AND HCOs

Section 23.01. Rationale
The following article provides for disclosures of ToVs to HCPs and HCOs, whether directly or indirectly. When deciding how a ToV 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 laws and regulations.

Section 23.02. Implementation and deviations
It is understood that if there is an inconsistency between this article and the applicable statutory law or regulation to which a Member Company is subject which would make adherence to this article not reasonably possible, the Member Company must comply with such law or regulation and such lack of adherence will not constitute a breach of this article.

Section 23.03. Disclosure Obligation
General Obligation. Subject to the terms of this article, each Member Company must document and disclose ToVs it makes, directly or indirectly, to or for the benefit of a Recipient, as described in more detail in Section 23.05 of the AIFP Code.

Excluded Disclosures. Without limitation, ToVs 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 of the AIFP Code), meals (governed by Article 10, especially Section 10.05 of the AIFP Code), Medical Samples (governed by Article 19 of the AIFP Code); 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 B for reference, reflecting the requirements of this article.

DISCLOSURE OF ToVs TO HCPs AND HCOs

CZ specific: Platform of Disclosure. Disclosures shall be made on the central platform established according to AIFP implementing guideline.

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

Language of Disclosure. Disclosures must be made in Czech and English languages.

Documentation and Retention of Records. Each Member Company must document all ToVs 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 years after the end of the relevant Reporting Period, unless a shorter period is required under applicable laws or regulations.

Section 23.05. Individual and Aggregate Disclosure
Individual Disclosure. Except as expressly provided by this article, ToVs must be disclosed on an individual basis. Each Member Company must disclose, on an individual basis for each clearly identifiable Recipient, the amounts attributable to ToVs to such Recipient in each Reporting Period which can be reasonably allocated to one of the categories set out below. Such ToVs may be aggregated on a category-by-category basis, provided that itemised disclosure must be made available upon request to (i) the relevant Recipient, and/or (ii) the relevant authorities.

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

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

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

   i. Registration fees;
   ii. Sponsorship agreements with HCOs or with Third Parties appointed by an HCO to manage an Event; and
   iii. Travel and accommodation (to the extent governed by Article 10 of the AIFP Code).

   c. Fees for Service and Consultancy. ToVs 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 ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

2. For ToVs 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 (to the extent governed by Article 10 of the AIFP Code).

   b. Fees for Service and Consultancy. ToVs 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 ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

DISCLOSURE OF ToVs TO HCPs AND HCOs

Aggregate Disclosure. For ToVs 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 ToVs in each Reporting Period on an aggregate basis. Such aggregate disclosure must identify, for each category, (i) the number of Recipients covered by such disclosure, on an absolute basis and as a percentage of all Recipients, and (ii) the aggregate amount attributable to ToVs to such Recipients.

Non duplication. Where a ToV required to be disclosed pursuant to Section 23.05 is made to an individual HCP indirectly via an HCO, such ToV must only be required to be disclosed once. To the extent possible, such disclosure must be made on an individual HCP named basis pursuant to Section 23.05.

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

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

ARTICLE 24
DISCLOSURE OF SUPPORT AND SERVICES PROVIDED TO POs

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

MISCELLANEOUS

ARTICLE 25

ETHICS COMMITTEE

Section 25.01. The AIFP Ethics Committee consists of 11–14 members. Three to five members are always independent experts, and the remaining members of the Ethics Committee are representatives of AIFP Member Companies.

Section 25.02. At least one of the independent experts should be a lawyer, at least one should be a medical professional and at least one should be a representative of a patient organisation. One of the independent experts shall be the Chair of the Ethics Committee. These members and the Chair of the Ethics Committee shall be nominated by the Board and elected by the General Assembly.

Section 25.03. At least one of the members of the Ethics Committee who are representatives of AIFP Member Companies should be a General Manager, at least one should be a Head of Medical Department (e.g. Medical Director), at least one should be a specialist in Compliance and at least one should be a specialist in Marketing/ Sales (e.g. Marketing/ Sales Director). These members shall be nominated by AIFP Member Companies and elected by the General Assembly.

Section 25.04. It is important to keep the continuity of the work of the Ethics Committee. Therefore, all members of the Ethics Committee will be elected for a two-year term. The re-election is possible.

A Member Company may have only one representative in the Ethics Committee. Membership in the Ethics Committee is incompatible with the function of a member of the Board of AIFP and member of the Controlling Committee of AIFP.

ARTICLE 26

COMPLAINTS AND SANCTIONS FOR BREACH OF THE AIFP CODE

Section 26.01. Rules for submitting and processing complaints, rules for commencement of the proceedings for violation of the AIFP Code on the Ethics Committee's own initiative as well as for imposing sanctions for breach of the AIFP Code are specified in Annex A of the AIFP Code.

ARTICLE 27

FINAL PROVISIONS

Section 27.01. In case of any discrepancy between the English and Czech version of the AIFP Code, the Czech version will prevail.

ANNEXES

ANNEX A

AIFP CODE DIRECTIVE – PROCESSING OF COMPLAINTS AND IMPOSITION OF SANCTIONS FOR BREACH OF THE AIFP CODE

The AIFP Code is administered by the Ethics Committee. The Ethics Committee is responsible for the provision of advice, guidance and training on the AIFP Code, for the supervision of compliance with the AIFP Code and its implementing regulations as well as for the complaint procedure. It is also responsible for arranging for conciliation between Member Companies when requested to do so and for arranging for the scrutiny of advertising and meetings on a regular basis. In the event of a complaint by a member company, the Ethics Committee is not an investigatory body as such. It asks the Defendant (Member Company against which a complaint is filed) for a complete response and may ask the parties to a case for further information in order to clarify the issues. It is essentially an adversarial process in which the evidence to be taken into account comes from the Claimant and the Defendant, though the Ethics Committee can seek evidence from third parties where necessary. A Claimant has the burden of proving their complaint on the balance of probabilities. The system is designed so that both parties can participate fully in the process. The names of individuals complaining from outside the pharmaceutical industry are kept confidential. In exceptional cases it may be necessary for a Member Company to know the identity of the Claimant so that the matter can be properly investigated. Even in these instances, the name of the Claimant is only disclosed with the Claimant's permission. All complaints are judged on the evidence provided by the parties. The weight to be attached to any evidence may be adversely affected if the source is anonymous and thus in some instances it will not be possible for such a complaint to proceed. Complaints made under the AIFP Code are considered by the Ethics Committee and, where required, by the Committee of Appeal. Reports on cases are published by the Ethics Committee and are available on request. Complaints should be submitted to the Executive Director of AIFP.

1. Application of complaint procedure

Procedure for submitting complaints according to AIFP Code is available to every individual or legal entity (including namely the Member Company, a healthcare professional, a representative of the general public, a government official or state authority, or patient organization) , acting in good faith and within the form and purposes of AIFP Code.

Proceedings under the AIFP Code may also be commenced by the Ethics Committee on its own initiative by a resolution provided that:

- a complaint under the AIFP Code has not been lodged in the same matter as of the date of commencement of such proceeding,
- indications of a possible violation of the AIFP Code (i) are publicly available (in the professional sphere and/or general public domain), or (ii) relate to reporting, transparency or disclosure obligations,
- the acts or omissions that are assessed in this way for possible non-compliance with the AIFP Code did not occur earlier than three years after the initiation of proceedings by the Ethics Committee on its own initiative and at the same time not earlier than the effective date of this version of the AIFP Code, i.e. not earlier than 14th September 2023,
- the AIFP Ethics Committee has decided to commence proceedings on its own initiative by a resolution adopted by a majority of at least 75% of the members of the Ethics Committee entitled to vote on the matter (i.e. without a conflict of interest in the matter); and
- the AIFP Executive Director has given his written consent to the Ethics Committee's decision to commence such proceeding.

ANNEX A

1.1. Claimant and Defendant

1.1.1. For purposes of AIFP Code shall an individual or legal entity submitting a complaint be regarded as the Claimant.

1.1.2. Member Company against which a complaint is filed or against which proceedings are commenced on the Ethics Committee's own initiative (i.e. a company which allegedly breached the rules of AIFP Code) shall be, for the purposes of AIFP Code, regarded as the Defendant.

1.2. Submitting of a complaint and commencement of the proceeding by the Ethics Committee on its own initiative

1.2.1. Complaints must be submitted in a written form, in Czech language and if filed by a Member Company then mandatorily in Czech and English language, and it must include:

- Identity of Claimant – full name (as registered in the respective Register at the relevant court) address of its registered office, identification number (including telephone number and e-mail, if possible; in case the Claimant is an individual, they will provide their full name, correspondent address and, if possible, telephone number and email; they will also mention if they represent any organization for the purposes of the complaint,
- Identity of Defendant – full name (as registered in the Commercial Register at the relevant court) address of its registered office, identification number (including telephone number. and e-mail, if possible)
- For every complaint name of product/products concerned or description of activities to which the complaint refers
- Relevant material which should be used as a proof of breach of the AIFP Code (in case of activity)
- For every case particular reference to the resource of commercial/activity which is subject to such complaint and/or printed material or other proof
- Date when alleged breach was discovered
- Date of submission of complaint
- Particular reference to the part of AIFP Code which was breached (article and section number)

1.2.2. If a proceeding is commenced on the Ethics Committee's own initiative, a report shall be drawn up by the Ethics Committee which shall include the following:

- identification of the defendant - full name (as entered in the commercial register of the competent court), registered office address, identification number (including telephone number and e-mail, if possible);
- the name of the product(s) concerned or a description of the activities which are the subject of the proceeding;
- relevant material or information that should be used as evidence of a breach of the AIFP Code (in the case of activity), if available;

- for each case, a specific reference to the source of the promotion/activity at issue and/or printed material or other evidence;
- the date on which the alleged breach was discovered;
- the date of the Ethics Committee's decision to commence the proceeding on its own initiative;
- the date of the AIFP Executive Director's written consent to the commencement of the proceeding;
- a specific reference to the part of the AIFP Code that has been allegedly breached (article or section number).

1.2.3. All communications hereunder shall be delivered to the address as follows:

AIFP
Attention: Executive Director
IBC Pobřežní 3
186 00 Prague 8

2. Procedure following the complaint submission

2.1. Complaint verification

2.1.1. If Ethics Committee receives complaint for alleged breach of the AIFP Code, it shall primarily verify:

- Whether adequate information enabling to examine the complaint exists, and
- Whether the complaint contains all prescribed details.

2.1.2. One complaint may comprise more than one case, e.g. complaint may apply to more than one advertisement concerning various subjects of complaint and/or to various products.

2.1.3. Initial step with every complaint shall be:

- Identification of the subject of complaint and Defendant, including its membership in AIFP, Board of managing directors or parent company and its registered address, if different
- Finding whether the case applies to company that is not (locally or through its parent company) member of EFPIA. Under such circumstances this case may not be formally administered. However, Ethics Committee may express its opinion regarding acting of such non-member company. Ethics Committee shall authorize one of its members to acquire information referred to in section 2.1.3.

2.1.4. Ethics Committee is obliged to undertake the complaint within 45 working days from the day it was delivered by the Claimant. The Ethics Committee is obliged to inform the Defendant about the complaint within 15 working days after handling the complaint. In the case of commencement of a proceeding on its own initiative, the Ethics Committee is obliged to conclude the proceeding within 45 working days from the day on which the report on the commencement of the proceeding was delivered to the Defendant. The Ethics Committee is obliged to inform the Defendant about the commencement of a proceeding on its own initiative within 15 working days from the date of granting written consent of the Executive Director of the AIFP to the commencement of such proceeding.

2.2. Proceedings following the notification of the Defendant

2.2.1. After receiving information by Ethics Committee, the Defendant has 15 working days to deliver its statement in writing to Ethics Committee. Ethics Committee or its Chairman may extend such period as an exception.

2.2.2. Provided that the Defendant acknowledges acting in contradiction with the AIFP Code, it shall inform the Ethics Committee about steps taken/to be taken in order to ensure redress, e.g. amicable settlement of dispute between interested parties. In such case, the Ethics Committee may decide on such acknowledged breach without hearing of the parties, including the decision on remedies and potential sanctions.

2.2.3. Provided that the Defendant refuses accusations referred to in the complaint/report on commencement of the proceeding, reasons for refusal must be stated clearly and, if appropriate, supporting data (e.g. scientific evidence or prove supporting controversial allegation), shall be submitted to Ethics Committee by Defendant.

2.3. Complaint discussion and decision

2.3.1. If the complaint is not settled as per 2.2.2. and after receiving Defendant's statement as per 2.2.1., Ethics Committee shall deal with the issue at its next meeting. Both the Claimant and the Defendant shall be about such meeting informed in time and invited at least 15 calendar days before a meeting in a written form to pronounce their opinion.

2.3.2. Ethics Committee shall decide whether a breach of the AIFP Code occurred and how such breach shall be defined (for the reasons of enlisting to the list of various AIFP Code's infringements, see Section Definitions in AIFP Code). The Ethics Committee votes about each breach of the AIFP Code separately. Ethics Committee decision is valid if at least six (6) members of the Ethics Committee are present at the meeting. The decision is valid if the simple majority of present Ethics Committee members votes for the decision. In case of equal votes, the Chairman's vote is decisive. In the case a member of the Ethics Committee is either a Claimant or a Defendant or associated with them or has any interest in either of them in a particular case, he or she may not take part in any evaluation, discussion and/or decision making concerning the case.

2.3.3. Ethics Committee informs about its decision both the Claimant and the Defendant in writing no later than 15 working days after the decision was made.

2.3.4. Provided that the Ethics Committee reaches the conclusion that no breach of the AIFP Code occurred, the Ethics Committee shall announce such decision to the Claimant and to the Defendant.

2.3.5. Provided that the Ethics Committee reaches the conclusion that a breach of the AIFP Code occurred, the Defendant shall within 15 calendar days after receipt of the decision provide a written commitment declaring the cessation of disputable activities or materials without any delay and as well as a commitment to take all possible steps to avoid such breach of the AIFP Code in the future. This commitment shall be signed by General Manager of the company (Defendant) and must be accompanied by details of the steps that are to be taken in order to realize this commitment, including the date when such promotional material appeared/was used for the last time and/or the date when last promotional activity took place.

2.3.6. Regarding the decision of the Ethics Committee, the Claimant or the Defendant may appeal to the Committee of Appeal within 15 working days from the receipt of the decision of the Ethics Committee and must contain reasons for which is the decision of the Ethics Committee not accepted

2.3.7. If any party appeals against the decision on the complaint of the Ethics Committee, it shall consign a bail of 50,000 CZK to the account of AIFP.

2.3.8. In case the Ethics Committee commences proceedings on its own initiative, the provisions of this Article shall apply accordingly.

ANNEX A

2.4. Composition of the Committee of Appeal

2.4.1. A function of the Committee of Appeal shall be performed by the AIFP Board. When performing the function of the Committee of Appeal, the AIFP Board shall be amended by a co-opted non-AIFP expert. However, the AIFP' Board member who is also member of Ethics Committee may not take part in the Committee of Appeal.

2.5. Procedure at and decision of the Committee of Appeal

2.5.1. After receipt of the appeal the Committee of Appeal shall convene it's meeting within 30 working days.

2.5.2. Claimant and Defendant shall be invited in a written form to the meeting to pronounce their opinion regarding the complaint at least 10 working days before the meeting term.

2.5.3. Committee of Appeal informs about its decision both parties in writing no later than 15 working days after the decision was made.

2.5.4. If the Committee of Appeal confirms the decision by the Ethics Committee and decides the AIFP Code was breached, the Defendant shall within 15 calendar days provide a written commitment as per 2.3.5. In this case the bail shall not be returned to the appealing party but will be used to cover the costs of the appeal.

2.5.5. If the Committee of Appeal accepts the appeal and decides that the AIFP Code was not breached the bail will be returned to the appealing party within 15 working days after the decision

2.5.6. The Committee of Appeal may change the fine amount imposed by the Ethics Committee. In this case the bail shall not be returned to the appealing party, unless specific circumstances justify a partial return of the bail.

2.5.7. The Committee of Appeal may decide to return case to the Ethics Committee if formal requirements were not met. In this case the bail will be returned to the appealing party within 15 working days after the decision

2.5.8. Unless the appeal is returned to the Ethics Committee as per 2.5.7., the decision of the Committee of Appeal is final.

2.5.9. The Ethics Committee monitors compliance with the final decision of the Ethics Committee or the Committee of Appeal.

2.5.10. If the Defendant does not provide the written commitment as per 2.3.5 or if the Defendant demonstrably does not comply with the commitment, the Ethics Committee informs the AIFP Board about the Defendant's failure to comply with his obligations. The AIFP Board shall submit a proposal to exclude the Defendant from AIFP at the next General Meeting.

2.5.11. In case the Ethics Committee commences proceedings on its own initiative, the provisions of this Article shall apply accordingly.

ANNEX A

3. General Provisions

3.1. Compliance with the AIFP Code

3.1.1. The Ethics Committee shall supervise compliance with the AIFP Code. Ethics Committee may request external expert advice in order to decide whether there was a breach of the AIFP Code or not.

3.1.2. Ethics committee opinions
Member Companies may submit to the Ethics committee questions regarding explanations of the AIFP Code. Ethics committee will issue its opinion and inform the Member Companies about the decision. This opinion serves as guidance to Member Companies had they similar questions.

3.2. Sanctions

3.2.1. Imposition of sanctions on subject Member Company is in accordance with this section of the AIFP Code. The fine is due within 30 working days from the receipt of the final decision of the EC or Committee of Appeal.

Decision of the AIFP EC is final, if no appeal is submitted within the time limit pursuant to Article 2.5.1. Decision of the Committee of Appeal is final unless the Committee of Appeal decides to refer the case back to AIFP EC.

3.2.2. Following sanctions can be imposed for a breach of AIFP Code:

- lesser breach, anonymous publication in semi-annual report
- minor breach, maximum of 200,000 CZK and anonymous publication in semi-annual report
- major breach, maximum of 500,000 CZK, named publication in semi-annual report and a named publication on the AIFP website
- repeated major breach, maximum of 1,000,000 CZK named publication in semi-annual report and a named publication on the AIFP website and a press release.

3.2.3. If the Ethics Committee is convinced that the breach of the AIFP Code gives it authority to submit a request for revocation of a company's membership or for cancellation of adoption of the AIFP Code, either temporarily or permanently, the Ethics Committee shall submit relevant proposal to the AIFP Board. AIFP Board may impose these following sanctions:

- temporary exclusion of a Member Company from the AIFP and/or suspension of adoption of the AIFP Code, for a definite period of time, or
- exclusion of a Member Company from the AIFP and/or cancellation of adoption of the AIFP Code.

Ethics Committee will submit the proposal to AIFP Board in case of 3 major breaches of the AIFP Code in 24 month and/or if the reputation of the pharmaceutical industry or AIFP is at risk.

3.2.4. Based on the AIFP Statutes, both these sanctions must be approved by the General Meeting of AIFP, by simple majority of votes.

Annex B – TEMPLATE

	Full Name	**HCPs:** City of Principal Practice HCO**s:** city where registered	Country of Principal Practice	Principal Practice Address	Unique country local identifyer *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 & Accomodation	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 *(named list, where appropriate)*					N/A	N/A	*number*	*number*	*number*	*number*		*Optional*
	% of total transfers of value to individual HCPs					N/A	N/A	%	%	%	%		N/A
HCOs	***INDIVIDUAL NAMED DISCLOSURE – one line per HCO (i.e. all transfers of value during a year for an individual HCO will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)***												
	HCO 1					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	HCO 2					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	etc.					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	OTHER, NOT INCLUDED ABOVE – where information cannot be disclosed on an individual basis for legal reasons												
	Aggregate amount attributable to transfers of value to such Recipients					*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*		*Optional*
	Number of Recipients in aggregate disclosure					*number*	*number*	*number*	*number*	*number*	*number*		*Optional*
	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed					%	%	%	%	%	%		N/A
R & D	***AGGREGATE DISCLOSURE***												
	Transfers of values re Research & Development as defined											*TOTAL AMOUNT*	*OPTIONAL*

ANNEX C

DECLARATION OF ADOPTION OF THE AIFP CODE OF PRACTICE

As another step in the long-term plan for cultivation of relationships in the Czech healthcare sector and in reaction to the unacceptable unethical behaviour of certain entities on the Market, the Czech Association of Innovative Pharmaceutical Industry (AIFP) has publicly called on other pharmaceutical companies, entities involved in the production, distribution and sale of pharmaceuticals and other organisations, individuals and entities within the healthcare system in the Czech Republic to adopt the ethical principles formulated in the AIFP Code of Practice (the "AIFP Code").

Based on familiarisation with the principles and rules of the valid AIFP Code, by issuing this declaration we hereby adopt these principles and rules and undertake to abide by and promote them in our activities. By pledging to comply with the AIFP Code, which is based on the Code of the European Federation of Pharmaceutical Industries and Associations for practices related to the promotion of pharmaceutical products (the EFPIA Code), we also pledge to comply with valid EU legislation and the national legislation of the Czech Republic regarding this particular sector. Last, but not least, by adopting the specified rules, we will be supporting the principles of the anti-corruption strategy outlined by the Czech Ministry of Health.

By adopting this Declaration, we bear in mind the binding nature of the rules outlined in the AIFP Code as well as their enforceability by competent AIFP bodies, including possible sanctions for their breach.

Organisation name: .....

Organisation ID No.: .....

Address: .....

Telephone number: .....

Fax: .....

www: .....

E-mail address of contact person: .....

Contact person: .....

aifp

Asociace inovativního
farmaceutického průmyslu

Association of Innovative Pharmaceutical Industry
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