THE CODE OF CONDUCT

OF THE ASSOCIATION OF INNOVATIVE PHARMACEUTICAL INDUSTRY

ADOPTED IN BRATISLAVA

ON 18 SEPTEMBER 2014

Full wording effective as of February, 8th 2022

TABLE OF CONTENTS

PREAMBLE

This Code owes its origin to the determination of AIFP* to secure universal acceptance and adherence to high ethical standards in the activities of its Members related to prescription-only medicinal products*.

This Code regulates the promotion of prescription-only medicinal products towards authorised persons, promotional activities of pharmaceutical companies towards healthcare professionals and the communication with them as well as mutual relations between pharmaceutical companies and healthcare professionals or healthcare organisations. This Code also regulates mutual relations between the Members and the patient organisations and competent authorities.

This Code is not intended to control or regulate the provision of non-promotional medical, scientific and factual information, nor is it intended to control or regulate activities directed towards the general public which relate solely to non-prescription medicinal products.

This Code shall not apply to the following:

- the labelling of medicinal products and accompanying package leaflets;
- correspondence, possibly accompanied by a 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, provided they include no medicinal product claims;
- non-promotional information relating to human health or diseases;
- activities which relate solely to non-prescription medicinal products;
- non-promotional general information about companies (such as information directed to investors or current/prospective employees), including financial data, descriptions of research and development programmes, and discussion of regulatory developments affecting a company and its products.

Acceptance and observance of the Code is a condition of membership of AIFP, whereby a Member of AIFP must comply with both the content and the spirit hereof. The Members of AIFP must ensure that all employees and/or agents acting on their behalf, including all their affiliates and subsidiaries, are fully conversant with, and obey the provisions of this Code.

The Members of AIFP shall be liable for discharging of their duties imposed hereunder, even if they commission other parties (e.g. medical representatives, sales forces, consultants, market research companies, advertising agencies etc.) to design, implement or engage in activities covered by this Code on their behalves or account. Also, the Members must always take reasonable steps to ensure that any third party they commissioned to design, implement or engage in activities covered by this Code but that do not act on behalf of the Member of AIFP (e.g. joint ventures, licensees etc.) comply with this Code.

Pharmaceutical companies being not Members of AIFP are hereby invited to accept and observe this Code.

The Code must be supervised and exercised by the Ethical Committee. The Ethical Committee may issue interpretation from time to time to construe certain sections of the

Code. Complaints concerning alleged breaches of the Code should be reported to the Ethical Committee.

A major guiding principle of this Code is that, whenever a promotional claim* is made for a medicinal product, it must be accompanied by the Product Information* in the Slovak language.

Failure to comply with this Code will result in sanctions being imposed under provisions of the Operating Procedures. Adherence to this Code in no way reduces Members' responsibilities to comply with the Slovak legislation and Codes which they are bound to obey.

In respect of the applicable laws, AIFP must facilitate the Members' awareness of and education about this Code, including guiding the Members to prevent breaches of this Code.

Promotion and interaction which take place within Europe must comply with applicable laws and legal regulations and the Member association National code of the country in which the promotion of interaction takes place.

ETHICAL PRINCIPLES

The Members are engaged in the development of new medicinal products and vaccines for present and future generations and provide the latest knowledge in the field of science and education in favour of patients and to support high-quality patient care. Pharmaceutical companies discover, develop, promote, sell and distribute medicinal products in an ethically compliant manner and following all rules and regulations applicable to medicinal products and healthcare.

This Code represents the base for the rules of conduct applicable to activities of the Members and any person acting on their behalf. Their conduct must abide by fundamental values such as trust, care, fairness, respect and honesty. These fundamental values and principles help ensure that their interactions with healthcare professionals and broader medical community must be adequate and consistent with expectations of an ever-changing society. The Ethical Code must be the basis for evolving the work of the Members, it must be the pillar for the given rules and must provide the frame for impeccable conduct irrespective of demandingness of circumstances.

TRUST

The Members must act with moral consistency and honesty in the interest of improving patient care and building trust and respect for the independence of healthcare provides, patients and other stakeholders. Recognising the importance and significance of interactions with healthcare providers, patients, as well as other stakeholders that are key to improving patient care and building trust, the Members seek to create awareness that they are a trusted and reliable partner, not just for their partners and other stakeholders, but also for the general public.

CARE

The Members must protect the safety of the users of their medicinal products – from the commencement of the clinical study, as well as during the entire life cycle of the drug.

INNOVATION

The Members must improve global health through innovative medicinal products and services adhering to the highest ethical, scientific and medical standards.

QUALITY

The Members commit to ensuring high-quality medicinal products with provable clinical efficacy and reliable safety profile.

FAIRNESS

The Members must support and respect fair business practices and open competition.

INTEGRITY

The Members undertake to act in a responsible, ethical and professional manner and not to offer, promise, provide or accept anything of value if that would induce undue influence of decision-making, profit, or gaining an unfair advantage.

RESPONSIBILITY

The Members must be responsible for their steps and decisions, including proper supervision over external third parties acting on their behalf.

RESPECT

The Members must respect all people and adopt a culture of diversity and inclusion. They must preserve the environment. They must duly look after animals in their care.

PROTECTION OF PRIVACY

The Members must respect the right for protection of privacy and personal data and must correctly process and protect personal data.

EDUCATION

The Members must support progress in the field of scientific and medical education in particular for the benefit of patients.

HONESTY

The Members must maintain honest and balanced communication with state authorities, healthcare professionals, patients and other stakeholders.

OPEN COMMUNICATION

The Members must support a culture of communication within their organisations, so that matters will be discussed openly and honestly, to learn from mistakes and to improve continually.

TRANSPARENCY

The Members must support progress in science and patient care through responsible, correct and appropriate disclosure of data from clinical trials sponsored by the concerned industry.

Note:

The Glossary of the definition of terms used herein forms an Annex hereto. Where the term referred to in the Glossary is herein used for the first time, it must be marked by the use of an asterisk (*).

PROVISIONS OF THE CODE

1. NATURE AND AVAILABILITY OF INFORMATION AND CLAIMS

1.1 Responsibility

It is the responsibility of Members, their employees and their medical or other advisors to ensure that the medical content* included in all promotional material* is true, correct*, accurate, updated, verifiable and fully supported by the Product Information, literature* or Data on File*, where the latter does not conflict with the former. Activities of the Member representatives* must comply with the Code at all times.

EXPLANATORY NOTES

1.1

This responsibility relates not only to the medicinal product being promoted but to any information given or claims made about other medicinal products.

Of importance is that any claim made must be consistent with SmPC of the medicinal product, irrespective of the source on which the claim is based.*

1.2 Provision of Substantiating Data

Further to the information compulsory supplied or generally available, the Member must, upon reasonable request, provide the healthcare professional with additional accurate and relevant information about products which it markets in the Slovak Republic.

Substantiating information must not rely solely on Data on File.

Data cited in promotional material in support of a claim, including Data on File or data "in the press" must be made available to healthcare professionals and the Members upon request.

EXPLANATORY NOTES

1.2

(a) All data to substantiate claims must be easily retrievable so that they could be supplied on request within 10 business days.

(b) Data contained in an application for marketing authorisation of the medicinal product may be used to substantiate claims. Such data must be supplied in detail when requested to substantiate a claim. A statement that the data are "Confidential" must not be accepted.

(c) If the information on which a claim is based may not be disclosed, e.g. an "in the press" article which is subject to confidentiality provisions, then such information may not be used to substantiate a claim to satisfy this section.

(d) Data relating to the cost-effectiveness of a product may be used to substantiate promotional claims, however, these data must conform to Sections 1.1, 1.2, 1.3, 1.5 and 1.7 hereof.

1.3 False or Misleading Claims

Information, medical claims* and graphical representations must be updated, accurate, balanced and must not mislead either directly, by implication, or by omission.

Information, claims and graphics* must be capable of substantiation*, such substantiation being provided without undue delay upon request of a healthcare professional.

EXPLANATORY NOTES

1.3

The following are examples of situations where the promotional material may breach this Code. This list is not all-inclusive and is based on the experience of the Ethical Committee.

(a) Literature references or quotations derived from a study or studies and citations of individual opinions which are significantly more favourable or unfavourable than has been demonstrated by the body of clinical evidence or experience. It is unreasonable to cite the results of an excessively favourable (or excessively unfavourable to a comparative product) study in a manner which suggests that those results are typical and may mislead.

(b) Information or conclusions from a study that is clearly inadequate in design, scope or conduct to furnish support for such information and conclusions.

(c) Citation of data previously valid but made obsolete or false by the evaluation of new data.

(d) Suggestions or representations of uses, dosages, indications or any other aspect of the Product Information which had not been approved.*

(e) Shortening an approved indication (e.g. in a by-line) so as to remove a qualification or limitation to the indication.

(f) Use of animal or laboratory data to directly support a clinical claim.

(g) Presentation of information in such a manner, e.g. Type size and layout, which could produce an incorrect perspective. The Type size used for qualifying statements must not be less than 2 mm. The qualifying statement must not be included with other reference material but must be situated on the same page as the original statement. The original statement and the qualifying statement must be linked by the use of an asterisk or a similar symbol.*

(h) Statements made about a competitive product, particularly negative statements, not balanced with corresponding information about the product being promoted.

(i) Shortening the title of graphical representations reproduced from literature which alters the original author's meaning.

(j) Use of Product Information from a foreign SmPC to support a claim where that information is inconsistent with the Slovak SmPC of the medicinal product.

(k) Literal or implied claims that a parameter, subject to a warning, precaution or adverse reaction in the Product Information is not caused for concern.

(l) Insufficient substantiation of claims not of a medical or scientific nature. It includes information or claims relating to marketing factors such as pricing and market share. Care should be taken when extrapolating prescribing practices from sales data.

If animal or laboratory data are used, a prominent statement identifying this type of data must be made on the same page and within reasonable proximity of the data in a manner that is not obscured by other material.

1.3.1 Unapproved products and indications

Products that have not been approved for marketing in the Slovak Republic must not be promoted. This restriction applies also to unapproved indications of medicinal products approved for marketing.

1.4 Good Taste

Promotional material (including graphics and other visual representations) should conform to generally accepted standards of good taste and recognise the professional standing of the recipients.

1.5 Unqualified Superlatives

Unqualified superlatives must not be used. Claims must not imply that a medicinal product or an active ingredient is unique* or has some special merit, quality or property unless this can be substantiated. The word "safe" must never be used without proper qualification. It must not be stated that a medicinal product has no side-effects, toxic hazards or risks of addiction or dependency.

1.6 New Medicinal Products

The word "new" must not be used to describe any medicinal product, presentation, or therapeutic indication which has been available and generally promoted for more than 12 months in the Slovak Republic.

1.7 Comparative Statements

Comparison of products must not be misleading or disparaging. It must be factual, fair, based on relevant and comparable aspects of the medicinal products and be capable of substantiation and referenced to its source. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by undue emphasis, the omission of an important attribute or property or in any other way. Comparisons which merely claim that a medicinal product is better, stronger, more widely prescribed etc. must not be used.

EXPLANATORY NOTES

1.7

Where a claim of comparative efficacy or safety is made, it must not be based solely on a comparison of information from the SmPCs, as those documents are based on different databases and are not directly comparable. This applies to Slovak as well as foreign SmPCs.

Claims of comparative efficacy or safety should be substantiated concerning all aspects of efficacy or safety of the medicinal product. Where a comparative claim relates to a specific parameter, any claims must be clearly identified as pertaining to that parameter.

The accepted level of statistical significance is $p < 0.05$. If comparative data that are not statistically significant are used, such data must comply with the following conditions:

- *the data must be clearly identified as such by a statement, not just by p-value,*

- *the data must not be used to generalise or to indicate superiority or inferiority.*

The statement that the claim is or is not statistically significant needs to be linked in some manner to the original claim, made on the same page and within reasonable proximity of the original claim in a manner that is not obscured by other material using a type size of not less than 2 mm.

Promotional claims regarding adverse effects must reflect available evidence or must be substantiated by clinical practice.

1.8 Imitation

Promotional information should not imitate the devices, copy slogans or general layout adopted by other Members in a way that is likely to easily mislead or confuse.

1.9 Medical Ethics

Doctors' names or photographs must not be used in any way that is contrary to medical ethics.

1.10 Distinction of Promotional Material

Promotional material must be clearly distinguishable as such.

EXPLANATORY NOTES

1.10

Advertisements in a journal should not be designed to resemble editorial matter unless clearly identified as an advertisement. See also Sections 3.2 and 3.3 hereof.

2. PRODUCT INFORMATION

All types of promotional material described in Section 3 hereof must be accompanied by either full or abridged Product Information, which must contain the following essentials:

- the date when the Product Information has been approved and/or the last time updated,
- the manner of dispensing of the medicinal product.

Wherever required, Product Information must appear in a type size of not less than 2 mm on a background sufficiently contrasting for legibility. Major headings should be easily identifiable.

Product Information must not be overprinted or interspersed with promotional phrases or graphics and must clearly identify any recent change of clinical significance*.

EXPLANATORY NOTES

2

This rule must apply to the abridged Product Information as well.

2.1 Full Product Information

Full Product Information means approved and applicable (up-to-date) version of SmPC for the Slovak Republic.

2.2 Abridged Product Information

Abridged Product Information may be used in medical publications.

2.2.1

Abridged Product Information must accurately reflect the full Product Information, while it may be a paraphrase or précis of the full Product Information.

2.2.2

Under the heading “Abridged Product Information”, the following must appear:

a) approved indications for use,
b) contra-indications,
c) clinically significant warnings,
d) clinically significant precautions for use,
e) clinically significant adverse effects and interactions,
f) available dosage forms,
g) dosage regimens and routes of administration,
h) dependence potential of clinical significance,
i) reference to special groups of patients,
j) classification of a medicinal product pursuant to the manner of its dispensing,
k) date of elaboration or updating of promotion and SmPC of a medicinal product.

2.3 Changes of Clinical Significance

2.3.1

Where a change of clinical significance relating to the safety of a medicinal product is incorporated into the Product Information, it should be indicated in all representations of the Product Information for a period of 12 months from the date of change by an asterisk(s) to a footnote in type size of not less than 2 mm: “Please note change(s) in the summary of product characteristics”.

2.3.2

The full wording of the changed section should be included in any abridged Product Information during the period specified in Section 2.3.1 hereof.

3. PROMOTIONAL MATERIAL

3.1 Acceptability and Legality of Promotion

3.1.1

The Members must maintain high ethical standards concerning the promotion of medicinal products at all times. The promotion must:

- never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry,
- be of nature which recognises the special nature of medicinal products and the professional standing of the recipient(s),
- not be likely to arouse indignation.

3.1.2

Unless this Code explicitly provides otherwise, a medicinal product must not be promoted prior to granting it the marketing authorisation (registration) in the Slovak Republic, allowing its sale or supply or promotion, outside of its approved indications.

3.1.3

Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned. It should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.

3.1.4

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 proven.

3.1.5

Promotion must always be consistent with the data listed in SmPC of the medicinal product.

3.1.6

Any promotion or information on medicinal product addressed to the healthcare professionals (hereinafter referred to as “providing of information to healthcare professionals”) may be performed or provided only by professionally competent persons appointed by the marketing authorisation holder of the medicinal product. When providing information to healthcare professionals, the aforesaid appointees must be obliged to hand over or make available also SmPC of the medicinal product, as well as information regarding price and reimbursement of the medicinal product. When providing information to healthcare professionals, it must be prohibited to donate, offer or promise any monetary or material advantage to healthcare professionals and/or to their related persons.

3.1.7

According to Slovak legislation, any promotion of prescription-only medicinal products aimed at the general public other than vaccination campaigns organised by the marketing authorisation holder or its proxy, if permitted by the Ministry of Health [Section 8 (5) (a) of Act 147/2001 Coll. on Advertising, as later amended] must be prohibited.

3.1.8

Any Promotional Material must under any circumstances conform to all requirements of acceptability and legality of promotion set forth in Section 3.1 hereof.

3.1.9

Promotion must not be disseminated by automated telephonic calling system, fax, e-mail, text messages or other electronic data forms of communication without the prior consent of its addressee.

3.2 Journal of Advertising

Journal Advertising must conform to the requirements set forth in Sections 3.2.1 to 3.2.3 hereof. Information required must appear in each publication in a type size of not less than 2 mm and should appear on a background sufficiently contrasting for legibility.

EXPLANATORY NOTES

3.2

Care should be taken to ensure that where an advertisement consists of a double-sided or multiple-page copy, the information contained on each page is not false or misleading when read in isolation.

3.2.1 Full advertisement*

3.2.1.1

A full advertisement must contain the following within the body of the advertisement:

a) brand name of the medicinal product,

b) INN* of the active ingredient(s),

c) name of the marketing authorisation holder and its mailing address in the Slovak Republic,

d) full or abridged Product Information,

e) classification of the medicinal pursuant to its dispensing,

f) date of elaboration or updating.

3.2.1.2

The full advertisement is mandatory for advertising of all new chemical entities* or new indications for 12 months from the date of their first advertising in medical publications, or longer at the discretion of the advertiser.

3.2.1.3

The Product Information should be placed adjacent to the body of the advertisement. Where it is not practicable to do so, the advertisement must carry a statement in a type size not less than 2 mm to the effect of the following statement: “Prior to prescribing, please review the product information. In this publication, the 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 should always form a fixed part of the journal.

EXPLANATORY NOTES

3.2.1.1

b) The INN should appear adjacent to the most prominent presentation of the trade name.

d) See Sections 2.1, 2.2 and 2.3 hereof.

3.2.1.3

The wording used to direct the reader to the location of Product Information may be varied but must contain a direction to review the Product Information before prescribing the medicinal product.
Loose-leaf inserts will not satisfy the requirements of this Section.

3.2.1.4

The abridged Product Information should be placed adjacent to the body of the advertisement. Where it is not practicable to do so, the advertisement will carry a statement in not less than 2 mm type size, to the effect of the following statement: “Prior to prescribing, please review the product information. In this publication, the 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 should always form a fixed part of the journal.

3.2.2 Short advertisement

3.2.2.1

A short advertisement is designed to remind a prescriber of a product’s existence, and must not contain promotional claims. The sole use of a short advertisement within any one issue of a publication must not be permitted prior to the expiration of 12 months from the first advertising of a new active substance or prior to the expiration of 12 months following a change of clinical significance made to SmPC of the medicinal product.

3.2.2.2

A short advertisement must contain:

a) brand name of the medicinal product,

b) INN of the active ingredient(s),

c) name of the marketing authorisation holder and its mailing address in the Slovak Republic,

d) basic information on the medicinal product in compliance with its SmPC,

e) classification of the medicinal pursuant to its dispensing,

f) date of elaboration or updating,

g) a statement to the effect that further information is available upon request from the supplier.

3.2.2.3

A short advertisement may contain:

a) up to 5 words describing therapeutic class*, but without the use of promotional phrases,

b) graphics,

c) a statement of available dosage forms,

d) a statement referring to the location of Product Information in a reference manual.

No other material or information save for SmPC must be permitted.

EXPLANATORY NOTES

3.2.2.2

b) The INN should appear adjacent to the most prominent presentation of the trade name.

3.2.3 Member Commissioned Articles

3.2.3.1

Member Commissioned Articles must be identified as such in a type size of not less than 2 mm.

3.2.3.2

The Member which is responsible for the insertion of the article it commissioned must be clearly identified at either the top or the bottom of the article it commissioned in a type size of not less than 2 mm. The Member Commissioned Articles must neither be presented as nor resemble an independent opinion of the third party and/or editorial material.

3.2.3.3

Member Commissioned Articles must conform to all relevant provisions of Sections 1 and 3.1 hereof. Member Commissioned Articles must also conform to the requirements of Sections 3.2.1 and 3.2.2 hereof.

EXPLANATORY NOTES

3.2.3

Sponsoring Members should ensure that statements by third parties which are quoted in Member Commissioned Articles comply with these requirements.

Independently edited supplements which are published in the Proceedings of a recognised congress must not be considered as Member Commissioned Articles. If a Member sponsors*

such a supplement, it is recommended that this fact should be stated clearly in such a supplement.

3.3 Materials for use by Medical Representatives*

A major guiding principle of this Code is that, whenever a promotional claim is made for a medicinal product, it must be accompanied by the Product Information, as provided for in Section 2.1 hereof. Where multiple forms of promotion items are intended to be distributed at one time, the Product Information must be included therein at least once.

3.3.1 Printed promotional material

3.3.1.1

All Member printed promotional materials must include the following information:

a) brand name of the product,

b) INN of the active ingredient(s),

c) name of the marketing authorisation holder and its mailing address in the Slovak Republic,

d) full or abridged Product Information,

e) classification of the medicinal pursuant to its dispensing,

f) date of elaboration or updating of the printed promotional material.

3.3.1.2

Where it is impractical to print the Product Information on the body of the promotional material, the promotional material will carry a statement to the effect of the following in a type size of not less than 2 mm: “Prior top prescribing, please review the product information. The product information is enclosed hereto.”. The item is then to be accompanied by full or abridged Product Information.

3.3.1.3

All artwork, including graphs, illustrations, photographs and tables taken from published studies included in promotional material should:

a) clearly indicate the precise source(s) of the artwork,

b) be faithfully reproduced; except where adaptation or modification is required to comply with any applicable code(s), in which case it must be clearly stated that the artwork had been adapted and/or modified.

Particular care must be taken to ensure that the artwork included in promotion does not mislead about the nature of a medicinal product (for example whether it is appropriate for use by children) or mislead about a claim or comparison (for example by using incomplete or statistically irrelevant information or unusual scales).

EXPLANATORY NOTES

3.3.1

This Section applies to aids, leaflets, posters and other materials prepared based on the available literature and intended for distribution to healthcare professionals, which contain promotional claims.

3.3.1.1

b) The INN should appear adjacent to the most prominent presentation of the trade name.

d) See Sections 2.1, 2.2 and 2.3 of this Code.

3.3.1.2

The wording used to direct the reader to the location of Product Information may be varied but must contain a direction to review the Product Information before prescribing the medicinal product.

3.3.2 Audio-visual promotional material

3.3.2.1

All audio-visual promotional material must be accompanied by a document which contains the following information:

a) brand name of the product,

b) INN* of the active ingredient(s),

c) name of the marketing authorisation holder and its mailing address in the Slovak Republic,

d) classification of the medicinal pursuant to its dispensing,

e) date of elaboration or updating,

f) the full or abridged Product Information.

3.3.2.2

Where an audio-visual item is demonstrated, the Product Information must be given to the individual reviewing the promotional material or offered to the audience in a group situation on completion of the presentation.

EXPLANATORY NOTES

3.3.2

This Section applies to audio-tapes and video-tapes for private use by healthcare professionals or demonstration purposes to groups of healthcare professionals.

3.3.2.1

b) The INN should appear adjacent to the most prominent presentation of the trade name.

d) See Sections 2.1, 2.2 and 2.3 of this Code.

3.3.3 Medical literature/reprints

3.3.3.1

The general tenor of any reprints of journal articles, proceedings of symposia or summaries of literature used in promotion must always be consistent with SmPC of the medicinal product.

3.3.3.2

Quotations from medical and scientific literature or personal communications must be faithfully reproduced, it must accurately reflect the meaning of the author and the significance of the study and precisely identify the sources.

EXPLANATORY NOTES

3.3.3

Healthcare professionals may request literature on subjects not covered by SmPC, such as non-approved indications. It is not acceptable to routinely disseminate such literature where unsolicited. It is acceptable to provide such information upon individual request by appointed persons.

Reprints themselves do not need to be accompanied by SmPC, but SmPC must be included with any accompanying material (e.g. a letter) or presentation made which makes promotional claims.

Quotations relating to prescription-only medicinal products should not be reproduced without the written consent of the author cited unless subsequently published. Due care should also be taken to avoid ascribing unpublished claims or views relating to prescription-only medicinal products to authors when such claims or views no longer represent, or may not represent, the current view of the author concerned.

3.3.4 Digital promotional material

3.3.4.1

Digital promotional material must comply with all relevant provisions of this Code related to the promotion of medicinal products.

3.3.4.2

Where an individual product is being promoted the appropriate SmPC must be given to an individual reviewing the promotional material, readily accessible via a computer or other data electronic device or offered to an audience in a group situation on completion of the presentation.

3.3.4.3

Where the Product Information is included in an interactive data system, instructions on its accessing must be clearly displayed.

EXPLANATORY NOTES

3.3.4

As a minimum, this section covers the following:

- *Promotional materials designed by Members to promote their products directly to healthcare professionals including such promotional tools as software programs used by medical representatives during interchanges with healthcare professionals.*
- *The use of external computer-generated programs by Members to promote their products including such programs as prescribing and dispensing software.*
- *The use of messages on the Internet by Members. Members considering the use of the Internet should refer to Slovak law which prohibits the promotion of prescription-only medicinal products to the general public.*

3.4 Mailings*

3.4.1

Mailings must comply will all relevant provisions of Sections 1 and 3.1 hereof.

3.4.2

The full or abridged Product Information as applicable must be included in all mailings where promotional claims are made.

3.4.3

Mailings should only be sent to those categories of health professionals whose need for, or interest in, the particular information can be reasonably assumed. Requests to be removed from promotional mailing lists must comply promptly and no name must be restored therein except at specific request or with written permission.

3.4.4

Exposed mailings including postcards, envelopes or wrappers must not carry any matter which might be regarded as advertising to the general public or which could be considered unsuitable for public view.

EXPLANATORY NOTES

3.4.1

Envelopes implying urgent attention should be restricted to matters relating to product recalls or important safety information only.

Envelopes bearing statements implying that their contents are non-promotional should not be used for dispatching promotional material.

Unsolicited reprints of journal articles must be consistent with the Product Information, and any covering letter should comply with Sections 1 and 3.1 hereof.

3.5 Document Transfer Media

Unsolicited electronic transmissions or replicas thereof must not be used for promotional purposes.

In compliance with the applicable legislation, electronic media may be used for transmission of the permitted promotion.

4. MEDICAL REPRESENTATIVES

4.1

Medical representatives must only use promotional material which conforms to the provisions of Section 3 hereof. Verbal statements made about a medicinal product must comply with the provisions of Section 1 hereof.

4.2

Members have a responsibility to maintain high standards and ongoing training for their medical representatives.

4.3

Medical representatives should possess sufficient medical and technical knowledge to present information on the Member's products in an accurate current and balanced manner and should be cognisant of all provisions of this Code.

Each Member must ensure that its medical representatives, including personnel retained by way of a contract with third parties, and any other Member representatives who call on healthcare professionals in connection with the promotion of medicinal products are familiar with the relevant requirements of this Code 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.

4.4

Medical representatives should at all times maintain a high standard of ethical conduct in the discharge of their duties. Prior to discharging their duties independently, all medical representatives must be trained and certified of knowledge and application of this Code. The certification must be valid for 3 years unless otherwise specified by the Ethical Committee.

4.5

Medical representatives must not employ any deception or use any inducement or subterfuge to gain an interview with a healthcare professional. In an interview, or when seeking an appointment for an interview, medical representatives must, from the outset, take reasonable steps to ensure that they do not mislead as to their identity or that of the Member they represent.

4.6

Medical representatives should ensure that the frequency, timing and duration of meetings with a healthcare professional, together with how they are made, are such as not to cause inconvenience. The organisational arrangements in force at any particular establishment must be observed by medical representatives. Medical representatives are not allowed to attend physicians authorised to prescribe medicinal products during their office hours if the intention is to promote a medicinal product.

4.7

Contacting by means of a telephone must not be used to promote medicinal products if refused by the healthcare professional.

4.8

Wherever a promotional claim is made, the medical representative must provide or make available SmPC pertinent to the promoted medicinal product, as well as other information required by applicable law and this Code.

4.9

Under no circumstances must medical representatives pay a fee to gain access to a healthcare professional.

4.10

Every Member must establish a medical department (which may be commissioned to carry out scientific service activities) in charge of information about its medicinal products. This department must include an authorised person responsible for approving any promotional material before release. Such person must certify that he/she has examined the final form of the promotional material and that in his/her belief it is following the requirements of this Code and any applicable laws and regulations, is consistent with SmPC of the medicinal product and is a fair and truthful presentation of the facts about the medicinal product.

4.11

Each Member must appoint at least one employee who must be responsible for supervising the Member and its subsidiaries to ensure that the standards of this Code are met.

4.12

Medical representatives must immediately provide the scientific service of their Member, respectively the person responsible for medical information and pharmacovigilance with relevant information which they obtain in respect of the use of such Member's medicinal products especially reports on side-effects of the medicinal products.

4.13

Medical representatives, as well as other employees of a Member attending professional events with the participation of healthcare professionals, must be obliged to be clearly and transparently labelled during the entire duration of the event indicating the business name of the Member they represent thereat, their name and surname (including their academic title, if applicable) and with the job title held with the Member to avoid any doubt about their affiliation to the Member they represent thereat. They must also be obliged to declare their affiliation to the Member they represent thereat, if at any time during the professional event they will have a presentation within the agenda of the professional event either in the form of a professional lecture, contribution or their opinion presented in a discussion etc. Aforementioned obligations

do not apply to professional events organised and sponsored by the sole Member (e.g. stand-alone professional events), provided they are clearly labelled as organised and sponsored exclusively by such sole Member.

EXPLANATORY NOTES

4.

Members should ensure that the medical representatives are familiar with the provisions hereof. Particular attention is drawn to Section 3.3 on materials for use by medical representatives, Section 5 *on samples and Section 6 on exhibitions at professional events.*

4.5, 4.6

Medical representatives may be used to obtain survey information following Section 3.3 hereof. However, the pretext of surveying to gain an extended interview and medicinal product promotion should be avoided.

5. PRODUCT SAMPLES

Under the Directive 2001/83/EC of the European Parliament and the Council and the Act 147/2001 Coll. on Advertising, and on the amendment to and supplementation of certain acts, as amended, free samples may be provided only to persons authorised to prescribe medicinal products and persons authorised to dispense medicinal products.

Samples must not be supplied to induce recommendation, prescription, purchase, supply, sale or administration of the specific medicinal products and must not be supplied for the sole reason of the patient treatment.

Samples may be supplied to the qualified persons so that they can familiarise themselves with new products and acquire experience in dealing with them.

5.1

Samples may be supplied by the marketing authorisation holder only to a person authorised to prescribe medicinal products subject to his/her written request. Such samples, however, must not exceed two samples of the smallest package of the registered medicinal product per year marked as "FREE OF CHARGE MEDICAL SAMPLE – UNMERCHANTABLE" and having SmPC attached thereto.

Samples may be supplied only within the first 2 years after the first placement of a medicinal product on the market; irrespective of the aforestated samples may be supplied to the particular healthcare professional within 2 years after his/her obtaining of authorisation to prescribe the respective medicinal product. The first placement on the market means the first placement on the market following granting of the marketing authorisation or following approval of a new therapeutic indication, or provided that due to change in a medicinal product registration a product administration is significantly altered.

5.2

Sample packs should be clearly identified as such and must be labelled in the following way clearly expressing that they are medical samples, free of charge and not for sale: "Free medicinal sample - unmerchantable."

5.3

Medical representatives must take adequate precautions to ensure the security of samples in their possession. Members must maintain an adequate system for controlling and tracking all samples they supply. Members should develop an appropriate recording system so that, if a product withdrawal is necessary, relevant samples will be included in such withdrawal.

5.4

Samples must not be supplied as gifts or donations. Donation of medicinal products to hospitals (however, the state-owned hospitals only) should be at a reasonable level and should be of public knowledge.

5.5

On request, Members must promptly accept the return of samples of their medicinal products.

5.6

No samples of the following medicinal products may be supplied:

a) medicinal products which contain substances defined as psychotropic or narcotic by an international convention, such as the United Nations Conventions of 1961 and 1971; and

b) any other medicinal products for which the supply of samples is inappropriate, as determined by competent authorities.

EXPLANATORY NOTES

5.

Members should ensure that they are kept informed of any changes in Slovak legislation concerning the supply of samples.

5.4

Public knowledge means that a written contract, which can be seen upon request, exists.

6. ORGANISING AND SUPPORT OF PROFESSIONAL EVENTS

General Principles

Professional events are important for the dissemination of knowledge and experience to healthcare professions. The prime objective in organising such professional events should be the enhancement of medical knowledge. Where hospitality is included in professional events, it should always be secondary to the main purpose of the professional event. As a general rule, it is recommended that professional events are financed from multiple sources.

6.1

Professional events must only be directed to healthcare professionals.

6.2

All professional events must be only targeted for scientific, professional or educational purposes and hospitality must always be secondary to the main purpose of the professional event.

6.3

The Member must not be allowed to either directly or through a third-person fund, sponsor or otherwise directly or indirectly support either financially or in-kind any event other than the professional event or participation of healthcare professional at any event other than the professional event.

6.4

Funding must not be offered to compensate for the time spent by healthcare professionals when attending a professional event.

6.5

The professional event must include, in a prominent position, the name of the sponsoring or financing Member; it must not, however, be positioned in the very lecture room.

6.6

Participating Members must comply with all requirements of the person organising a professional event.

6.7 Collateral activities

Professional events may to a reasonable extent include collateral promotional activities (especially in the form of exhibition stands), the time scope of which must not exceed 20 % of total professional event time scope and which must not be contrary to law. The time necessary for travel and accommodation is not included in the total time scope of a professional event.

SmPC of the medicinal products being presented within the scope of permitted promotional activities at the professional event must be always available.

Except for lecture rooms, in the premises where the professional event is being held it must be allowed:

- to position informative and/or promotional stand or a promotional panel of the Member,
- to use Member's name and logo in the communication with healthcare professionals,
- to use a trademark of the medicinal product and its logo or other visual representation thereof in the communication with healthcare professionals,
- to use promotional materials concerning the Member or its medicinal product,
- to discuss illness or a specific therapeutic field,
- to use SmPC of medicinal products,
- to provide copies of presentations or abstracts from a professional event,
- to use scientific works reprints,
- to provide price lists of medicinal products.

Within the scope of the professional event's lecture blocks which are held mainly in lecture rooms, it must be allowed:

- to use Member's name and logo in a professional presentation or in declaring Member's eventual conflict of interest, however not in a promotional manner; unless otherwise stated herein, Member's name and logo must not be included in any promotional carriers (promotional materials, promotional slides, promotional banners etc.) which are positioned in lecture rooms,
- to use SmPC of medicinal products,
- to use solely generic (INN) names in invitations, agenda, block name and presentations (the obligation to use generic names must not apply to permitted promotion pursuant to the following paragraph herein below).

Print or electronic form of the professional event's agenda may also include the promotion of medicinal products; accordingly, promotion of medicinal products may be also included in the abstract or other written output of the professional event. In both cases, however, such promotion must be duly marked as a promotion and must be clearly distinguished from other professional event's agenda or the content of abstract or other written output of the professional event. If professional event's agenda or abstract contains promotion of medicinal products pursuant to Section 8(4) of Act 147/2001 Coll. on Advertisement, as later amended, any dissemination or disclosure thereof must only be allowed towards persons authorised to prescribe medicinal products and to persons authorised to dispense medicinal products.

If a professional event is being held virtually, i.e. participants participate in such a professional event by electronic means without their personal presence thereat, for the virtual space in which the individual lectures are displayed, the same rules apply as for the lecture room in a professional event with personal (non-virtual) participation. Promotional activities within the scope of virtual professional events must be allowed only outside the time during which individual lectures are presented (displayed) in the virtual space of the professional event.

EXPLANATORY NOTES

The fundamental principle of medicinal products and Members promotion at professional events is that such promotion must not be performed or positioned in lecture rooms and places where the professional event's professional agenda is being held unless explicitly permitted by this Code. The aforementioned rule does not apply to the trade names and logos of Members if they are mentioned in the presentations of individual speakers at a professional event exclusively in the form of a reference to the entities that supported the creation of the respective presentation.

6.8 Professional event agenda

It must be clear from the professional event's agenda, its schedule and structure that the event has an actual scientific purpose.

The professional event must be considered appropriate if its agenda does not contain any leisure time or sports activities and when its working part is not interrupted by any leisure and sports activities during the day (skiing, surfing, golf, tournaments, tours etc.).

Official professional event's agenda should clearly distinguish the scope of scientific or working parts of professional event's agenda which should be mandatory for the participants.

6.9 Hospitality

Hospitality offered in connection with professional events directly or indirectly must be limited to cover travel, accommodation, meals and registration fees. Hospitality may be offered exclusively to qualified professional event participants (healthcare professionals) and must not be extended to the period prior to the beginning and after the official closing of the professional event.

Any forms of hospitality offered to healthcare professionals must not exceed a reasonable level and must be strictly limited to the main purpose of the professional event. As a general rule, only such hospitality should be provided by which it may be reasonably expected that a participant (healthcare professional) would be willing to pay for him/herself.

Members may support the professional event which agenda includes also leisure activities (the so-called "social events" - leisure, social, cultural, sports and other activities) organised for the participants thereat, but only provided that such leisure activities must be exercised outside the scope of professional event's official professional or working agenda, that they are not reimbursed from the registration fee or Member's sponsor contributions but rather exclusively from participant's own resources and provided that the scope and subject matter of leisure activities had been known and publicly disclosed sufficiently prior the concerned leisure activities took place (at least 1 month in advance). The amount of leisure activities participation fee must reasonably correspond to the adequate fair market value. Participation in leisure activities must be voluntary. The time of leisure activities must not overlap with the professional event's professional agenda, leisure activities must be exclusive of a secondary nature in relation to the professional event as a whole and they must not serve as a motivation for the professional event participant to participate at the professional event. The professional agenda must be presented individually and separately from leisure activities; that must apply to agendas and invitations in a printed form as well as in an electronic form available at the websites of the organiser or of the professional event.

6.10

The following must apply to the Members who directly or indirectly sponsor the participation of healthcare professionals at professional events held within or outside the territory of the Slovak Republic:

All professional events organised or sponsored by the Member must be held in an appropriate venue that satisfies the qualification criteria pursuant to Section 6.11 hereof that is adequate to the main purpose of the event while hospitality may only be offered only if appropriate and otherwise compliant with the provisions of this Code.

No Member may organise or sponsor a professional event that takes place outside the Slovak Republic, unless:

a) the majority of the invitees comes from abroad and, given the countries of origin of the majority of the invitees, it makes greater logistical sense to hold the professional event in another country; or

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

All international professional events must be notified to the relevant subsidiary or branch of a Member in the particular state (provided that it has been established in the particular state), or local advice must be taken, save for the professional events organised by the professional societies.

Hospitality must not include organising or sponsoring of social events (for example sporting or recreation) or any leisure activities. Members should avoid using venues renowned for their entertainment facilities.

Travel agenda and programme of professional events should be duly approved by the operating procedure of the respective Member.

Participation at the professional event should not be made dependent on any request or consent to prescribe a certain medicinal product.

EXPLANATORY NOTES

The Slovak Republic must be an adequate location in case of professional events organised by the Member. Location is not restricted in cases of international events organised by the international medical society and free-standing company symposia with significant international participation.

International events organised by the Member's "mother" company from abroad must comply with the locally applicable legislation and the Ethical Code.

If a prevailing number of foreign participants (taking the number of participants from the Slovak Republic into consideration) participate at the international professional event held in the Slovak Republic, it is acceptable thereat to display or supply educational materials related to a medicinal product not approved for marketing in the Slovak Republic or a non-approved indication of a medicinal product already registered in the Slovak Republic, provided that such

a medicinal product or indication is approved in the country where the foreign participants of the professional event come from while any display material or educational material used must clearly identify that it refers to a product or indication not approved in the Slovak Republic and that the medicinal product or indication, as appropriate, is approved abroad. Any appropriately worded label prominently located would be sufficient to satisfy this Section. This label must enable the reader to unambiguously recognise that the medicinal product or indication is unapproved in the Slovak Republic.

Information regarding such medicinal products must be consistent with the approved SmPC in the country where the medicinal product is registered. Such SmPC must be available and distributed as per this Code.

6.11 Qualifying criteria for venues for organising professional events organised or sponsored by AIFP Members

All professional events, such as e.g. congresses, conferences, symposia and other similar events (including, but not limited to advisory boards meetings, visits to research or manufacturing sites, and planning, training or investigator meetings for clinical trials or non-interventional clinical studies) organised or sponsored by AIFP Members, or on their behalf, must be held in an appropriate, not renowned or extravagant venue properly reflecting the main purpose of the professional event.

Any professional event sponsored or organised by AIFP Members, as regards qualifying criteria of the venue where it is being held, must therefore comply with the following requirements:

1. As a general rule, the venue where the professional meeting is being organised or held and its facilities must not represent, for most of its participant, the motivator to participate at the professional event. That includes both geographical and facilities features of the venue.

2. Another general rule is that the professional event must always be organised or held in a venue which can be reasonably presumed to be selected by the professional event participants as a venue of the concerned professional event and that all costs related to their participation at the professional event would be borne by themselves.

3. The professional event must always be organised or held in an appropriate venue and as such not renown or extravagant.

4. The venue is appropriate for organising professional events if the main purposes of its regular use include the holding of professional, educational or scientific events, or if it is commonly renowned for being used for the said purposes, for which it is also adequately equipped.

5. The venue is considered renown if it is generally known and recognised for its superb or luxurious peculiarities or features and as such is considered as mostly sports, cultural, entertainment and/or tourism venue sought mainly for leisure activities. For example, renown venues comprise golf, amusement or ski resorts, casinos and other gambling establishments, all kinds of aquaparks, vineyards, etc. The geographical location of the venue is not making it automatically renown.

6. The venue is considered extravagant if it is generally known and recognised as luxurious and spectacular. For example, extravagant venues generally are five and more-star hotels, extra-urban facilities in castles and palaces, etc.

7. The professional event must always be held out of the time for which the venue is generally being renowned. For example, if the venue is renowned for the ultimate proximity of skiing facilities in the winter season (from 1st December to 31st March), the venue must not be selected for organising professional events in winter, district cities are allowed. However, if the distance of such skiing facilities from the venue is greater than 10 kilometres via road, the venue must be considered as appropriate and not renown.

8. If the professional event is organised or held in a venue which allows for the use of its own or adjacent facilities intended for leisure time (i.e. not intended for professional, educational or scientific use), the use of such facilities must never be included in any payments made by Members when sponsoring or organising the professional event, nor hid in any kind of calculation made by the entity running the venue, and the professional event participants must cover all costs related to the use of such facilities themselves. The professional event organiser must ensure and declare in writing that the event participants will not have access to such leisure facilities neither as part of the registration or participation fee nor as part of the payment for accommodation, not even in the form of preferential access or discount.

Qualifying criteria pursuant to Section 6.11 hereof must become effective as of 1 January 2017 concerning professional events organised by Members and as of 1 July 2017 they must become effective concerning professional events organised by third parties provided that they are supported or sponsored by the Members.

The Ethical Committee must handle individual requests of the Members to review the particular venue for organising professional events organised or sponsored by the Members hereunder within 15 days following the receipt of such Member's request.

Besides the foregoing, the Members must be also bound by international conference evaluation in the EU obeying the rules published at the website of the European Federation of Pharmaceutical Industries and Associations (FFPIA) at www.efpia-e4ethics.eu. A program that must be published at the website of the assessed event must serve as a reference.

6.12 Contests

Contests which are organised as part of the professional event must follow general principles pursuant to this Section and must exclusively concern professional knowledge or skills in a

particular professional field. No contributions whatsoever must be provided to the contestants in connection with their participation in the contest.

6.13 Materials

Any materials used at professional events must satisfy requirements pursuant to Sections 1.3.1 and 3.3 of this Code while the Members must have the right to use third parties' intellectual property within the concerned materials (such as logos etc.).

EXPLANATORY NOTES

6.

Provisions of this Section must apply to a professional event en-bloc including any branches thereof (such for example satellite symposia).

6.13

See also Section 3.1 hereof.

7. RESEARCH

The following provisions must relate to any financially rewarded research performed and/or sponsored by the pharmaceutical industry, except for the clinical trial as defined and regulated by Sections 29-44 of the Act 362/2011 Coll. on Drugs and Medical Devices and on amendment to and supplementation of certain acts, as later amended, regardless of the fact whether it is performed by the manufacturer or by an organisation acting according to or based on the manufacturer's instructions.

Researches must mean the following

a) non-interventional clinical trial as defined in Section 45 of the Act 362/2011 Coll. on Drugs and Medical Devices and on amendment to and supplementation of certain acts, as later amended,

b) other studies and researches, where data collection is not directly related to the prescription of a certain medicinal product (as specified in more detail in Section 7.2.1 hereof).

EXPLANATORY NOTES

Research sponsorship must mean financial and other compensation provided in exchange for information.

7.1 Non-interventional Clinical Trial (NCT)

7.1.1

NCT aims to acquire scientific and professional information defined in the NCT protocol. The purpose of NCT must be acquiring a response on a scientific question which has not yet been answered. When performing NCT, provisions of the Act 18/2018 Coll. on Personal Data Protection and on amendment to and supplementation of certain acts, as later amended, must be obeyed. NCT must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer the specific medicinal product.

7.1.2

NCT is defined in Section 45 of the Act 362/2011 Coll. on Drugs and Medical Devices and on amendment to and supplementation of certain acts, as later amended. NCT can only be performed upon the prior written consent of the healthcare insurance company of the NCT participant subject to the NCT protocol submitted by the professional guarantor.

7.1.3

Each NCT must have a formal protocol containing the following information:

a) name and surname or trade name of the NCT sponsor,

b) residential address or registered office of the NCT sponsor,

c) title of NCT,

d) objective of NCT,

e) commencement date and completion date of NCT,

f) name and surname of the professional guarantor,

g) NCT design and data processing method,

h) date, form and duration of publication of NCT results not shorter than two months following completion of NCT,

i) financial compensation of the professional guarantor of NCT.

Each NCT must have its own code on every page of the protocol and questionnaire for identification. The Protocol must be approved by the scientific service of a Member, which must be also obliged to supervise the performance of NCT, as well as by the healthcare insurance company of each NCT participant. The NCT sponsor must forward the protocol approved by the healthcare insurance company of the NCT participant to the National Centre of Medical Information which must publish it on its website within three days following the delivery. The NCT sponsor must forward a copy of processed NCT results to the healthcare insurance company of the NCT participant as well as to the National Centre of Medical Information which must publish it on its website within three days following the delivery.

EXPLANATORY NOTES

7.1.3

c) Title

It should give a clear idea about the essence of NCT in one sentence.

d) Objective(s)

Description of what the NCT sponsor is monitoring, where possible stating a hypothesis/hypotheses.

f) Name and surname of the professional guarantor

Name of a professional - physician in the field in which NCT is performed. He/she should guarantee a professional level of NCT. He/she must not be in a permanent labour relation with the NCT sponsor.

g) NCT design and data processing method

Should at least contain the following information:

- *number of centres,*
- *number of patients,*
- *number of physicians,*
- *evaluation form (e. g. questionnaire),*
- *statistical evaluation of NCT.*

The number of patients and physicians involved must not exceed the inevitable number necessary to answer the question resulting from the purpose of NCT.

NCT data processing method. Statistical methods planned to be used in the evaluation of the collected data.

Form of notification of adverse effects. To whom and how the adverse effects are to be notified.

h) Expected date and form of publication of results

Publishing must mean a presentation of results to the professional public. The form may be a lecture, a poster or a publication in a professional periodical.

7.1.4

The protocol must be handed over to each NCT solving team member upon commencement of his/her cooperation on NCT. Moreover, a written agreement needs to be concluded with each NCT solving team member outlining terms of cooperation and compensation.

7.1.5

The distribution of samples of medicinal products must not be a part of NCT. It is prohibited to encourage commencement or change of treatment through the medicinal product of the NCT sponsor.

7.1.6

The compensation of a solving team member for cooperation on NCT has to be per the work performed and it may not exceed the usual amount with respect to the character of the work done.

7.1.7

The results of NCT must be published within 12 months from the completion of data collection.

7.1.8

Medical representatives authorised to carry out activities in the field of marketing and medicinal products sale are excluded from the NCT.

Medical representatives may in no event entice solving team members to recruit patients for NCT. The visit of a physician involved in the NCT by a medical representative with an objective related to the NCT cannot be connected with any promotional activities.

7.1.9

Prior to its implementation, any NCT must be notified through an electronic form located on the AIFP intranet in the section "Reporting". The mandatory notification must contain the following:

- the title and the goal of the trial,
- identification of the organisation or sponsor who organises and/or performs NCT,
- time schedule - expected commencement date and completion date of data collection,
- number of patients/centres involved,
- planned date and form of publication of results,
- date of approval by the competent Ethical Committee according to Sections 2 (12) and Section 5 of the Act 576/2004 Coll. on Health Care, Healthcare Related Services, and on amendment to and supplementation of certain acts, as later amended,
- hourly compensation for one completed patient record paid to the solving team member,
- total maximum compensation paid within one centre.

7.2 Other Studies

7.2.1

The objective of the other studies carried out and/or sponsored by the Member (hereinafter referred to as the "other studies") may be acquiring scientific, professional and other information in line with legitimate business needs of the sponsor. Efficacy/safety of the particular medicinal product must not be monitored in these studies.

The following lists some examples of other studies:

- epidemiological researches and studies to ascertain the occurrence of a certain disease,
- marketing researches to establish the position of a medicinal product in relation to other medicinal product of the particular group,
- marketing researches to establish the quality of work of the sponsor (medical representatives, marketing, etc.),
- marketing researches to establish the therapeutic habits of physicians,
- pharmaco-economic observation (for example Delphi panel, qualitative cross-sectional survey),
- retrospective data analysis without a direct impact of results thereof on the patients whose data have been used in the concerned analysis,
- observation of therapeutic practices of disease treatment without monitoring the effects of particular drugs.

Other studies themselves must be clearly labelled as such from the outset.

7.2.2

No promotion of the sponsor or its products may be connected with other studies. Offer for cooperation on other studies must not be connected with prescription or recommendation of any products of the sponsor. Cooperation on other study may be only be agreed with the person authorised to provide the requested data. The sponsor must be obliged to ensure contractually with the person performing the other study that no medical services (services falling under the scope of healthcare providing) reimbursed from the public health insurance are induced by virtue of, or in connection with, carrying out the other study.

7.2.3

The compensation of a respondent for cooperation on other studies has to be following the work performed, and it may not exceed the usual amount with respect to the character of the performed work.

7.2.4

Other studies may not be carried out by medical representatives or other employees working in the sales field except for the situation when the physician is involved in other studies free of charge. Medical representatives may only participate on organisational and logistic support of other studies (handing/completion of the forms, submission of the prearranged contracts, etc.).

7.2.5

Prior to implementation of the other studies, the sponsor must be obliged to make a notification thereof through an electronic form located on the AIFP intranet in the section "Reporting". The mandatory notification of each other study must contain the following information:

- the name and the goal of the other study,
- identification of the organisation or sponsor who organises and/or performs the other study,
- expected number of respondents,
- hourly compensation for respondents' participation,
- total compensation for the participation of one respondent,
- time schedule - expected commencement date and completion date of data collection,
- in case it is planned to publish results - the planned date and form,
- in case it is not planned to publish results - the reasons for such a decision.

EXPLANATORY NOTES

7.2

The provisions of this article do not apply to short surveys (telephone, online, written) which are not linked to the remuneration for participating in the survey. The questions in such short surveys must not be related to the disease or the medicinal product or its active substance and must not contain or suggest any advertising claims. Typically, the provisions of this article do not apply to obtaining feedback on the quality of work of employees of a member company, the quality of a professional event, etc.

7.3 Notification

NCT as described in Section 7.1 hereof and other studies as described in Section 7.2 hereof must be notified electronically through the AIFP intranet in the section "Reporting".

7.4 Disclosure and Supervision

The notifications as described in Section 7.3 hereof must be published and made available for disclosure to all Members on the AIFP intranet in the section "Reporting".

The Ethical Committee of AIFP performs inspections of NCTs and other studies regularly. Upon request of the Ethical Committee of AIFP, the Member must be obliged to provide the required assistance and submit all requested documents proving compliance of NCT or other studies with this Code.

8. RELATIONS WITH HEALTHCARE PROFESSIONALS

Members may choose to support professional activities, by financial or other means. Such support must be able to successfully withstand public and professional scrutiny, and conform to professional standards of ethics and of good taste.

8.1 Hospitality

Hospitality offered to healthcare professionals should always be appropriate, and always secondary to the educational content and in proportion to the respective event. Hospitality offered in the form of meals should be limited to the amount of € 75 per the main course (lunch/dinner), € 100 for an all-day meal in the Slovak Republic and the amount of € 100 for the main course abroad. If the hospitality is offered abroad, and the host country where the professional event is held has adopted its own limitations on hospitality, such limitations applicable in the host country must prevail.

8.2 Medical Educational Material

8.2.1

Materials supplied for medical education must be authorised or must include the name of the manufacturer or sponsor and its mailing address in the Slovak Republic.

8.2.2

Material supplied to healthcare professionals may include promotional claims and/or statements which in such an event will not be educational material but must comply with Section 3 hereof.

8.2.3

Informational and educational material cannot induce recommendation, prescription, purchase, supply, sale or administration of the specific medicinal product.

8.3 Payments for Services

Any remuneration for services rendered should not exceed what is commensurate with the services supplied. Contracts between Members and institutions, organisations or associations of healthcare professionals under which such institutions, organisations or associations provide any type of services to Members (or any other type of funding not covered under Section 8.5 hereof or not otherwise covered by this Code) are only allowed if such services (or other funding): (i) are provided to support healthcare or research or education in the field of healthcare; and (ii) do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer the specific medicinal product.

8.4 Gifts and Inducements

When medicinal products are promoted to healthcare professionals, no gift, pecuniary advantage or benefit in kind may be supplied, offered or promised to such healthcare professionals. It must also be prohibited to supply, offer and promise any gifts, pecuniary advantages or benefits in kind to healthcare professionals with the purpose to induce recommendation, prescription, purchase, supply, sale or administration of a medicinal product.

Gifts for the personal benefit of healthcare professionals (such as tickets to entertainment events) must not be offered or provided.

8.5 Donations and Grants Supporting Healthcare or Research

Donations, grants and benefits in kind to institutions, organisations or associations comprising healthcare professionals and/or providing healthcare or conducting research (which are not otherwise covered by this Code) are only allowed if:

a) made to support healthcare or research,

b) documented and kept on record by the donor or grantor, and

c) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a specific medicinal product.

Donations (unless satisfying conditions set out in Section 8.4 hereof) and grants to individual healthcare professionals are not permitted under this Section. Member sponsorship of healthcare professionals to attend professional events is covered by Section 6 hereof. Members are encouraged to make available to public information about donations, grants or benefits in kind made by them under this Section 8.5.

8.6 Donations

Providing pecuniary donations and benefits in kind must be limited to non-profit organisations (organisations which do not gain any profit) only and state-owned hospitals. For the said purpose, state-owned hospitals are defined as healthcare providers 100 % owned by the state, a municipality (city) or higher territorial unit. Healthcare professionals being employees of the state-owned hospitals are only allowed to accept donations through their employer. Healthcare professionals being employees of private healthcare providers are not allowed to accept any donations from the Members.

Any direct or indirect provision of gifts of a personal nature (such as tickets to sporting or entertainment events or other social events) to healthcare professionals, healthcare providers or members of healthcare organisations must be prohibited.

It must also be prohibited for these persons to offer cash, any of its equivalents or personal services. For the said purpose, services of a personal nature are defined as any services which are not related to the exercise of the recipient's profession or activity and which constitute a benefit on the part of their recipient.

EXPLANATORY NOTES

8.6

- *Medicinal products donations are only admissible for charitable reasons.*
- *Determination, if an organisation is of a non-profit character (organisation which does not gain any profit), should always be made with regards to the objective of such organisation which is usually set by its establishment. The legal form of an organisation is secondary [e.g. joint-stock company or limited liability company may be established and registered according to the Commercial Code as non-profit organisations (organisations which do not gain any profit)].*

8.7 Prohibition of Lease

Simulated or false lease, whether royalty-free or for a symbolic remuneration, in the location of a healthcare provider, must be prohibited.

8.8 The Use of Consultants

8.8.1

It is permitted to use healthcare professionals as consultants and advisors, whether in groups or individually, for services such as speaking at and 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 travel. The arrangements that cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

a) a written contract or agreement is concluded prior to commencement of the provision of the services specifying the nature of a service to be provided and, subject to clause (g) below, also the basis for payment of remuneration for such services;

b) a legitimate need for the services has been clearly identified in advance of requesting the services and entering into an arrangement with the prospective consultants;

c) the criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants to have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;

d) the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified need;

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

f) the hiring of the healthcare professional to provide the relevant service is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product, and

g) the compensation for the services is reasonable and reflects the fair market value of the services provided. In this regard, token consultancy arrangements should not be used to justify compensating healthcare professionals.

8.8.2

In their written contracts with consultants, Members are strongly encouraged to include provisions regarding the obligation of the consultant to declare that he/she is a consultant to this Member whenever he/she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that Member. Similarly, Members that employ, on a part-time basis, healthcare professionals that are still practising their profession are strongly encouraged to ensure that such persons have an obligation to declare his/her employment arrangement with the Member whenever he/she writes or speaks in public about a matter that is the subject of the employment or any other issue relating to that Member.

8.8.3

Limited market research, such as one-off phone interviews or mail/e-mail/internet questionnaires are excluded from the scope of this Section 8.8.2, provided that the healthcare

professional 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.

EXPLANATORY NOTES

8.8.3

The minimum remuneration must mean a remuneration not exceeding € 20 per one healthcare professional per one limited market research.

8.8.4

If a healthcare professional attends a professional event (an international or other) in a consultant or advisory capacity, the relevant provisions of Section 6 hereof must apply.

8.9

Effective as of 1 April 2015, Members are prohibited to use, in any manner whatsoever, agreements on works performed out of employment, i.e. Work Performance Agreement and Agreement on Work Activity, for the regulation of their relations with healthcare professionals.

8.10 Health education

The purpose of health education is to increase the scientific knowledge and competencies of healthcare providers to improve health practice and outcomes provided to patients.

Members may participate in health education, but such activities may not include the promotion of drugs.

In the event of supporting health education or its organisation directly or in cooperation with third parties, the Members are obliged to ensure that their participation and role is clearly and unambiguously marked from the beginning. If a Member participates in the content of health education, it must be liable for the content presented in health education. Such content must be true, balanced and objective and allow the expression of diverse theories and opinions.

9. RELATIONS WITH PATIENTS ORGANISATIONS

The pharmaceutical industry cooperates with patient organisations to gain experience from the health diagnoses of patients providing a true picture of life with a specific disease, how a person is assisted, how it affects patients, their work and family, and how medicinal products and other means of treatment can change the quality of life and meet their needs.

The code of relationships of AIFP with patient organisations has been constituted to ensure relationships between the pharmaceutical industry and patient organisations ethically and transparently. The independence of patient organisations, in terms of their political judgement, policies and activities, must be assured.

All partnerships between patient organisations and pharmaceutical companies must be based on mutual respect, with the views and decisions of each partner having equal value.

Pharmaceutical companies must not request, nor must patient organisations undertake, the promotion of particular prescription-only medicinal products.

The objectives and scope of any partnership must be transparent. Financial and non-financial support provided by pharmaceutical companies must always be sufficiently documented. Patient organisations play a key role in shaping, developing and defining outcomes that will have a major impact on patients. Given the need to increase confidence in the pharmaceutical industry, the Members disclose the values provided to patient organisations in terms of interactions and interactions with them.

Generally, broad funding of patient organisations from multiple sources must be welcomed.

EXPLANATORY NOTES

Patient organisations must mean non-profit entities (including the umbrella organisations to which they belong) mainly composed of patients and/or healthcare providers, that represent and/or support the needs of patients and/or healthcare providers.

A representative of a patient organisation means a person authorised or empowered to represent the patient organisation and to express the collective views, attitudes and opinions of the patient organisation in a particular area.

To avoid doubts, the term "pharmaceutical company", as used in this Section 9, must mean any legal entity or a third person authorised by such legal entity which provides financial support or is involved in the activities with patient organisations, having its registered office in the Slovak Republic or Europe, being either the parent company (e.g. the headquarters, the seat of the Board of Directors or the governing body of a business company), subsidiary or any other corporate form or organisation.

"Activity" must mean any mutual interaction, including funding.

9.1 Written Agreements

When pharmaceutical companies provide financial support, significant indirect support and/or significant non-financial support to patient organisations, such support must be a subject matter of a written agreement. Such agreement must include the amount of funding and also its purpose (e.g. unrestricted grant, specific meeting or publication, etc.). It must also include a description of significant indirect support (e.g. donation of public relations agency's time) and significant

non-financial support. Each Member should have an appropriate approval process in place for these agreements.

EXPLANATORY NOTES

The significant support must mean any support to an individual subject exceeding an aggregate amount of € 4,000 per one calendar year.

Any written agreements must contain the following terms:

a) name of activity;

b) names of partnering organisations (pharmaceutical companies, patient organisations, and where applicable, third parties that will participate in the activity, as agreed by both the pharmaceutical company and the patient organisation);

c) type of activity (e. g. whether the agreement relates to unrestricted grant, particular event, publication, etc.);

d) objectives;

e) agreed roles of pharmaceutical company and patient organisation;

f) time-frame;

g) amount of funding;

h) description of significant indirect/non-financial support (e. g. the donation of public relations agency's time, free training courses);

i) a declaration, that all parties are aware that the sponsorship must be clearly acknowledged and apparent from the outset;

j) applicable codes;

k) names of signatories to the agreement;

l) date of the agreement.

Measures concerning transparency of activity details must be subject to the agreement, however, their minimal scope must meet requirements set out herein.

9.2 The Use of Logos and Materials

The public use of a patient organisation's logo and/or proprietary material by Members 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.

9.3 Editorial Control

Members must not seek to influence the text of patient organisation material they sponsor in a manner favourable to their own commercial interests. This does not preclude Members from correcting factual inaccuracies.

9.4 Transparency

9.4.1

Each Member must, within six months from the end of the general reporting period, make publicly available on their website a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support and to subsequently keep it publicly available thereat for at least three years, unless (i) the applicable legal regulations on personal data protection or other legislation require a shorter period of publication, or (ii) the relevant legal basis for the processing of personal data subject to the applicable legal regulations on personal data protection has ceased to exist. This should include a sufficiently detailed description of the nature of the support to enable the average reader to understand the importance of such support. The description should include the pecuniary amount of financial support and invoiced costs. Provided that significant non-financial support cannot be equivalently expressed in terms of money, a description should then clearly specify the nature of a non-financial benefit which patient organisation will receive. This information may be provided on a national or European level and should be updated at least once a year.

The general reporting period is a calendar year. The publication must be made annually, and each reporting period must cover the entire calendar year.

9.4.2

Members must ensure that their sponsorship is always clearly acknowledged and apparent from the outset.

9.4.3

Each Member must make publicly available a list of patient organisations which are engaged in the provision of significant contractual services. This should include a description of the nature of the services providing that the level of their completion adequately informs an average reader of the cause of the contract without disclosing confidential information. Members must also disclose the total amount paid to each patient organisation during the respective period for which the data is reported.

9.4.4 Methodology

Each member must publish the methodologies by it in preparing the disclosures and identifying supports and services provided pursuant to Article 9.4 hereof.

9.4.5 Template

For consistency purposes, disclosures should be made using an optional structure set forth in Section 9.4.6 hereof.

9.4.6 Standard template for disclosure

PUBLICATION TEMPLATE of transfers of values related to the support of patient organizations (PO) for the year ..... Date of publication:					
	Full Name of PO	Principal Practice Address	Financial supprt (amount)	Nonfinancial support (desctiption)	**Purpose of financial support (desctiption)**
POs	***PO NAMED DISCLOSURE - one line per PO*** *(i.e. all transfers of value during a year for an individual PO will be summed up)*				
	PO 1		*Yearly amount*		
	PO 2		*Yearly amount*		
	etc.		*Yearly amount*		

9.5 Exclusive Funding by Members

No Member may require that it be the sole funder of a patient organisation or any of its major programmes.

EXPLANATORY NOTES

The main programmes of patient organisations must mean business activities of Members, artistic work, sports and motion activities, rehabilitation stays, consultancy and patients' rights protection, lecturing and education, participation at workshops and congresses related to the physical and mental health of patients, proactive participation on the law-making process related to the rights of patients.

9.6 Events and Hospitality

9.6.1

All events sponsored or organised by or on behalf of a Member must be held in an appropriate venue that is conducive to the main purpose of the event. They should not be held in "extravagant" or "renowned" venues, or those which are famous for their entertainment facilities.

Except as otherwise provided in this Article 9, the conditions set forth in Article 6 hereof must apply mutatis mutandis to events sponsored or organised by a Member.

9.6.2

All forms of hospitality provided by Members to patient organisations and their members, as well as to the representatives of patient organisations, must be reasonable in level and secondary to the main purpose of the event, regardless of whether the event is organised by the patient organisation or the Member. The general rule is to provide such hospitality which the participant would be willing to pay for him/herself.

Except as otherwise provided in this Article 9, the hospitality provided must comply with the conditions set forth in Article 6.9 hereof.

EXPLANATORY NOTES

9.6.1

An appropriate venue must mean a commonly accepted standard for patients. The Slovak Republic must be adequate for this purpose if the event is organised by the Member. The locality must not be limited with respect to international events organised by international companies and individual workshops of companies with significant international participation.

Renowned and extravagant venues must mean centres, the main operational purpose of which is entertainment, relax and sport.

9.6.2

The reasonable level of hospitality must mean hospitality which the event's participant would normally be willing to pay for him/herself.

9.6.3

Hospitality provided in connection with events should be limited to travel, meals, accommodation and genuine registration fees. Hospitality may only be provided to persons who are qualified participants of the event. Exceptionally, in case of apparent medical needs (e. g. invalidity) travel, meals, accommodation and registration fees of the accompanying person must be considered reasonable. All forms of hospitality offered to patient organisations and their representatives must be "reasonable" in level and strictly limited to the main purpose of the event. Hospitality must not include sponsoring or organising entertainment (e. g. sporting or leisure) events.

9.6.4

No Member may organise or sponsor an event that takes place outside the country in which it has its registered office, unless:

a) most of the invitees are from outside of its home country and with regards to acquiring accommodation for the invitees it is reasonable to hold the event in another country; or

b) given the location of the relevant resource or expertise that is the object or subject matter of the event with regards to acquiring accommodation for the invitees, it is reasonable to hold the event in another country.

9.7 Donations and Grants

Donations and grants and benefits in kind to patient organisations (not otherwise regulated by this Code) are permitted only if:

a) are provided to promote healthcare, research or education,

b) are documented and kept in the records of the donor or grant provider; and

c) they do not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer a particular drug.

Donations (unless they meet the conditions specified in Article 9.7 hereof) and grants to patient organisations are hereby prohibited. Sponsorship by Members for the participation of representatives of patients' organisations in events is governed by Article 9 and, as appropriate, Article 6 hereof. Members are encouraged to publicly disclose information about donations, grants or benefits in kind provided by them under this Article 9.7.

Any direct or indirect provision of gifts of a personal nature (such as tickets to sporting or entertainment events or other social events) to representatives of patients' organisations must be prohibited.

It must also be prohibited for these persons to offer cash, any of its equivalents or personal services. For this purpose, services of a personal nature are defined as any services which are not related to the exercise of the recipient's profession or activity and which constitute a benefit on the part of their recipient.

Any provision or offering of promotion aids to representatives of patients' organisations in connection with the promotion of medicinal products must be prohibited. For this purpose, promotion aid means a non-monetary benefit provided for promotion purposes (except for promotional materials within the meaning of Article 3 hereof).

9.8 Contractual Services

Contracts between Members and patient organisations under which such organisations provide any type of services to Members are only allowed if such services are provided to support healthcare or research. It is permitted to use patient organisations as consultants and advisors for services such as speaking or participation at advisory board meetings. The arrangements that cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

a) a written agreement is concluded prior to the commencement of services which specifies the nature of services to be provided and, subject to clause (g) below, the basis for payment of such services;

b) a legitimate need for the services has been clearly identified before requesting such services and entering into arrangements;

c) the criteria for services selection are directly linked to the identified need and the persons responsible for selecting services have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;

d) the scope of services retained is not greater than the scope reasonably necessary to achieve the identified need;

e) the contracting Member maintains records concerning, and makes appropriate use of, the provided services;

f) engagement of patient organisation must not constitute an inducement to recommend the specific medicinal product;

g) the compensation for the services is reasonable and reflects the fair market value of the services provided. In this regard, token arrangements should not be used to justify compensating patient organisations;

h) in their written contracts Members are strongly encouraged to include provisions regarding the obligation of the patient organisations to declare that they are paid-for

services providers to this Member whenever they write or speak in public about a matter that is the subject of the agreement or any other issue relating to that Member;

i) each Member must make publicly available a list of patient organisations used to provide paid-for services – *see Section 9.4.3 above, Explanatory Notes.*

9.9 Health Education

The purpose of health education is to increase the scientific knowledge and competencies of healthcare providers to improve health practice and outcomes provided to patients.

Members may participate in health education, but such activities may not include the promotion of drugs.

In the event of support of health education or its organisation directly or in cooperation with third parties, the Members must be obliged to ensure that their participation and role is clearly and unambiguously marked from the beginning. If a Member participates in the content of health education, it must be liable for the content presented in health education. Such content must be true, balanced and objective and allow the expression of diverse theories and opinions.

10. RULES FOR DIALOGUE AND NEGOTIATION WITH DECISION-MAKERS

10.1 General Provisions

Pharmaceutical companies are a party to continuous dialogues and negotiations with political representatives and regulatory authorities seeking optimisation of mutual interests and creation of a base for improvement of patients' and public access to an optimal level of medical prevention and treatment.

The ethical rules provide a framework for dialogue between pharmaceutical companies and political representatives or regulatory authorities for such dialogue to be of an open, honest, honourable and authentic character. The ethical rules must also ensure that mutual relations of the parties to the dialogue are not economically based and that no mutual pressure of the parties occurs.

10.2 Definitions

"**Political Representatives**" must mean members (or candidates) to the National Council of the Slovak Republic, the local council (or municipal council), regional council or the European Parliament.

"**Officers**" must mean all employees of public authority which holds regulatory or suchlike competences. For example, Officers are employees of:

- ministries, supervisory authorities, national agencies and headquarters and institutes, councils and bureaus, in connection with the above stated;
- regional councils and municipal councils;
- multiple private associations and companies, the members or owners of which are a party to the public sector. This applies for example to employees or elected representatives of regional councils or municipalities;
- the European Commission or other administrative body of the EU.

"**Decision Maker**" must mean a Political Representative or an Officer.

"**Pharmaceutical Company**" must mean Members or their representatives.

"**External Consultant**" must mean the third party acting on behalf of the Pharmaceutical Company during dialogues and negotiations with Decision Makers. External Consultant of this kind may be, for example, public relations agency or communication agency, legal representative, etc.

"**Company Representative**" must mean an employee of a Pharmaceutical Company or External Consultant working for the given company.

Provisions of this Section 10 must also apply for: physicians, stomatologists, veterinarians, pharmacists, nurses, veterinary nurses, pharmacy-economists and the students of these particular specialisations.

"**Dialogue**" must mean all types of oral and written communication carried out between Company Representatives and Decision Makers.

"**Negotiation**" must mean the situation where a Company Representative is carrying out a dialogue with a Decision Maker with a purpose of reaching a mutual agreement on a specific request or suggestion of the Pharmaceutical Company or a purpose of obtaining support therefor.

10.3 The scope

10.3.1

These ethical rules lay down a minimal scope of rules binding for the Members. Taking the aforesaid into account, Pharmaceutical Companies may have their own rules of ethical conduct exceeding the scope of these rules.

10.3.2

These ethical rules are binding for Dialogues and Negotiations carried out between Company Representatives and Decision Makers (Political Representatives and Officers) on the international, national, regional or local level.

10.3.3

If an external consultant has been engaged in a Dialogue or Negotiation with Decision Makers, the Pharmaceutical Company must be obliged to ensure the full adherence to these ethical rules by that External Consultant.

10.4 Transparency

10.4.1

An absolute openness must exist about who and whose interests are represented by the particular Company Representative. Company Representatives are therefore obliged to introduce themselves and specify the name of the Pharmaceutical Company they represent at the very beginning and without the need of a prior invitation. The said also applies where an individual External Consultant represents the interests of more Pharmaceutical Companies.

10.4.2

Pharmaceutical Company must be obliged to ensure and demonstrate the full openness when providing remuneration to the Decision Maker (compare exemptions included in Section 10.8.3 hereof).

10.4.3

All Pharmaceutical Companies are obliged to disclose on their websites the list of their public relations agency or communication agency, legal representative or similar External Consultants commissioned by the given Pharmaceutical Company to carry out Dialogues and Negotiations with Decision Makers. Disclosure is performed by stating the name or registered business name of the particular External agency / Consultant / legal representative.

In terms of time, the disclosure should be carried out without undue delay following agreeing with External Consultant and should be located on the publicly available domain for the minimum of three months during the course of the project.

The particular Document of the Pharmaceutical Company located on its website must further explicitly state that the Pharmaceutical Company had advised the External Consultant with the applicable rules of this Code and that the Pharmaceutical Company takes the responsibility for ensuring adherence to these rules by the External Consultant.

10.5 Information Requirements

10.5.1

Information addressed to Decision Makers must be current and complete and must not include defective or misleading data.

10.6 Decent Behaviour

10.6.1

During Dialogues and Negotiations with Decision Makers decent behaviour should be observed maintaining the following standards:

a) credit and honour of the Decision Maker must not be questioned by the Company Representative,

b) no misleading, false, abusive or discriminatory implications or references must be introduced in relation to the third parties,

c) irrelevant information of the personal character cannot be used in the manner evolving pressure or intimidation.

10.7 Confidential Information

10.7.1

Company Representative must be obliged to always act with discretion and fully respect information confidentially obtained from the Decision Maker, save for the case that it would be unlawful. Confidentiality must also be respected in cases where confidential information had been obtained incidentally or by mistake. Attempts to obtain confidential information by unfair means must be prohibited.

10.8 Independence

10.8.1

Any kind of financial dependence among Pharmaceutical Companies and Company Representatives on the one side and the Decision Maker on the other side must be prohibited. Concurrently, Company Representatives must not act in the manner which would induce suspicion of bribery.

10.8.2

Under no circumstance must Company Representatives provide financial support or sponsorship to Officers or Political Representatives individually or through organisations or associations (e.g. political parties, election financing, etc.). Pharmaceutical Companies though

can sponsor particular professional activities, campaigns and other similar events organised and arranged by the public authority.

10.8.3

Neither Pharmaceutical Companies nor Company Representatives are in any way allowed to remunerate Officers or Political Representatives who perform their official duties, affecting of which may be an in the direct interest of the Pharmaceutical Company. Nevertheless, the said must be exclusively permitted as regards the following persons:

A) Decision Maker who is primarily a permanent employee of the Pharmaceutical Company and whose remuneration is exclusively related to that primary occupation. If the Pharmaceutical Company hires Decision Maker which, within his/her primary occupation or responsibility, is obliged to carry out Dialogues and Negotiations with Decision Makers on behalf of the Pharmaceutical Company (e. g. employees responsible for public and external matters), that Pharmaceutical Company must be particularly responsible for the following:
   a) legal rules and principles related to conflict of interests are always kept at least in the minimal scope;
   b) person leading Dialogues and Negotiations with other Decision Makers is always and without any exception fully transparent, taking into consideration the character of his/her work (compare Sections 10.3 and 10.4 hereof), so that no doubts related to conflict of interests would arise.

B) Decision-Maker, being at the same time a healthcare professional, who within his/her obligations exclusively provides professional services to the Pharmaceutical Company. The remuneration must be provided only concerning those professional services and must be otherwise reasonable as compared to the services provided.

C) Decision Maker who provides specific limited services for the Pharmaceutical Company related to education, lecturing, etc. The remuneration can be provided only concerning those services related to education or lecturing and must be reasonable as compared to the services provided.

10.8.4

Neither Pharmaceutical Companies nor Company Representatives can in any other way offer or provide to the Decision Makers gifts or other payments in kind having financial value for the recipient and which do not possess any professional purpose, such as private gifts, tickets to sports events, cultural or amusement events, travelling, vacations, extravagant restaurants visits, etc.

Irrespective of the above stated, Company Representatives are allowed to provide professional information materials (reports, textbooks, analysis, films) which are intended by the Pharmaceutical Company to provide appropriate information and which, concurrently, form a natural and transparent part of the Dialogue of the Pharmaceutical Company with Decision Makers.

10.8.5

Company Representative may provide relevant hospitality at direct meetings of Company Representative and the Decision Maker or the presence at thematic days, conferences, etc. held and financed by the Pharmaceutical Company; the said must not apply if such event was

intended to promote medicinal products. Company Representative may, as a part of the above-listed events, reimburse travelling costs and accommodation of the Decision Maker.

The above costs related to meals, transportation and accommodation must be reasonable to the willingness of the participants to bear them themselves.

An approved volume of the above-stated costs, including meals, transportation and accommodation, should be governed by the same strict scope as the one applicable to relations of Pharmaceutical Companies and healthcare professionals.

10.9 Legislation

All activities regarded to Dialogues and Negotiations with Decision Makers must comply with applicable law. Unlawful activities or *quid pro quo* suggested by the counterparty must be denied at all events.

It is an obligation of a Company Representative to actively intervene against the breach of law where he/she is aware that such breach is happening or has been planned to be committed by the third party.

11. PUBLIC AND MEDIA RELATIONS

The information delivered to the public has to be used exclusively for the improvement of public knowledge from medical and healthcare area only and cannot be used for the promotion of medicinal products. Such information about new chemical entities, new medicinal products and ways of treatment delivered to public and media:

- has to be truthful, verified, full, clear and understandable;
- must not contain any unproven assumptions and expectations;
- must not create a false illusion for patients about treatment efficacy or unverified hope for certain improvement of their health status;
- has to be free of intention to cheat journalist or patient or intention to damage competitor.

No pressure may be imposed on media professionals to publish delivered information. They should have freedom for their own decision on how to use obtained information according to their professional opinion and the reader's interests.

Media may not be financially motivated by advertising or other barters to publish certain information about prescription-only medicinal products. In such an event, it is advertising which is prohibited by law.

11.1 No Advice on Personal Medical Matters

In the event of requests from individual members of the general public for advice on personal medical matters, the enquirer should be advised to consult a healthcare professional.

11.2 Press Releases

The press release has to follow all rules stated under this Section 11. Content of press release has to use proved facts without advertising messages.

11.3 Press Conferences

The information delivered to journalists has to follow all rules stated under this Section 11. It is recommended to use as speakers for medical information, methods of treatment and medicinal products related information preferably medical professionals who are not Member's employees. Hospitality must be appropriate and in proportion to the occasion. The press release has to be the standard part of a press conference.

11.4 Radio and TV

Radio and TV broadcasts have to follow all rules stated under this Section 11.

11.5 Hospitality and Incentives

Hospitality offered to journalists should be appropriate and in proportion to the occasion and must not motivate or oblige journalists to publish information delivered by a Member in wished manner.

The journalists may be invited by Members to foreign trips or trips within Slovakia for the educational or expert purpose only and hospitality must be secondary to the main purpose of the event.

12. MARKETING OF PHARMACEUTICAL PRODUCTS ON THE INTERNET – RULES FOR WEBSITES INTENDED FOR HEALTHCARE PROFESSIONALS, PATIENTS AND GENERAL PUBLIC

General rules:

- Any internet communication concerning the presentation of Members and their medicinal products on the internet has to comply with the provisions of this Code.
- Concerning marketing and promotion activities, the internet is considered information and promotion medium for both general public and healthcare professionals.

12.1 Transparency of Origin, Content and Purpose of Websites

Each website has to clearly identify the following:

a) identity, mailing and electronic addresses of the website sponsor;

b) information source for any information used on the website, the date on which it was published, and the identity together with recommendations (including the date of receipt) of any person providing information used on the website;

c) selection procedure for the information contained on the website;

d) target group of the website (e. g. healthcare professionals, patients, general public or any combination thereof); and

e) purpose or objective of the website.

12.2 Content of the Website

a) Any information made available on the website needs to be updated on regular basis and the date of the last site and/or article update has to be shown clearly.

b) Examples of information that can be made available on an individual or common website include (i) general Member information; (ii) information related to medical education; (iii) information meant for healthcare professionals, including any promotional information, and (iv) non-promotional information for patients and the general public.

   (i) General corporate information. Websites can also contain information, including financial data, research and development schedules, information for potential employees, etc., that may be of interest for investors, mass media and the public.

   (ii) Information on medical education. Websites can also comprise non-promotional information on medical education related to characteristics of diseases, preventive methods, screening and treatment, and any other information aimed to promote public health. Websites with medical education information must always recommend individuals to consult a professional for further information.

   (iii) Information intended for healthcare professionals. Any promotional information for healthcare professionals has to comply with applicable legislation and any other regulations governing the subject matter and form of advertisement and promotion of medicinal products. Such information has to be clearly marked as "information for healthcare professionals", where such information does not need to be encoded or limited in any other way.

   (iv) Non-promotional information for patients and the general public. Under the terms and conditions established by applicable legislation, websites can comprise an up-

to-date list of Products produced or distributed by Members. For each product, a full and up-to-date SmPC and patient information leaflet (PIL) need to be provided.

12.3 E-mail Queries

The website can contain a contact e-mail address for healthcare professionals, patients or the general public. The said address must enable e-mail communication to allow obtaining further information (such as feedback concerning the website). A Member can respond to queries in the same way (via e-mail) as if it would respond to questions received on the telephone, via postal mail or differently. In communication with patients and the general public, it is essential to avoid personal medical issues. If such information is provided, it has to be treated confidentially. If necessary, answers should include a recommendation to consult a professional on any further issues.

12.4 Links from Other Websites

Links to a Member sponsored website can be established on websites sponsored by other persons. However, on websites aimed at the general public, Members should not establish links to websites sponsored by Members, which are aimed at healthcare professionals. In the same manner, links to other websites can be established, including the sites sponsored by a Member or by any other persons. Usually, links should refer to the home page of the website or make sure by any other means that the reader is aware of the identity of the website.

12.5 Websites Referred to on the Package

Under the applicable legislation, website addresses (URLs) of Member sponsored sites that comply with these regulations can be referred to on the packages of medicinal products.

12.6 Scientific Reviews

Members should make sure that any scientific and medical information for their websites is reviewed to be under applicable regulations.

12.7 Privacy

Websites have to comply with applicable legislation and regulations governing confidentiality, safety and personal data protection.

EXPLANATORY NOTES

General treatment information cannot be placed on the same website or linked directly to the SmPC, PIL or the price list of the particular medicinal product.

13. DISCLOSURE OF TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

13.1 General Rules

Within the framework of mutual cooperation, healthcare professionals and healthcare organisations provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and management experience. Such expertise makes an immanent contribution to the effort of this industry to improve the quality of patient care with benefits not only for individuals but for the society at large. Healthcare professionals and healthcare organisations should be fairly compensated for legitimate expertise and services, which they provide to the pharmaceutical industry.

Prescription-only medicinal products developed by the pharmaceutical industry are complex products designed to address the needs of patients and educating healthcare professionals about medicines and the diseases they treat benefits patients. The pharmaceutical industry can provide a legitimate forum for the education of healthcare professionals and the exchange of knowledge among healthcare professionals and industry.

AIFP believes that interaction between the pharmaceutical industry and healthcare professionals has a profound and positive influence on the quality of patient treatment and the value of future research. AIFP also believes that the integrity of a decision of a healthcare professional to prescribe a medicinal product is one of the pillars of the healthcare system. AIFP recognises that interactions between pharmaceutical industry ad healthcare professionals can create the potential for the conflict of interest. Consequently, AIFP is joining the initiative of EFPIA (European Federation of Pharmaceutical Industry and Associations), which had adopted codes and guidelines to ensure that these interactions meet the high standards of integrity, expected by the patients, government and other stakeholders involved.

AIFP believes that the interest of patients and other stakeholders in the transparency of these interactions is compelling. AIFP recognises that disclosure can raise data privacy concerns and it, therefore, seeks to work with healthcare professionals to ensure that these concerns are addressed. Nonetheless, AIFP believes that transparency can be achieved even without sacrificing the legitimate privacy interests of healthcare professionals and legislation should not therefore impose excessive restrictions on disclosure by the pharmaceutical industry.

The following provisions stipulate disclosure of Transfers of Value from the Members to healthcare professionals, whether directly or indirectly. When deciding how a Transfer of Value should be disclosed the Members should, wherever possible, identify and publish those transfers at the individual healthcare professional (rather than healthcare organisation) level, as long as this can be achieved with accuracy, consistency and compliance with applicable law.

Obligation to disclose Transfers of Value to healthcare professionals and healthcare organisations – healthcare providers pursuant to this Code is to commence for the first time in 2016 and refers to the Transfers of Value for the calendar year 2015. Obligation to disclose Transfers of Value pursuant to this Code must be implemented by the Members in a manner consistent with applicable competition and data protection laws and regulations and all other applicable legal requirements.

Provisions of this Section 13 set down the minimum standards to apply to all Members. All Members are required to satisfy them in compliance with applicable legal regulations.

Reporting and disclosure of monetary or non-monetary benefits provided to healthcare professionals and healthcare providers by the Members pursuant to applicable legal regulations must not be affected by the provisions of this Code whatsoever. In the extent disclosure is requested by special legal regulations in more detail and/or under a different structure, the disclosure pursuant to such legal regulations must be considered as meeting requirements stipulated in this Section 13.

Disclose of Transfers of Value which is not required by applicable legal regulations, such as providing monetary or non-monetary benefits to Universities and scientific institutions, expenses spent on research and development paid by other than Slovak affiliates of the Members, expenses spent on research and development commenced before 31 December 2015 or cross-boundary Transfers of Value, must be governed by Section 13 hereof.

13.2 Disclosure Obligation

13.2.1 General obligation

Each Member must under the conditions laid down herein document and disclose Transfers of Value it makes, directly or indirectly, to or for the benefit of a recipient being a healthcare professional.

13.2.2 Excluded disclosures

Transfers of Value which (i) are solely related to over-the-counter medicinal products, (ii) are not listed in Section 13.4 hereof, such as items of medical utility, meals and drinks, medical samples, or (iii) are part of the ordinary course of purchases and sales of medicinal products between the Member and healthcare professional (such as a pharmacist) or healthcare organisation, do not fall within the scope of the disclosure obligation.

13.3 Form of Disclosure

13.3.1 Annual disclosure cycle

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

13.3.2 Time of disclosure

Disclosures must be made by each Member within six 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 three years after the time such information is first disclosed following Section 13.3.4 hereof unless in each case (i) a shorter period is required under applicable data privacy or other laws or regulations, or (ii) the relevant legal basis for the processing of personal data has ceased to exist pursuant to the applicable legal regulations on personal data protection.

13.3.3 Template

For consistency purposes, disclosures will be made using a structure set forth in Section 13.7 hereof.

13.3.4 Platform for Disclosure

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

(i) on the relevant website of the Member, or

(ii) on a central platform, such as one provided by the relevant government, regulatory or professional authority or body or an association, provided that disclosures made on a central platform must be made, so far as possible, using a structure set forth in Section 13.8 hereof.

13.3.5 Language of disclosure

Disclosures must be made in the Slovak language. Members are also encouraged to make disclosures in the English language in addition.

13.3.6 Documentation and Retention of Records

Each Member must document all Transfers of Value required to be disclosed pursuant to this Code and maintain the relevant records of the disclosures made under this Code for a minimum of five years after the end of the relevant Reporting Period unless a shorter period is required under applicable national data privacy or other laws or regulations.

13.3.7 Application for correction of disclosed data

The healthcare professional whose personal data have been disclosed under Section 13 hereof may at any time ask the Member, being the data controller, in writing for rectification of his/her incorrect, incomplete or non-actual disclosed personal data.

The Member who disclosed such personal data of the healthcare professional must review the received request of the healthcare professional and respond to it within 30 days from its delivery; it must, if necessary, ask the healthcare professional concerned to specify the personal data which should be rectified.

Provided that the disclosed personal data of the healthcare professional had been proven incorrect, non-actual or incomplete, the Member must rectify such data within 30 days, otherwise, the Member must maintain the personal data of the healthcare professional as originally disclosed.

13.4 Individual and Aggregate Disclosure

13.4.1 Individual disclosure

Except as expressly provided by this Code, Transfers of Value must be disclosed on an individual basis. Each Member must disclose, on an individual basis for each clearly identifiable recipient, the amounts attributable to Transfers of Value to such recipient in each Reporting Period which can be reasonably allocated to one of the categories set out below. Such Transfers of Value 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. *As regards Transfers of Value to healthcare organisations, an amount related to any of the categories set forth below:*

   a) Donations and grants. Donations and grants to healthcare organisations to support healthcare including donations and grants (either cash or benefits in kind) to institutions, organisations or associations comprising of healthcare professionals and/or providing healthcare services.

   b) Contribution to costs related to professional events. Contribution to costs related to professional events, through healthcare organisations or third parties, including sponsorship of healthcare professionals to attend professional events such as:

      (i) registration fees;

      (ii) sponsorship agreements with healthcare organisations or third parties appointed by healthcare organisations to manage a professional event and

      (iii) travel and accommodation.

   c) Fees for services and consultancy. Transfers of value resulting from or related to contracts between Members and institutions, organisations or associations of healthcare professionals, under which such institutions, organisations and associations provide any type of services to a Member or any type of funding not covered in the previous categories. Fees, on the one hand, and the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

2. *As regards Transfers of Value to healthcare professionals:*

   a) Contribution to costs related to professional events. Contribution to costs related to professional events such as:

      (i) registration fees; and

      (ii) travel and accommodation.

   b) Fees for services and consultancy. Transfers of value resulting from or related to (i) contracts between Members and healthcare professionals, under which healthcare professionals provide any type of services to Members or any other type of funding not covered in the previous categories. Fees, on the one hand, and the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

13.4.2 Aggregate Disclosure

Regarding Transfers of Value where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Section 13.4.1 hereof, cannot be disclosed on an individual basis for legal reasons, a Member must disclose the amounts attributable to such Transfers of Value 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 Transfers of Value to such recipients.

13.4.3 Non Duplication

Where a Transfer of Value required to be disclosed pursuant to Section 13.4.1 or 13.4.2 hereof, is made to an individual healthcare professional indirectly via healthcare organisation, such transfer can be only published once. To the extent possible, such disclosure must be made on an individual healthcare professional named basis pursuant to Section 13.4.1 (2) hereof.

13.4.4 Research and Development Transfers of Value

Research and Development Transfers of Value in each Reporting Period must be disclosed by each Member on an aggregate basis. Costs related to professional events that are clearly related to activities covered in this Section 13.4.4, can be included in the aggregate amount under the "Research and Development Transfers of Value" category".

13.4.5 Methodology

Each Member must publish a note summarising the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category described in Section 13.4.1 hereof. 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, and other issues related to the timing and amount of Transfers of Value for purposes of this Code, as applicable.

13.5 Enforcement

13.5.1 Enforcement through EFPIA Member Associations

Each EFPIA Member Association must adopt implementation and procedure rules which will be binding upon its members and set forth the framework for the implementation of Section 13 hereof, the processing of complaints and the enforcement of sanctions in a manner consistent with applicable data protection, competition and other applicable laws and regulations.[1]

13.5.2 Disclosure Requirements Different from this Code

If the applicable legal regulation prescribes equivalent or more stringent disclosure requirements, the relevant Member must comply with such equivalent or more stringent requirements in a manner as consistent as possible with the substantive disclosure requirements of this Code.

13.5.3 Sanctions

Provisions laying down sanctions and their imposition for violations of provisions of this Code are also subject of this Code.

13.5.4 Reporting

The AIFP Ethics Working Group together with AIFP Ethical Committee must produce, at least annually, reports summarising adherence to obligations set out in Section 13 hereof (the first such report is expected to be produced in September 2016).

[1] When making a Transfer of Value to a healthcare professional or healthcare organisation and in their written contracts with healthcare professionals or healthcare organisations, Members are encouraged to include provisions relating to the recipients' consent to disclose Transfers of Value in accordance with this Code. Moreover, Members are encouraged to renegotiate existing contracts at their earliest convenience to include such consent to disclosure.

13.6 Amendments and Guidance Concerning Compliance with Provisions on Disclosure

13.6.1 Compliance with Provisions on Disclosure

The AIFP Ethics Working Group together with AIFP Ethical Committee must assist the Members to comply with their obligations under Section 13 hereof.

13.6.2 Amendments of Provisions on Disclosure

The AIFP Ethics Working Group together with AIFP Ethical Committee must regularly review adherence to Section 13 hereof and all instructions issued concerning compliance with Section 13 hereof. Proposed amendments to Section 13 hereof must be submitted to the Supervisory Board for review and to the General Meeting for approval.

13.7 Standard template for disclosure

PUBLICATION TEMPLATE

Date of publication: .....

	Full Name	**HCPs:** City of Principal Practice **HCOs:** city where registered	Country of Principal Practice	Principal Practice Address	Unique country identifier OPTIONAL	Donations and Grants to HCOs	Contribution to costs of Events			Fee for service and consultancy			TOTAL OPTIONAL
							Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accommodation	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract		
HCPs	*INDIVIDUAL NAMED DISCLOSURE - one line per HCP (i.e. all transfers of value during a year for an individual HCP will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)*												
	Dr A					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		
	Dr B					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		
	etc.					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
	Aggregate amount attributable to transfers of value to such Recipients					N/A	N/A	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*		*Optional*
	Number of Recipients in aggregate disclosure					N/A	N/A	*number*	*number*	*number*	*number*		*Optional*
	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed					N/A	N/A	%	%	%	%		N/A
HCOs	*INDIVIDUAL NAMED DISCLOSURE - one line per HCO (i.e. all transfers of value during a year for an individual HCO will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)*												
	HCO 1					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	HCO 2					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	etc.					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
	Aggregate amount attributable to transfers of value to such Recipients					*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*		*Optional*
	Number of Recipients in aggregate disclosure					*number*	*number*	*number*	*number*	*number*	*number*		*Optional*
	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed					%	%	%	%	%	%		N/A
R&D	*AGGREGATE DISCLOSURE*												
	Transfers of Value re Research & Development as defined - *Article 13.4.4 and Annex No. 1*											TOTAL AMOUNT	OPTIONAL

13.8 Implementation and procedure rules

13.8.1

Implementation of provisions laying down the framework for disclosure of Transfers of Value from pharmaceutical companies to healthcare professionals and healthcare organisations had been performed subject to the approval of applicability of the original wording of the Code of EFPIA (EFPIA HCP/HCO Disclosure Code) for AIFP Members by the General Meeting of AIFP held on 16 April 2014.

13.8.2

By adaptation of an original text and wording of the EFPIA Code and its approval by the General Meeting of AIFP, these provisions (Section 13) must become an integral part of the AIFP Ethical Code since 18 September 2014. All other relevant provisions hereof, including, but not limited to, Annexes: 2. – Statute of Ethical Committee and 3. – Guidelines for Reviewing Complaints, must be adequately applicable thereto.

ANNEX NO. 1 TO THE ETHICAL CODE

DEFINITIONS

IN ENGLISH ALPHABETICAL ORDER

A

"**AIFP**" means the Association of Innovative Pharmaceutical Industry.

"**Association**" means the Association of Innovative Pharmaceutical Industry (AIFP).

"**Authorised person**" includes a person authorised to prescribe medicinal products and a person authorised to dispense medicinal products.

B

"**Brand name reminders**" means such items of low monetary value which are intended to remind healthcare professionals of the existence of a medicinal product.

"**Breaches after the termination of activities**" means severe breaches of this Code where the promotional activity has been completed prior the breach has been found.

"**Breach repetitions**" means the situation where a Member repeats the same type of breach within a period of 12 months in the promotion of any of the Member's medicinal products.

C

. "**Change of clinical significance**" is any change in the Product Information that could alter a decision to prescribe or not to prescribe the medicinal product and may include the following:

a) approved indications for use,

b) precautions for use,

c) contra-indications,

d) warnings (cautions),

e) adverse effects and interactions,

f) available dosage forms,

g) dosage regimens and routes of administration,

h) dependence potential,

i) reference to special groups of patients (where necessary).

"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

"**Data on file**" is the body of unpublished clinical or scientific information held by the Member. It does not include evaluated data submitted to SIDC following the Slovak Guidelines for the Registration of Drugs or preceding Guidelines.

"**Donations and Grants**" collectively, means those donations and grants, either cash or benefits in kind or services provided free of charge to promote healthcare, scientific research or education without the obligation to reimburse such benefits or any refund thereof. Unless otherwise provided herein, donations and grants must mean donations and grants within the meaning stipulated in Section 8 hereof and must include donations and grants provided about activities with patient organisations.

E

"**Educational material**" means any representation or literature which is intended to provide information about a disease or therapy which does not contain specific promotional claims.

"**Event**" includes, unless otherwise provided herein, all scientific, professional and educational events, congresses, conferences, meetings, symposia or other events organised or supported by or on behalf of a Member. Unless it contradicts other provisions hereof, the term Event also includes a Professional Event.

"**Executive officer**" means the person appointed to manage the affairs of the Association under the Rules of the Association.

"**Exhibition**" means a display or exhibit of professional, scientific or educational material about a product or medicinal products.

F

"**Full advertisement**" means an advertisement that requires the full or abridged Product Information to be included as set out in Section 2.1 hereof.

G

"**General public**" are any persons other than the healthcare professionals.

"**Graphics**" means the use of any pictorial or graphical representation in promotional material, including photographs, drawings, x-rays, graphs and bar charts but excludes any related promotional text.

H

"**Health education**" means education in the field of human health and disease and specialised non-promotional education in the field of medicinal products for human use as defined in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

"**Healthcare organisation**" means any legal person (i) that is an association or organisation providing healthcare, medical or research association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in the Slovak Republic or (ii) through which one or more healthcare professionals provide services.

"**Healthcare professional**" means 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/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 the Slovak Republic. For the avoidance of doubt, the definition of healthcare professional includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a Member whose primary occupation is that of a practising healthcare professional, but excludes (x) all other employees of a Member and (y) a wholesaler or distributor of medicinal products.

"**Healthcare professions**" include members of the medical, dental, pharmaceutical or nursing professions and any other persons who in the course of their professional activities may prescribe, supply or administer a medicinal product.

"**Hospitality**" means, unless otherwise provided herein, the performance provided in connection with the participation of healthcare professionals or representatives of patients' organisations in the Event, to the extent and under the conditions set forth in Article 6.9 hereof.

I

"**Industry**" means Members of AIFP.

"**Information**" means educational facts regarding the attributes of a medicinal product.

"**INN**" means International Non-proprietary Name.

"**International Congress**" means a congress held in the Slovak Republic where a society or university in another country is actively organising and has joint control over the conference with a Slovak society or university.

L

"**Literature**" means that body of published trials, findings and reviews which have appeared in medical and scientific publications.

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

M

"**Mailings**" means promotional material designed for distribution through the postal system or by private means"**Manufacturer**" includes the manufacturer, importer or a Slovak distributor of a medicinal product.

"**Market research**" is the gathering of data on the scope or dimensions of a market and its components, including the needs of the customers in that market.

"**Medical content**" means that portion of promotional material which makes a medical claim.

"**Medical claims**" means any statement which conveys the attributes of a product in respect of its therapeutic use, that is, use for or in connection with:

a) preventing, diagnosing, treatment or alleviating a disease, defect or injury in man;

b) influencing, inhibiting or modifying a physiological process in man;

c) testing the susceptibility of man to a disease or ailment; or

d) destroying or inhibiting micro-organisms that may be harmful to man.

"**Medical representative**" means a person expressly employed by a Member whose main purpose is the promoting of the Member's medicinal products to healthcare professionals.

"**Medicinal product**" means any substance or combination of substances presented for treating or preventing disease in human beings. Any substance or combination of substances which may be administered to human beings to make a medical diagnosis or to restore, correct or modify physiological functions in human beings is likewise considered a medicinal product.

"**Member**" means any person being a full or associated Member of AIFP as defined by the Statutes of the Association. This term also includes a person who is not a Member of AIFP but had adopted this Code and opted to be bound thereby.

"**Member Commissioned Article**" means an article or series of articles the publication of which is paid for by a Member or otherwise procured or ensured by a Member.

"**Member representatives**" are those persons, including medical representatives, authorised by the Member for spreading information about the medicinal product among healthcare professionals.

"Minimum monthly wage" is the currently applicable amount of minimum monthly wage stipulated by Act 663/2007 Coll. on Minimum Wages, as amended, or the amount established by any other generally binding legal regulation by which the said Act may be replaced in future.

"**Minor breach**" is a breach of this Code that has no safety implications to the patient's well-being and will have no major effect on how the persons authorised to prescribe medicinal products will prescribe the medicinal product.

"**Moderate breach**" is a breach of this Code that has no safety implications to the patient's well-being but may have an effect on how the persons authorised to prescribe medicinal products will prescribe the medicinal product.

N

"**New chemical entity**" means a medicinal product containing an active substance which has not been previously included in a medicinal product approved for registration in the Slovak Republic for human use, including new combinations, salts or esters of previously marketed substances.

"**New indication(s)**" means an additional indication of the medicinal product which was approved by SIDC after the original registration of the medicinal product.

P

"**Personal health data**" includes any data relating to the physical or mental health or acquired characteristics of an identified or identifiable natural person, including data on the provision of healthcare or healthcare-related services which reveal information about his or her state of health.

"**Product Information**" means a document containing information about the medicinal product under SmPC of the medicinal product. Product Information can be full or abridged (see Section 2.2 hereof).

"**Professional event**" means an event organised exclusively for professional, scientific or educational purposes for healthcare professionals. Such an event can be accompanied in a reasonable measure by activities whose time range will not exceed 20% of the scheduled event time and cannot be contrary to the Advertising Act. The time necessary for travelling and accommodation must not be counted into the scheduled professional event time.

"**Promotion**", "**Promotional**", or "**Promotional claim**" means the presentation of a medicinal product in any form whatsoever intending to employ it on the market. It includes any door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products, as well as statements concerning the efficacy, rate of adverse reactions or other cautionary aspects of the medicinal product and comparative information.

"**Promotional material**" means any representation concerning the attributes of a medicinal product conveyed by any means whatsoever to encourage the prescription, dispense, sale or consumption of a medicinal product.

R

"**Reasoning**" means giving reasonable grounds to support a promotional claim. Supporting information must adhere to the requirements of Section 1.3 hereof and cannot be limited to data on file only.

"**Recipient**" means any healthcare professional or healthcare organisation or patients organisation as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in the Slovak Republic.

"**Reference manual**" is a serial or monographic publication designed by its publisher to provide information in classified sequence for prompt reference to pharmacological or medical data.

"**Registration**" is the issue of a decision on registration of a medicinal product by the particular authority (SIDC, EMA) required for the marketing of a medicinal product in the Slovak Republic.

"**Repeat of the previous breach**" means the situation where the same or similar breach is repeated in the promotion of a particular medicinal product of a Member, which had been found in breach of this Code in the preceding 24 months.

"**Representatives of patients' organizations**" are persons authorised or empowered to represent patients' organisations and to express the collective views, attitudes and opinions of patients' organisations in a given area.

"**Research and Development Transfers of Value**" means Transfers of Value to healthcare professional or healthcare organisation 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 Directive 2001/20/EC); or (iii) non-interventional studies that are prospective in nature and that involve the collection of patient data from or through an individual, or groups of healthcare professionals, specifically for the study.

"**Rules**" means the Rules of the Association for the time being in force.

S

"**Samples**" means by law specified quantity of a medicinal product supplied free of charge to physicians by a marketing authorisation holder.

"**Severe breach**" is a breach of this Code that will have safety implications to the patient's well-being and/or will have a major effect on how persons authorised to prescribe medicinal products will prescribe the medicinal product.

"**SmPC**" means the applicable Summary of Product Characteristics of a medicinal product.

"**Substance**" means any matter irrespective of origin which may be (i) human, (ii) animal, (iii) vegetable, or (iv) chemical.

T

"**Therapeutic class**" means the classification system used for defining and grouping medicinal products in an approved reference manual.

"**Trade pack**" means a package of a medicinal product which is sold by the Member.

"**Transfers of Value**" means direct and indirect transfers of value, whether in cash, in-kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only medicinal products exclusively for human use. Direct transfers of value are those made directly by a Member for the benefit of a recipient. Indirect transfers of value are those made on behalf of a Member for the benefit of a recipient, or transfers of value made through an intermediate and where the Member knows or can identify the healthcare professional or healthcare organisation that will benefit from the Transfer of Value.

"**Type size**" means the height of a lower case letter "o".

U

"**Unique**" means being the first, different from all others and the only one of its class on the Slovak market.

V

"**Venue**" refers to the logistic place where the Event is organized (i.e. the hotel, the congress center, …).

W

"**Working hours**" means standard 8 hours of a working day.

DEFINITIONS

IN SLOVAK ALPHABETICAL ORDER

A

"**AIFP**" means the Association of Innovative Pharmaceutical Industry.

"**Data on file**" is the body of unpublished clinical or scientific information held by the Member. It does not include evaluated data submitted to SIDC following the Slovak Guidelines for the Registration of Drugs or preceding Guidelines.

"**Association**" means the Association of Innovative Pharmaceutical Industry (AIFP).

Č

"**Journal**" means a serial publication whose distribution is restricted to the members of the healthcare professions.

"**Member Commissioned Article**" means an article or series of articles the publication of which is paid for by a Member or otherwise procured or ensured by a Member.

"**Member**" means any person being a full or associated Member of AIFP as defined by the Statutes of the Association. This term also includes a person who is not a Member of AIFP but had adopted this Code and opted to be bound thereby.

D

"**Donations and Grants**" collectively, means those donations and grants, either cash or benefits in kind or services provided free of charge to promote healthcare, scientific research or education without the obligation to reimburse such benefits or any refund thereof. Unless otherwise provided herein, donations and grants must mean donations and grants within the meaning stipulated in Section 8 hereof and must include donations and grants provided about activities with patient organisations.

G

"**Graphics**" means the use of any pictorial or graphical representation in promotional material, including photographs, drawings, x-rays, graphs and bar charts but excludes any related promotional text.

I

"**Information**" means educational facts regarding the attributes of a medicinal product.

"**Product Information**" means a document containing information about the medicinal product under SmPC of the medicinal product. Product Information can be full or abridged (see Section 2.2 hereof).

"**INN**" means International Non-proprietary Name.

J

"**Unique**" means being the first, different from all others and the only one of its class on the Slovak market.

K

"**Change of clinical significance**" is any change in the Product Information that could alter a decision to prescribe or not to prescribe the medicinal product and may include the following:

j) approved indications for use,

k) precautions for use,

l) contra-indications,

m) warnings (cautions),

n) adverse effects and interactions,

o) available dosage forms,

p) dosage regimens and routes of administration,

q) dependence potential,

r) reference to special groups of patients (where necessary).

"**Congress**" means an event sponsored and/or organised by a society, college, university or other non-business entity.

L

"**General public**" are any persons other than the healthcare professionals.

"**Substance**" means any matter irrespective of origin which may be (i) human, (ii) animal, (iii) vegetable, or (iv) chemical.

"**Medical representative**" means a person expressly employed by a Member whose main purpose is the promoting of the Member's medicinal products to healthcare professionals.

"**Medicinal product**" means any substance or combination of substances presented for treating or preventing disease in human beings. Any substance or combination of substances which may be administered to human beings to make a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.

"**Literature**" means that body of published trials, findings and reviews which have appeared in medical and scientific publications.

M

"**Medical content**" means that portion of promotional material which makes a medical claim.

"**Medical claims**" means any statement which conveys the attributes of a product in respect of its therapeutic use, that is, use for or in connection with:

e) preventing, diagnosing, treatment or alleviating a disease, defect or injury in man;

f) influencing, inhibiting or modifying a physiological process in man;

g) testing the susceptibility of man to a disease or ailment; or

destroying or inhibiting micro-organisms that may be harmful to man.

"**International Congress**" means a congress held in the Slovak Republic where a society or university in another country is actively organising and has joint control over the conference with a Slovak society or university.

"Minimum monthly wage" is the currently applicable amount of minimum monthly wage stipulated by Act 663/2007 Coll. on Minimum Wages, as amended, or the amount established by any other generally binding legal regulation by which the said Act may be replaced in future.

"**Moderate breach**" is a breach of this Code that has no safety implications to the patient's well-being but may have an effect on how the persons authorised to prescribe medicinal products will prescribe the medicinal product.

"**Venue**" refers to the logistic place where the Event is organized (i.e. the hotel, the congress center, …).

N

"**Minor breach**" is a breach of this Code that has no safety implications to the patient's well-being and will have no major effect on how the persons authorised to prescribe medicinal products will prescribe the medicinal product.

"**New chemical entity**" means a medicinal product containing an active substance which has not been previously included in a medicinal product approved for registration in the Slovak Republic for human use, including new combinations, salts or esters of previously marketed substances.

"**New indication(s)**" means an additional indication of the medicinal product which was approved by SIDC after the original registration of the medicinal product.

O

"**Trade pack**" means a package of a medicinal product which is sold by the Member.

"**Professional event**" means an event organised exclusively for professional, scientific or educational purposes for healthcare professionals. Such an event can be accompanied in a reasonable measure by activities whose time range will not exceed 20% of the scheduled event time and cannot be contrary to the Advertising Act. The time necessary for travelling and accommodation shall not be counted into the scheduled professional event time.

"**Breach repetitions**" means the situation where a Member repeats the same type of breach within a period of 12 months in the promotion of any of the Member's medicinal products.

"**Repeat of the previous breach**" means the situation where the same or similar breach is repeated in the promotion of a particular medicinal product of a Member, which had been found in breach of this Code in the preceding 24 months.

"**Authorised person**" includes a person authorised to prescribe medicinal products and a person authorised to dispense medicinal products.

"**Personal health data**" includes any data relating to the physical or mental health or acquired characteristics of an identified or identifiable natural person, including data on the provision of healthcare or healthcare-related services which reveal information about his or her state of health.

P

"**Hospitality**" means, unless otherwise provided herein, the performance provided in connection with the participation of healthcare professionals or representatives of patients' organisations in the Event, to the extent and under the conditions set forth in Article 6.9 hereof.

"**Event**" includes, unless otherwise provided herein, all scientific, professional and educational events, congresses, conferences, meetings, symposia or other events organised or supported by or on behalf of a Member. Unless it contradicts other provisions hereof, the term Event also includes a Professional Event.

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

"**Breaches after the termination of activities**" means severe breaches of this Code where the promotional activity has been completed prior the breach has been found.

"**Mailings**" means promotional material designed for distribution through the postal system or by private means.

"**Working hours**" means standard 8 hours of a working day.

"**Rules**" means the Rules of the Association for the time being in force.

"**Transfers of Value**" means direct and indirect transfers of value, whether in cash, in-kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only medicinal products exclusively for human use. Direct transfers of value are those made directly by a Member for the benefit of a recipient. Indirect transfers of value are those made on behalf of a Member for the benefit of a recipient, or transfers of value made through an intermediate and where the Member knows or can identify the healthcare professional or healthcare organisation that will benefit from the Transfer of Value.

"**Research and Development Transfers of Value**" means Transfers of Value to healthcare professional or healthcare organisation 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 Directive 2001/20/EC); or (iii) non-interventional studies that are prospective in nature and that involve the collection of patient data from or through an individual, or groups of healthcare professionals, specifically for the study.

"**Industry**" means Members of AIFP.

"**Market research**" is the gathering of data on the scope or dimensions of a market and its components, including the needs of the customers in that market.

"**Recipient**" means any healthcare professional or healthcare organisation or patient organisation as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in the Slovak Republic.

"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.

R

"**Reference manual**" is a serial or monographic publication designed by its publisher to provide information in classified sequence for prompt reference to pharmacological or medical data.

"**Registration**" is the issue of a decision on registration of a medicinal product by the particular authority (SIDC, EMA) required for the marketing of a medicinal product in the Slovak Republic.

"**Promotion**", "**Promotional**", or "**Promotional claim**" means the presentation of a medicinal product in any form whatsoever intending to employ it on the market. It includes any door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products, as well as statements concerning the efficacy, rate of adverse reactions or other cautionary aspects of the medicinal product and comparative information.

"**Promotional material**" means any representation concerning the attributes of a medicinal product conveyed by any means whatsoever to encourage the prescription, dispense, sale or consumption of a medicinal product.

S

"**SmPC**" means the applicable Summary of Product Characteristics of a medicinal product.

"**Correct**" means a balanced representation of all the available data.

T

"**Therapeutic class**" means the classification system used for defining and grouping medicinal products in an approved reference manual.

U

"**Full advertisement**" means an advertisement that requires the full or abridged Product Information to be included as set out in Section 2.1 hereof.

"**Brand name reminders**" means such items of low monetary value which are intended to remind healthcare professionals of the existence of a medicinal product.

V

"**Severe breach**" is a breach of this Code that will have safety implications to the patient's well-being and/or will have a major effect on how persons authorised to prescribe medicinal products will prescribe the medicinal product.

"**Type size**" means the height of a lower case letter "o".

"**Executive officer**" means the person appointed to manage the affairs of the Association under the Rules of the Association.

"**Manufacturer**" includes the manufacturer, importer or a Slovak distributor of a medicinal product.

"**Exhibition**" means a display or exhibit of professional, scientific or educational material about a product or medicinal products.

"**Educational material**" means any representation or literature which is intended to provide information about a disease or therapy which does not contain specific promotional claims.

"**Samples**" means by law specified quantity of a medicinal product supplied free of charge to physicians by a marketing authorisation holder.

Z

"**Member representatives**" are those persons, including medical representatives, authorised by the Member for spreading information about the medicinal product among healthcare professionals.

"**Representatives of patients' organizations**" are persons authorised or empowered to represent patients' organisations and to express the collective views, attitudes and opinions of patients' organisations in a given area.

"**Reasoning**" means giving reasonable grounds to support a promotional claim. Supporting information must adhere to the requirements of Section 1.3 hereof and cannot be limited to data on file only.

"**Healthcare professions**" include members of the medical, dental, pharmaceutical or nursing professions and any other persons who in the course of their professional activities may prescribe, supply or administer a medicinal product.

"**Healthcare organisation**" means any legal person (i) that is an association or organisation providing healthcare, medical or research association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in the Slovak Republic or (ii) through which one or more healthcare professionals provide services.

"**Healthcare professional**" means 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/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 the Slovak Republic. For the avoidance of doubt, the definition of healthcare professional includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a Member whose primary occupation is that of a practising healthcare professional, but excludes (x) all other employees of a Member and (y) a wholesaler or distributor of medicinal products.

"**Health education**" means education in the field of human health and disease and specialised non-promotional education in the field of medicinal products for human use as defined in

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

ANNEX No. 2 OF THE ETHICAL CODE

THE STATUTE OF THE ETHICAL COMMITTEE OF AIFP

1. Formation

The Ethical Committee of AIFP (hereinafter referred to as the "**Ethical Committee**") is a body whose main objective is to enforce the rules of this Code and supervise their compliance.

The Code, its application and potential sanctions are adopted by the Members voluntarily as a prerequisite of their membership in AIFP.

Conduct of the Ethical Committee is not legally binding and should be understood as conduct aimed to promote resolving of complaints and settling disputes in such a way so that the similar situations could be precluded in the future. In no way does any interference of the Ethical Committee limit any Member in its independent conduct.

No statements adopted by the Ethical Committee must bear any legal power and therefore none of them should preclude the Members from using any legitimate legal means related to the activity complained about before the Ethical Committee.

Members must confirm in writing that they will not initiate any legal steps against AIFP, the Ethical Committee or particular members of the Ethical Committee based on a decision issued by the Ethical Committee in a specific matter.

Subject to approval by the Supervisory Board of AIFP (hereinafter referred to as the "**Supervisory Board**"), the Ethical Committee must be entitled to disclose details of its decisions to professional as well as the general public.

2. Composition

The Ethical Committee consists of nine members, four are internal (Member representatives) and five are external. Discharge of an office of the Ethical Committee member is unsubstitutable. The Chairman of the Ethical Committee is elected by the members of the Ethical Committee on its first meeting for two years and subsequently following the end of the term of his/her office.

2.1 Internal Members

The Chairman of the AIFP Ethics Working Group (Ways of working & Ethics) must, at the same time, be always an internal member of the Ethical Committee. Another three internal members must be nominated by the AIFP Ethics Working Group from among its members. The nominees must be appointed by the Supervisory Board.

2.2 External Members

External members of the Ethical Committee may be:

- a physician with active ambulant or hospital practise,
- a representative of the Pharmaceutical or Medicine Faculty,
- a representative of the patient organisations,

- lawyer.

External members are nominated by the AIFP Ethics Working Group and appointed by the Supervisory Board. The qualification criteria for the selection of individual external members is their active conduct in the area of ethics, respectively general awareness of their strong ethical and moral values.

3. Organisational Support

Executive Director of AIFP must ensure logistic organisation of the Ethical Committee meetings, minutes from each meeting, underlying materials for discussion, etc.

4. Data Confidentiality

Members of the Ethical Committee and all authorised employees of AIFP office dealing with the Ethical Committee agenda must keep strict confidentiality on handled cases and treat documentation on handled cases as confidential.

The Ethical Committee can ask the members of AIFP working groups, eventually also Members to support it for specific complaints when further expertise is required.

5. Terms of Office

Term of office of internal elected members of the Ethical Committee is two years. Re-election of an internal member is possible, while the total time of consecutive terms may not exceed in total 4 years.

As it is important to keep the continuity of work of the Ethical Committee, according to the Statute, one internal member of the Ethical Committee must be elected for a one year term and two members must be elected for a two years term. Internal elected members of the Ethical Committee appointed in the following years must be elected for a two years term, what means that a new Member or Members (either one or two, depending on the year of election) of the Ethical Committee will be elected every year.

The term of office of the Ethical Committee member, who is at the same time the Chairman of the AIFP Ethics Working Group, continues to last concurrently with his/her office of the Chairman of the said Working Group.

External members of the Ethical Committee are recommended to remain at their office for at least two years. External members of the Ethical Committee must confirm their willingness to continue their work for the Ethical Committee every year.

If the office of the elected internal member of the Ethical Committee ceases to exist, the AIFP Ethics Working Group must appoint a new member of the Ethical Committee until the end of the elective period of the member whose office must be replaced.

If the office of the elected external member or the Chairman of the AIFP Ethics Working Group ceases to exist, the AIFP Ethics Working Group must appoint a new member of the Ethical Committee until the new external member or Chairman of that working group is elected regularly.

6. Termination of the Office

The office of an internal elected member of the Ethical Committee must become extinct if the following situations occur:

- expiration of the office term of an internal member of the Ethical Committee,
- submitting a written resignation notice to the Chairman of the AIFP Ethics Working Group by the internal member,
- recalling from the office by the Supervisory Board subject to the proposal of the AIFP Ethics Working Group,
- termination of his/her employment with the Member,
- termination of membership in AIFP,
- death.

The office of the internal member being the Chairman of the AIFP Ethics Working Group must become extinct if the following situations occur:

- expiration of the office term of the Chairman of the AIFP Ethics Working Group,
- resignation on or recall from the office of the Chairman of the AIFP Ethics Working Group,
- termination of his/her employment with the Member,
- termination of membership in AIFP,
- death.

The office of the external member must become extinct if the following situations occur:

- submitting a written resignation notice to the Chairman of the AIFP Ethics Working Group by the external member,
- recalling from the office by the Supervisory Board subject to the proposal of the AIFP Ethics Working Group,
- death.

7. Remuneration

External members of the Ethical Committee must be paid a remuneration for their service at the Ethical Committee determined by the Supervisory Board. The office of the internal member of the Ethical Committee is free of any consideration.

8. Voting

A decision of the Ethical Committee must be adopted if more than half of all members of the Ethical Committee had voted for it. *Per rollam* voting must be also permitted (for example via an e-mail).

9. EFPIA Code of Practice on the Promotion of Medicinal Products and Ethical Code of AIFP

The Ethical Committee must follow this Code. The Code of Practice on the Promotion of Medicines of the European Federation of Pharmaceutical Industries and Associations (EFPIA Code) is a base for the establishment of this Code.

10. Conflict of Interests

If the member of the Ethical Committee or the Member he/she represents files a complaint, such member must be then excluded from reviewing and arbitrating on that complaint. Concurrently, that member of the Ethical Committee is excluded against whom a complaint is filed and must be also excluded in the event of a complaint filed against the Member he/she represents.

External member must be excluded from the reviewing process too provided that, with regards to his/her relation to the reviewed matter, or the Member filing a complaint, or to the Member against which the complaint is aimed, his/her impartiality may be reasonably doubted. Concurrently, the external member must be also excluded if he/she challenges his/her impartiality him/herself concerning the reviewed matter, or to the Member filing the complaint, or to the Member against which the complaint is aimed.

In the event of a conflict of interests, the Ethical Committee may invite an ad hoc member of the AIFP Ethics Working Group to join the Ethical Committee.

11. The Appellate Body

The Supervisory Board serves as the Appellate Body whose task is to review decisions of the Ethical Committee.

A decision of the Appellate Body must be adopted if more than half of all members of the Supervisory Board had voted for it. *Per rollam* voting must be also permitted (for example via an e-mail).

If the member of the Appellate Body or the Member he/she represents files a complaint, such member of the Appellate Body must be excluded from reviewing and arbitrating on such complaint. Concurrently, that member of the Appellate Body must be excluded against which the complaint is filed and must also be excluded in the event of a complaint filed against the Member he/she represents.

12. Providing Information to the public

The pharmaceutical industry, healthcare professionals as well as the general public must be informed that the Statute on the processing of complaints of AIFP had been adopted.

ANNEX No. 3 OF THE ETHICAL CODE

COMPLAINTS REVIEW PROCEDURES

THE PROCEDURE ON PROCESSING COMPLAINTS CONCERNING VIOLATION OF THE AIFP ETHICAL CODE

1. Use and Purpose of the Complaints Review Procedure

The Complaints Review Procedures concerning violation of the Code is open to any Member, healthcare professional or the public, acting in good faith within the spirit and intentions of the Code.

In implementing the Code, the Ethical Committee is primarily concerned with education and directing the behaviour of Members in such a way as to maintain and enhance the reputation of the pharmaceutical industry in the Slovak Republic. Thus, the Complaints Review Procedure is intended to be as fair and consultative as possible and to provide an opportunity for Members to take steps to improve their behaviour wherever necessary. However, for the application of the Code to be taken seriously, imposing of penalties will be necessary on occasion, and will be applied in the event of serious, deliberate or repeated breaches of the Code or breaches of obligations imposed or undertaken to rectify such breaches of the Code.

1.1 Plaintiff and Defendant

1.1.1 A plaintiff, for this Code, is a person, institution or a Member submitting a complaint.

1.1.2 A defendant, for this Code, is the Member being complained about.

1.2. Submission of Complaints

1.2.1 A complaint concerning activities of a Member who is alleged to be breaching the Code can be submitted by any of the following:

a) the AIFP Member,

b) a healthcare professional,

c) a representative of the public,

d) a government official or state authority;

e) patients organisation.

1.2.2 In the event where no formal complaint about the behaviour of a Member is made to the Ethical Committee, but where the activities of a Member are attracting publicity which is deemed inconsistent with the Code, then the Ethical Committee retains the right to act on its own initiative and consider whether the Code has been breached.

1.2.3 Complaints must be filed in writing in Slovak language and if filed by the Member they also must be filed mandatorily in the English language as well and they must contain the following essentials:

a) Identity of the plaintiff comprising of its registered business name, address of its registered office, identification number, its mailing address (if it differs from the address of its registered office), if the plaintiff is a legal entity; name, surname and

the residential address, if the plaintiff is an individual; including e-mail address, if available.

b) The full address of headquarters of the plaintiff, if the plaintiff is a Member, and the name of the person authorised to act on its behalf.

c) Identity of the defendant comprising of its registered business name, address of its registered office, identification number, its mailing address (if it differs from the address of its registered office), eventually also including e-mail address.

d) Name of a medicinal product or medicinal products, if affected by the complaint.

e) Reference material which must be used as evidence of the alleged breach of the Code if applicable.

f) For each case in the complaint, a specific reference to the source of the activity which is the subject of the complaint and/or printed material or other evidence.

g) The date when the plaintiff has learned of or ascertained the alleged breach of the Code.

h) The date of filing of the complaint.

i) A specific reference to the provision of the Code that has been allegedly breached by the defendant (section and paragraph number(s) if the complaint is filed by the Member.

j) For each case, a brief description of the complaint is necessary.

1.2.4. The complaint together with all annexes and supporting material thereto should be addressed to the Executive Director of AIFP and to the AIFP whether via post or electronically to the address of the Executive Director of AIFP.

2. Procedure for Filing Complaints concerning the Code

2.1 Validation and Referral of the Complaint

2.1.1. A complaint may be filed with the Ethical Committee by the Member only provided that mutual negotiation with the alleged Code's violator to achieve amicable settlement was unsuccessful.

2.1.2. When a complaint, alleging a breach of the Code is received by Ethical Committee, it is first validated to ensure that:

- it appears to be a real case, submitted in a good faith,
- the complaint contains all prescribed details,
- there is sufficient information to enable the complaint to be processed.

2.1.3. A single complaint may cover more than one case, i.e. the complaint may refer to several alleged Code breaches (e.g. advertisements from different subjects of complaint and/or for different medicinal products). Each case is handled separately by the Ethical Committee under the main complaint reference.

2.1.4. The first action of the Ethical Committee in each case is to identify:

- the defendant, its membership with AIFP, its head office or parent company and its location, if different,

- when a case refers to a company which is not a Member to AIFP (either locally, or through its parent company), the case cannot be processed formally. However, the Ethical Committee is entitled to express in the complaint refusal its opinion concerning the behaviour of the non-member company.

2.1.5. The Ethical Committee will inform without any delay the plaintiff and the defendant, as well as responsible Regional Manager of the defendant if the complaint was accepted for further proceeding.

2.1.6. In the event of a rejection of the complaint, the Ethical Committee must inform the plaintiff thereof. The plaintiff may file an appeal against the resolution of the Ethical Committee on the rejection of the complaint. The appeal procedure within the meaning of Article 2.5 of these Complaints Review Procedures must apply mutatis mutandis in such an event.

2.2 Time Limits

2.2.1 Upon receiving the copy of the complaint from the Ethical Committee, the defendant must have fifteen working days to submit its statement or comments in writing to the Ethical Committee. Under exceptional circumstances, an extension of the said time period may be allowed by the Ethical Committee.

2.3 Response

2.3.1 Where the defendant acknowledges that it has acted in breach of the Code, the Ethical Committee may immediately decide on the relevance of that breach, remedy and potential sanctions.

2.3.2 Where the allegations are rejected by the defendant, the reasons for such rejection must be clearly stated and, where appropriate, supporting data (e.g. scientific evidence to support claims which have been questioned) must be provided by the defendant to the Ethical Committee.

2.3.3 The defendant must provide the Ethical Committee with the full address of headquarters of its company and the name of responsible Regional Manager (including his/her e-mail address) within fifteen working days from the receipt of the copy of the complaint from the Ethical Committee.

2.4 Adjudicating of Complaints, Rulings

2.4.1 After receiving the statement from the defendant or upon expiration of the period for submitting the defendant's written statement or comments, the Ethical Committee must process the complaint during its next meeting. If the Ethical Committee finds it necessary or required the plaintiff and the defendant may be invited to this meeting to present their statements.

2.4.2 The Ethical Committee must rule whether the Code was breached. Provided that it rules that the breach had occurred, it must concurrently detect one of the following levels of its seriousness:

"**Minor breach**" is a breach of this Code that has no safety implications to the patient's well-being and will have no major effect on how the persons authorised to prescribe medicinal product will prescribe the medicinal product (e.g. advertisement and

promotional material with mistakes or defective claims which do not neglect safety nor exceed the approved indications).

"**Moderate breach**" is a breach of this Code that has no safety implications to the patient's well-being but may have an effect on how the persons authorised to prescribe medicinal product will prescribe the medicinal product (e.g. advertisement or promotional material indicating wider indications, unsubstantiated claims, imprecise data publishing regarded to value transfer, etc.).

"**Severe breach**" is a breach of this Code that will have safety implications to the patient's well-being and/or will have a major effect on how the persons authorised to prescribe medicinal product will prescribe the medicinal product and/or will have a negative impact on a pharmaceutical industry reputation (e.g. unsubstantiated claims on safety of a medicinal product, prescription induction, data suppression or failure to publish data on value transfer, etc.).

"**Repeat of the previous breach**" means the situation where the same or similar breach is repeated in the promotion of a particular medicinal product of a Member, which had been found in breach of this Code in the preceding 24 months.

"**Breach repetitions**" means the situation where a Member repeats the same type of breach within a period of 12 months in the promotion of any of the Member's products.

The Ethical Committee must advise the plaintiff and the defendant on its ruling without any undue delay.

2.4.3 If the Ethical Committee rules that the Code was breached, and the defendants do not appeal such ruling following Section 2.5.1 hereinbelow, the defendant must be obliged to submit to the Ethical Committee its acceptance of the said ruling within fifteen working days from being notified thereof, containing a written undertaking that the activity, which was at variance with the Code, will cease forthwith and that all possible steps will be taken to avoid a similar breach of the Code in the future. This undertaking must be signed by the General Manager of the defendant or the appointed representative of the defendant for the membership in the AIFP and must be accompanied by the details of the actions taken by the defendant to implement the undertaking, also including the time schedule for implementation thereof, as well as the last date on which the activity breaching the Code took place.

2.5 Procedure of the Appeal

2.5.1. If the plaintiff or the defendant does not accept the ruling of the Ethical Committee, it has the right to appeal and submit its arguments in writing supporting its appeal to the Supervisory Board as the Appellate Body within 15 working days following notification of the ruling.

2.6 Ruling of the Appellate Body

2.6.1 After receiving an appeal, the Appellate Body must meet during the next four weeks.

2.6.2 The representatives of the Ethical Committee together with the plaintiff and the defendant are invited to the meeting of the Appellate Bod to present their statements.

2.6.3 Where the Appellate Body rules that there is a breach of the Code, the defendant must be advised in writing on such ruling and must be given the reasons for such a decision.

The defendant then has ten working days to provide a written undertaking providing the information specified in Section 2.4.3 above.

2.6.4 Where the Appellate Body rules that there is no breach of the Code, the plaintiff, the defendant and the Ethical Committee are advised on the ruling in writing.

2.6.5 The decision of the Appellate Body is final.

2.7 Special Provisions for Decisions of the Appellate Body in Matters of Appeals Against a Resolution of the Ethical Committee on the Rejection of a Complaint

2.7.1 After the plaintiff's appeal against the resolution of the Ethical Committee on the rejection of the complaint pursuant to Article 2.1.6 has been received by the Appellate Body, it must meet for a meeting within the next four weeks.

2.7.2 Representatives of the Ethical Committee and the appellant who has filed the appeal are invited to a meeting of the Appellate Body to present their views.

2.7.3 If the Appellate Body decides that the complaint should have been accepted for review by the Ethical Committee, it must issue a decision ordering the Ethical Committee to accept and discuss the complaint. This decision must be notified in writing to the Ethical Committee and the plaintiff.

2.7.4 In the event referred to in the previous paragraph, the Ethical Committee must be obliged to accept and discuss the complaint following these Complaints Review Procedures.

2.7.5 If the Appellate Body decides that the plaintiff's complaint has been rightfully rejected, it must issue a decision to that effect and notify the plaintiff and the Ethical Committee thereof in writing.

2.7.6 The decision of the Appellate Body is final and cannot be appealed.

2.8 Execution of Rulings

2.8.1 The Member who has submitted a written undertaking to the Ethical Committee under Section 2.4.3 above must be obliged to observe and duly discharge such undertaking.

2.8.2 The Member must be obliged to duly fulfil sanctions and measures imposed by the Ethical Committee in compliance with the respective ruling of the Ethical Committee.

2.8.3 If the Member has not appealed the ruling of the Ethical Committee following Section 2.5.1 above, but it failed to fulfil its obligation under Section 2.4.3 above, the Ethical Committee may impose a sanction in form of a fine up to € 5,000 upon it, even repeatedly, until the Member duly fulfils its obligation under Section 2.4.3 above.

2.8.4 If the Member has not appealed the ruling of the Ethical Committee following Section 2.5.1 above and failed to fulfil sanctions or measures imposed by the Ethical Committee duly and on time, or if it fails to pay the fine imposed under Section 2.8.3 above, the Ethical Committee may impose a sanction in form of a fine up to € 10,000 upon it, even repeatedly, until the Member duly fulfils imposed obligation or measures, including the payment of the fine; in such an event the Ethical Committee may, at its own discretion, submit a proposal to the Supervisory Board for expelling the respective Member from AIFP.

2.8.5 If a Member does not accept the ruling of the Appellate Body and does not submit a written undertaking containing the information specified in Section 2.4.3 above to it, or if it accepts the ruling of the Appellate Body but fails to fulfil its obligation to submit a written undertaking under Section 2.4.3 above to it, or if it fails to fulfil sanctions or measures imposed by the Appellate Body, the Appellate Body must be obliged to submit a proposal for expelling the respective Member from AIFP at the next General Meeting.

2.8.6 Provisions of this Section 2.8 must apply to all complaint review procedures under this Annex and all rulings of the Ethical Committee and Members' written undertakings under Section 2.4.3 above, including those which as of 1 July 2019 have not been executed duly and on time.

Typical Decisions and Actions Taken by the Ethical Committee:

A.1

Decision:

The complaint is not justified.

Action:

Reply to the plaintiff advising that the complaint is not justified and explaining the reasons for this decision and, eventually, request the plaintiff to provide more evidence.

A.2

Decision:

There is insufficient evidence to judge complaint.

Action:

Reply to the plaintiff requesting more information.

A.3

Decision:

The complaint is justified but is of a minor nature and it is the first offence by the Member.

Action:

Advise the respective Member of the Ethical Committee's decision. The Member would be requested to write and confirm that it:

(i) accepts the Ethical Committee's decision;

(ii) agrees not to repeat the offending activity;

(iii) writes and apologise to the plaintiff.

If a Member does not agree with the ruling of the Ethical Committee, it must have the right to appeal and present its case directly to the meeting of the Appellate Body.

A.4

Decision:

The complaint is justified but is of a major nature or it is the repeated offence by the Member committed within the past 24 months.

Action:

Advise in writing to the superior Managing body (Regional manager, Medical Director or CEO) of the Member's parent company on the Committee's findings by sending the decision of the Ethical Committee and, as applicable, of the Appellate Body and request confirmation that the Member:

(i) accepts the Ethical Committee's decision;

(ii) agrees not to repeat the offending activity;

(iii) apologises in public in a way determined by the Ethical Committee provided that such an obligation has been imposed upon it.

If a Member's parent company does not agree with the ruling of the Ethical Committee which has not been appealed by the Member, a Member's parent company must have the right to appeal for the Member within 15 days following the receipt of the Ethical Committee's decision; in such event, provisions concerning the procedure applicable to appeal filed directly by the Member must apply to the appeal and the procedure held before the Appellate Body mutatis mutandis.

3. General Provisions

3.1 Enforcing the Code

3.1.1 The enforcing of the Code must be supervised by the Ethical Committee which must be responsible to the General Meeting of AIFP. Expert advice may be sought externally by the Ethical Committee in deciding as to whether or not a breach of the Code has occurred.

3.1.2 Under meeting conditions specified herein, the Ethical Committee may submit a proposal for expelling the Member from AIFP to the Supervisory Board.

3.1.3 Subject to the Ethical Committee's proposal, the Supervisory Board may submit a proposal for expelling the Member from AIFP to the General Meeting.

3.1.4 Unless otherwise provided herein, the terms and expressions contained herein must have the meaning defined or assigned to them in the Code.

3.2 Issuing of an Annual Report

3.2.1 The Ethical Committee must prepare an annual report and distribute it to all Members. The Ethical Committee can recommend publishing this report. This report must contain the following information:

a) sections of the Code which were breached and the reasons for the breach,

b) the sanctions imposed for the breach,

c) the total number of complaints received and the totals from the various sections of the industry,

d) the total number of breaches,

e) the total number of appeals and the outcome of those appeals.

3.2.2 The Ethical Committee must be obliged to ensure to publicise all final decisions issued in particular cases in their full wording, or if only selected information is made public, to such extent of information which reflects the seriousness and/or the span of the breach, as follows:

a) in cases of severe or repeated breach the name of the Member(s) who has breached provisions of the Code together with the details on the case must be disclosed;

b) in cases of minor or moderate breaches, or if the breach was not proven, disclosing details on the case does not have to contain the name(s) of the concerned Member(s);

c) the Ethical Committee may issue the summary in Slovak and English language to the members of those cases which are precedential or are of importance as regards to the application practise (i.e. both those, where the breach had occurred as well as those where the breach not been proven but the case is remarkable and valuable).

3.3 Sanctions

3.3.1 Imposing a fine by the Ethical Committee or the Appellate Body upon the defendant is fully following the Code's provisions.

3.3.2 Sanctions may be imposed in the following form:

- fines,
- a duty to apologise in public in a way determined by the Ethical Committee or the Appellate Body, or
- suspension of membership or expelling from AIFP (this sanction falls under the supplementary approval of the General Meeting of AIFP).

3.3.3 The fine is due within 15 days following expiration of the time period for submission of appeal and in case of an appellate decision within 30 days following delivery of a written notification on the Appellate Body's decision. The fine imposed pursuant to Section 2.8.3 of this Annex must be payable within 15 days following receipt of the decision on its imposing by the respective Member.

3.3.4 The schedule of fines for breaches under the Code must be as follows:

Minor Breach *	up to € 2,000
Moderate Breach* *	up to € 4,000
Severe Breach*	up to € 7,000
Repeat of Previous * (within past 24 months)	up to € 20,000

Breach Repetitions*	a fine for repetition of the previous breach is always two times higher, but the maximum fine is € 20,000

3.3.5 If the Ethical Committee or the Appellate Body believe that a breach of the Code warrants the suspension or the expulsion of the Member, it will make such a recommendation to the General Meeting of AIFP which may then impose the following sanctions:

- suspension of the Member's membership in AIFP for a certain period of time,
- expulsion of the Member from AIFP.

EXPLANATORY NOTES

The fine is paid in the form of an additional membership fee.

This Ethical Code must become effective on 19 September 2014.

Date of the last text revision: February, 8th 2022

Name:	MUDr. Branislav Budke, v.r.	Name:	Ing. Iveta Pálešová, v.r.
Office:	Chairman of the Supervisory Board of AIFP	Office:	Executive director
Date:	8.2.2022	Date:	8.2.2022