

THE CODE OF CONDUCT
OF THE ASSOCIATION OF INNOVATIVE
PHARMACEUTICAL INDUSTRY

ADOPTED IN BRATISLAVA

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PREAMBLE

- A. This Code owes its origin to the determination of AIFP* to secure universal acceptance and adherence to high ethical standards in the marketing of prescription-only medicinal products*.
- B. This Code regulates 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.
- C. 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.
- D. This Code shall not apply to the following:
- the labelling of medicinal products and accompanying package leaflets;
 - correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;
 - factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general precautions, 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 to current/prospective employees), including financial data, descriptions of research and development programmes, and discussion of regulatory developments affecting a company and its products.
- E. 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.
- F. 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. In addition, the Members shall 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.

- G. Pharmaceutical companies being not Members of AIFP are hereby invited to accept and observe this Code.
- H. The Code shall be supervised and exercised by the Ethical Committee. The Ethical Committee may issue interpretation from time to time in order to construe certain sections of the Code. Complaints concerning alleged breaches of the Code should be reported to the Ethical Committee.
- I. A major guiding principle of this Code is that, whenever a promotional claim* is made for a medicinal product, it shall be accompanied by the Product Information* in Slovak language.
- J. Failure to comply with this Code will result into 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.
- K. In respect of the applicable laws, AIFP must facilitate the Members' awareness of and education about this Code, including providing guidance to the Members in order to prevent breaches of this Code.
- L. 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 or interaction takes place.

Note:

The Glossary of 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 shall be marked by 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 any and all promotional material* is true, correct*, accurate, updated, verifiable and fully supported by the Product Information, literature* or Data on File*, where the latter do 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 manufacturer shall, 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 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” shall not be accepted.

(c) In the event that information on which a claim is based may not be disclosed, e.g. an “in press” article which is subject to confidentiality provisions, then such information may not be used to substantiate a claim for the purposes of satisfying 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 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 cause 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, 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 with respect to 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 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 a 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.

1.8 Imitation

Promotional information should not imitate the devices, copy slogans or general layout adopted by other manufacturers in a way that is likely to 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 so as 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 shall 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 shall 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 a promotion and SmPC of a medicinal product.

2.3 Changes of Clinical Significance

2.3.1

Where a change of clinical significance relating to 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.

2.3.3

Where a Member is not actively promoting the medicinal product, written advice of the change of SmPC should be notified in writing to the appropriate healthcare professionals authorised to prescribe such medicinal product.

3. PROMOTIONAL MATERIAL

3.1 Acceptability and Legality of Promotion

3.1.1

The Members must maintain high ethical standards at all times. The promotion must:

- never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry,
- be of a 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 shall 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 shall 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 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 the Act 147/2001 Coll. on Advertising, as later amended] shall 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 prior consent of its addressee.

3.2 Journal Advertising

Journal Advertising must conform to the requirements set forth in Sections 3.2.1 to 3.2.3 hereof. Information required shall 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 individual 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 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 shall not be permitted prior to expiration of 12 months from the first advertising of a new active substance or prior to 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 shall 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 shall 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 shall not be considered as Member Commissioned Articles. In the event that a Member sponsors such a supplement, it is recommended that this fact should be stated clearly in such 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 shall 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 to prescribing, please review the product information. The product information is enclosed hereto.". The item is then to be accompanied by a 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 in order 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 for 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 from personal communications must be faithfully reproduced, it must accurately reflect the meaning of the author and 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. 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 Computer based promotional material

3.3.4.1

Computer based promotional material must comply with all relevant provisions of this Code related to 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 the computer based material 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 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 with 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 be complied promptly and no name shall 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 of 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 of ongoing training for their medical representatives.

4.3

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

Each Member shall ensure that its medical representatives, including personnel retained by way of contract with third parties, and any other company 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. Certification shall 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 the manner in which they are made, are such as not to cause inconvenience. The wishes of an individual healthcare representative, or the arrangements in force at any particular establishment, must be observed by medical representatives. Medical representatives are not allowed to attend healthcare professionals

during the doctor's office hours of the healthcare professional, if the intention is to promote a medicinal product.

4.7

Medical representatives must not use the telephone to promote medicinal products to the healthcare professionals, if refused by the healthcare professional.

4.8

Wherever a promotional claim is made, the medical representative shall provide SmPC, as well as other information required by law and this Code.

4.9

Under no circumstances shall medical representatives pay a fee in order to gain access to a healthcare professional.

4.10

Every Member must establish a scientific service in charge of information about its medicinal products. This scientific service must include a doctor or a pharmacist 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 in accordance with 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 company must appoint at least one employee who shall be responsible for supervising the company 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 with any information which they obtain in respect of the use of their 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 participation of healthcare professionals, shall 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 in order to avoid any doubt about their affiliation to the Member they represent thereat. They shall 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 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 professional events.

4.5, 4.6

Medical representatives may be used to obtain survey information in accordance with Section 3.3 hereof. However, the pretext of carrying out a survey to gain an extended interview should be avoided.

5. PRODUCT SAMPLES

In accordance with the Directive 2001/83/EC of the European Parliament and of the Council, free samples shall be provided on an exceptional basis only and only to qualified persons.

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

Samples may be supplied to the qualified persons so that they can familiarise 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 afore stated samples may be supplied to the particular healthcare professional within 2 years after his/her obtaining of an 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 of 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 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 supply of samples.

5.4

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

6. EXHIBITIONS AT PROFESSIONAL EVENTS

General Principle

Exhibitions are important for the dissemination of knowledge and experience to healthcare professions. The prime objective in organising such exhibitions should be the enhancement of medical knowledge. Where hospitality is associated with exhibitions, it should always be secondary to the main purpose of the exhibition.

6.1

Exhibitions must only be directed to healthcare professionals.

6.2

An exhibition must include, in a prominent position, the name of the sponsoring or financing Member.

6.3

Exhibitors must comply with all requirements of the person organising professional event when mounting and conducting an exhibition.

6.4

SmPC of the medicinal products being presented at the exhibition must be available at the exhibition stand.

6.5

Competitions that are held as part of an exhibition must be consistent with the general rules of this Section.

6.6

All materials used at the exhibition must be consistent with the requirements of Sections 1.3.1 and 3.3 hereof.

EXPLANATORY NOTES

6.

All material used at exhibitions must be consistent with the requirements of Section 3.3 hereof.

However, given the nature of attendees at international professional events 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 registered in the Slovak Republic, provided that any display

material or educational material used clearly identifies 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 recognise that the medicinal product or indication is unapproved in the Slovak Republic.

Information regarding such 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.

6.6

See also Section 3.1 hereof.

7. TRAINING ACTIVITIES

7.1

The following shall apply to Members sponsoring delegates travelling from or within the Slovak Republic to professional events:

All professional events organised or sponsored by a Member must be held in an appropriate venue that is conducive to the main purpose of the event and may only offer hospitality when such hospitality is appropriate and otherwise complies with the provisions of this Code.

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

- a) the majority of the invitees comes from outside of the Slovak Republic 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, alternatively, a local advise must be taken, save for the professional events organised by the professional societies.

Hospitality provided in connection with professional events shall be limited to travel, meals, accommodation and genuine registration fees. Hospitality may only be provided to qualified participants of the professional event (healthcare professionals).

All forms of hospitality offered to healthcare professionals shall be reasonable in level and strictly limited to the main purpose of the professional event. As a general rule, the hospitality provided must not exceed what recipients (healthcare professionals) would normally be willing to pay for themselves.

Hospitality shall not include organising or sponsoring of entertainment events (e.g. sporting or leisure) events. Members should avoid using venues renowned for their entertainment facilities.

Travel agenda and programme of professional events should be approved in accordance with operating procedure of the respective Member.

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

7.2

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

7.3

The professional event's focus should be only targeted on scientific, professional or educational purposes and hospitality must always be secondary to the main purpose of the professional event.

7.4 **Qualifying criteria for venues for organising professional events organised or sponsored by AIFP members**

All professional events (events held for professional, scientific or educational purpose), 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) (hereinafter referred to as the "professional event") 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.

A hospitality may be offered at the professional event only when such hospitality is appropriate and otherwise complies with the AIFP Ethical Code. Generally, the term "hospitality" refers to the relationship between a guest and a host, wherein the host receives the guest with goodwill, including the reception and entertainment of guests. Hospitality, therefore, is not limited just to boarding and nourishment of the professional event participants but includes also other forms of spending their leisure time at 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 shall not represent, for the 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 shall always be organised or held in a venue which can be presumed to be possibly selected if no sponsorship or involvement of pharmaceutical industry would occur there, i.e. what the professional event participants would select as a venue of their professional event if all their costs related to their participation at the professional event would be borne by themselves.
3. The professional event shall always be organised or held in a venue that is appropriate and as such not renowned or extravagant.
4. The venue is appropriate for organising professional events if the main purpose of its regular use, for which it is also adequately equipped, is holding of professional, educational or scientific events, or if it is commonly renowned for being used for the said purposes. Such venues mainly include educational or conference centres and conference hotels in cities with good transport access and parking. Five and more-stars hotels are not considered to be adequate for organising professional events.
5. The venue is considered renowned if it is generally known and recognised for its superb or exclusive peculiarities or features and as such is considered as sports, cultural,

entertainment and/or tourism venue sought mainly for leisure activities. For example, renown venues comprise holiday, golf, spa, amusement or ski resorts, casinos, vineyards, etc. Geographical location of the venue is not making it automatically renown, unless the venue's facilities (its own or located in its proximity – as defined herein below) are renown.

6. The venue is considered extravagant if it is generally known and recognised as luxurious and spectacular place that is not commonly perceived as professional, educational, scientific or congress centre. For example, extravagant venues are five and more-star hotels, extra-urban facilities in refurbished castles and palaces, etc.
7. The professional event shall 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, the venue shall not be selected for organising professional events in winter. However, if the distance of such skiing facilities from the venue is greater than 10 kilometres, the venue shall be considered as appropriate and not renown.
8. The professional event shall not be held in a venue whose general characteristics promoted, advertised or perceived by lay public are considered as entertaining. For example, the said characteristics shall include all types of aqua parks, amusement parks, spas, casinos and gambling facilities.
9. If the professional event is organised or held in a venue which, but just in a marginal or non-significant scope, allows for the use of its own or adjacent facilities intended for a 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 the AIFP member companies when sponsoring or organising the professional event, nor hidden 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.

These Qualifying criteria shall become effective as of 1 January 2017 in relation to professional events organised by Members and as of 1 July 2017 they shall become effective in relation to professional events organised by third parties provided that they are supported or sponsored by the Members.

The Ethical Committee shall 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.

EXPLANATORY NOTES

7.1

Appropriate centre is international standard generally accepted for medical audience. Adequate location is the Slovak Republic in case of events organised by the Member. Location is not restricted in cases of international events organised by international medical society and free standing company symposia with significant international participation.

International events organised by the “mother” company from abroad must comply with the local applicable legislation and the Ethical Code.

8. RESEARCH

The following provisions shall relate to any financially rewarded research performed and/or sponsored by the pharmaceutical industry, with the exception of 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 of and supplement to certain acts, as later amended, regardless of the fact whether it is performed by the manufacturer or by an organisation acting according to or on the basis of the manufacturer's instructions.

Researches shall 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 of and supplement to certain acts, as later amended,
- b) other studies and researches, where data collection is not directly related to the prescription of a certain drug (e.g. epidemiological studies, marketing researches).

EXPLANATORY NOTES

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

8.1 Non-interventional Clinical Trial (NCT)

8.1.1

The aim of NCT is to acquire scientific and professional information defined in 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 122/2013 Coll. on Personal Data Protection and on amendment of and supplement to certain acts, as later amended, must be obeyed. NCT must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal product.

8.1.2

NCT is defined in Section 45 of the Act 362/2011 Coll. on Drugs and Medical Devices and on amendment of and supplement to 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.

8.1.3

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 results not shorter than two months following completion of NCT,
- i) financial compensation of the professional guarantor of NCT.

Each NCT must have an 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 shall be also obliged to supervise performance of NCT, as well as by the healthcare insurance company of each NCT participant. The NCT sponsor shall forward the protocol approved by the healthcare insurance company of the NCT participant to the National Centre of Medical Information which shall publish it on its website within three days following the delivery. The NCT sponsor shall forward a copy of processed results to the healthcare insurance company of the NCT participant as well as to the National Centre of Medical Information which shall publish it on its website within three days following the delivery.

EXPLANATORY NOTES

8.1.3

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 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 absolutely inevitable number necessary to answer the question resulting from the purpose of NCT.

Data processing method. Statistical methods planned to be used in 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 shall mean presentation of results to the professional public. The form may be a lecture, a poster or a publication in a professional periodical.

8.1.4

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.

8.1.5

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.

8.1.6

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

8.1.7

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

8.1.8

Medical representatives are excluded from the following stages of NCT:

- formal compilation of the agreement (completion of the necessary forms, etc.),
- agreement concerning compensation for the cooperation,
- payment of any compensation.

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

EXPLANATORY NOTES

8.1.8

- *Medical representatives must be informed before NCT commences on how to report adverse events and who is the contact person for the adverse events reporting at the Slovak branch or at the headquarters.*
- *Medical representative should only deliver contract which was already prepared by the sponsor, and if it is signed by the healthcare professional he/she should bring it back to the sponsor.*
- *Medical representatives shall distribute protocols, questionnaires and contracts and if the post is not used, they collect questionnaires.*

8.1.9

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 of and supplement to certain act, as later amended,
- hourly compensation for one completed patient record paid to the solving team member,
- total maximum compensation paid within one centre.

8.2 Other Studies

8.2.1

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 shall not be monitored in these studies.

The following lists some examples of other studies:

- marketing researches to establish the position of a medicinal product in relation to other medicinal product of the 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,
- epidemiological researches to establish the occurrence of a certain disease.

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

8.2.2

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. The sponsor shall 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.

8.2.3

The compensation of a solving team member for cooperation on other studies has to be in accordance with the work performed, and it may not exceed the usual amount with respect to the character of the performed work.

8.2.4

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.).

8.2.5

Prior to implementation of the other studies the sponsor shall be obliged to make a notification thereof through an electronic form located on the AIFP website in the section Ethics Working Group. 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 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.

8.3 Notification

NCT as described in Section 8.1 hereof and other studies as described in Section 8.2 hereof shall be notified electronically through the AIFP website in the section Ethics Working Group.

8.4 Disclosure and Supervision

The notifications as described in Section 8.3 hereof shall be published and made available for disclosure to all Members on the AIFP website in the section Ethics Working Group.

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

9. 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.

9.1 Hospitality

Hospitality offered to healthcare professionals should always be appropriate, 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 shall prevail.

9.2 Medical Educational Material

9.2.1

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.

9.2.2

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

9.2.3

Informational and educational material cannot induce recommendation, prescription, purchase, supply, sale or administration of the specific medicinal product and its value may not exceed € 20 per item.

9.3 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 9.5 hereof or not otherwise covered by this Code) are only allowed if such services (or other funding): (i) are provided for the purpose of supporting healthcare or research; and (ii) do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal product.

9.4 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 shall also be prohibited to supply, offer and promise gifts, pecuniary advantages or benefits in kind to healthcare professionals in order 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.

9.5 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 for the purpose of supporting 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 9.4 hereof) and grants to individual healthcare professionals are not permitted under this Section. Company sponsorship of healthcare professionals to attend professional events is covered by Section 7 hereof. Members are encouraged to make available publicly information about donations, grants or benefits in kind made by them under this Section 9.5.

9.6 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. Private healthcare providers (individuals and entities) are excluded from donations. 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.

EXPLANATORY NOTES

9.6

- *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. 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)].*

9.7 Prohibition of Lease

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

9.8 The Use of Consultants

9.8.1

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 consultancy 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 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 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 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.

9.8.2

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.

9.8.3

Limited market research, such as one-off phone interviews or mail/e-mail/internet questionnaires are excluded from the scope of this Section 9.8.2, 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

9.8.3

The minimum remuneration shall mean a remuneration not exceeding 1/3 of the minimum monthly wage per one healthcare professional, Member and year.

9.8.4

If a healthcare professional attends a professional event (an international or other) in a consultant or advisory capacity, the relevant provisions of Section 7 hereof shall apply.

9.9

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.

10. RELATIONS WITH PATIENTS ORGANISATIONS

The code of relationships of AIFP with patient organisations has been constituted in order to ensure relationships between pharmaceutical industry and patient organisations in ethical and transparent manner. The independence of patient organisations, in terms of their political judgement, policies and activities, shall be assured.

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

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

The objectives and scope of any partnership shall be transparent. Financial and non-financial support provided by pharmaceutical companies shall always be sufficiently documented.

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

EXPLANATORY NOTES

Patient organisations shall 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.

In order to avoid doubts, the term “pharmaceutical company”, as used in this Section 10, shall 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” shall mean any mutual interaction, including funding.

10.1 Written Agreements

When pharmaceutical companies provide financial support, significant indirect support and/or significant non-financial support to patient organisations, such a 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 description of significant indirect support (e.g. donation of public relations agency’s time) and significant non-financial support. Each Member should have an approval process in place for these agreements.

EXPLANATORY NOTES

The significant support shall 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 on 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 shall be subject to the agreement, however their minimal scope must meet requirements set out herein.

10.2 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.

10.3 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.

10.4 Transparency

10.4.1

Each Member must at least once a year, however no later than by March 31 of the following year, make publicly available on their website or on the website of AIFP a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support. This should include a detailed description of the nature of the support in order to enable the average reader understand importance of such support. The description should include amount of the financial support and invoiced costs. Provided that a significant non-financial support cannot be equivalently expressed in terms of money, a description should then clearly specify a 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.

10.4.2

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

10.4.3

Each Member must make publicly available a list of patient organisations which it 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 shall also disclose the total amount paid to each patient organisation during the respective period for which the data is reported.

10.5 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 shall mean business activities of Members, artistic work, sport activities, rehabilitation stays, consultancy and patients' rights protection, lecturing and education, participation at workshops and congresses related to physical and mental health of patients, proactive participation on the law-making process related to the rights of patients.

10.6 Events and Hospitality

10.6.1

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

10.6.2

All forms of hospitality provided by Members to patient organisations and their members shall be reasonable in level and secondary to the main purpose of the event, whether the event is organised by the patient organisation or the Member.

EXPLANATORY NOTES

10.6.1

An appropriate venue shall mean a commonly accepted standard for patients. The Slovak Republic shall be adequate for this purpose if the event is organised by the Member. The locality shall 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 shall mean centres, the main operational purpose of which is entertainment, relax and sport.

10.6.2

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

10.6.3

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

10.6.4

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.

10.7 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 for the purpose of supporting 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 consultancy 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 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 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 significant contractual support – *see Section 10.4.3 above, Explanatory Notes.*

11. RULES FOR DIALOGUE AND NEGOTIATION WITH DECISION MAKERS

11.1 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 in order for such dialogue to be of an open, honest, honourable and authentic character. The ethical rules shall also ensure that mutual relations of the parties to the dialogue are not economically based and that no mutual pressure of the parties occurs.

11.2 Definitions

“Political Representatives” shall mean members (or candidates) to the National Council of the Slovak Republic, local council (or municipal council), regional council or the European Parliament.

“Officers” shall 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 is applicable for example to employees or elected representatives of regional councils or municipalities;
- the European Commission or other administrative body of the EU.

“Decision Maker” shall mean a Political Representative or an Officer.

“Pharmaceutical Company” shall mean Members or their representatives.

“External Consultant” shall 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” shall mean an employee of a Pharmaceutical Company or External Consultant working for the given company.

Provisions of this Section 11 shall also apply with respect to: physicians, stomatologists, veterinarians, pharmacists, nurses, veterinary nurses, pharmacy-economists and the students of these particular specialisations.

“Dialogue” shall mean all types of oral and written communication carried out between Company Representatives and Decision Makers.

“Negotiation” shall 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.

11.3 The scope

11.3.1

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.

11.3.2

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.

11.3.3

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

11.4 Transparency

11.4.1

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 prior invitation. The said also applies where an individual External Consultant represents interests of more Pharmaceutical Companies.

11.4.2

Pharmaceutical Company shall be obliged to ensure and demonstrate the full openness when providing remuneration to the Decision Maker (compare exemptions included in Section 11.8.3 hereof).

11.4.3

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 through stating the name or registered business name of the particular External agency / Consultant / legal representative.

In terms of time, disclosure should be carried out without undue delay following entering into agreement 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.

11.5 Information Requirements

11.5.1

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

11.6 Decent Behaviour

11.6.1

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 shall 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.

11.7 Confidential Information

11.7.1

Company Representative shall 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 shall be prohibited.

11.8 Independence

11.8.1

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

11.8.2

Under no circumstance shall 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.

11.8.3

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 a in a direct interest of the Pharmaceutical Company. Nevertheless, the said shall 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 shall 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 11.3 and 11.4 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 shall be provided only with respect to 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 with respect to those services related to education or lecturing and must be reasonable as compared to the services provided.

11.8.4

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.

11.8.5

Company Representative may provide relevant hospitality at direct meetings of Company Representative and the Decision Maker or at the presence at thematic days, conferences, etc. held and financed by the Pharmaceutical Company; the said shall 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 with respect to 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.

11.9 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.

12. PUBLIC AND MEDIA RELATIONS

Information delivered to public has to be used exclusively for improvement of public knowledge from medical and healthcare area only and cannot be used for 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 unproved 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 to 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 reader's interests.

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

12.1 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.

12.2 Press Releases

Press release has to follow all rules stated under this Section 12. Content of press release has to use proved facts without advertising messages.

12.3 Press Conferences

Information delivered to journalists has to follow all rules stated under this Section 12. 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.

12.4 Radio and TV

Radio and TV broadcasts have to follow all rules stated under this Section 12.

12.5 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 educational or expert purpose only and hospitality must be secondary to the main purpose of the event.

EXPLANATORY NOTES

No name of medicinal product or active substance may be used in Member communication addressed to the general public.

13. 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.
- In relation to marketing and promotion activities, internet is considered information and promotion medium for both general public and healthcare professionals.

13.1 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 any combination thereof); and
- e) purpose or objective of the website.

13.2 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 corporate 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 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 shall 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 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.

13.3 E-mail Queries

The website can contain a contact e-mail address for healthcare professionals, patients or general public. The said address shall enable e-mail communication in order 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 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.

13.4 Links from Other Websites

Links to a Member sponsored website can be established on websites sponsored by other persons. However, on websites aimed to general public, Members should not establish links to websites sponsored by Members, which are aimed to 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.

13.5 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.

13.6 Scientific Reviews

Members should make sure that any scientific and medical information for their websites are reviewed in order to be in accordance with applicable regulations.

13.7 Privacy

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

EXPLANATORY NOTES

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

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

14.1 General Rules

Within the framework of a 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 pharmaceutical industry and healthcare professionals has a profound and positive influence on the quality of patient treatment and the value of a future research. AIFP also believes that integrity of a decision of a healthcare professional to prescribe a medicinal product is one of the pillars of healthcare system. AIFP recognises that interactions between pharmaceutical industry and 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 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 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 shall 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 14 set down the minimum standards to be applicable to all Members. All Members are required to satisfy them in compliance with applicable legal regulations. Where specific legal regulations request disclosure in more detail and/or under a different structure, providing such disclosure shall be considered as meeting requirements stipulated in this Section 14.

14.2 Disclosure Obligation

14.2.1 General obligation

Each Member shall 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 healthcare professional.

14.2.2 Excluded disclosures

Transfers of Value which (i) are solely related to over-the-counter medicinal products, (ii) are not listed in Section 14.4 hereof, such as items of medical utility, meals and drinks, medical samples, or (iii) are part of 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.

14.3 Form of Disclosure

14.3.1 Annual disclosure cycle

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

14.3.2 Time of disclosure

Disclosures shall be made by each Member Company within six months after the end of the relevant Reporting Period and the information disclosed shall be required to remain in the public domain for a minimum of three years after the time such information is first disclosed in accordance with Section 14.3.4 hereof, unless in each case (i) a shorter period is required under applicable data privacy or other laws or regulations, or (ii) the recipient’s consent relating to a specific disclosure, if required by applicable national law or regulation, has been revoked.

14.3.3 Template

For consistency purposes, disclosures will be made using a structure set forth in Section 0 hereof.

14.3.4 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 shall be made, so far as possible, using a structure set forth in Section 14.7 hereof.

14.3.5 Language of disclosure

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

14.3.6 Documentation and Retention of Records

Each Member shall 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.

14.3.7 Application for correction of disclosed data

The healthcare professional whose personal data have been disclosed under Section 14 hereof may at any time ask the Member, being the data controller, in writing for rectification of its incorrect, incomplete or non-actual disclosed personal data.

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

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

14.4 Individual and Aggregate Disclosure

14.4.1 Individual disclosure

Except as expressly provided by this Code, Transfers of Value shall be disclosed on an individual basis. Each Member shall 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 shall 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 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 on 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 on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

14.4.2 Aggregate Disclosure

Regarding Transfers of Value where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Section 14.4.1 hereof, cannot be disclosed on an individual basis for legal reasons, a Member shall disclose the amounts attributable to such Transfers of Value in each Reporting Period on an aggregate basis. Such aggregate disclosure shall 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.

14.4.3 Non Duplication

Where a Transfer of Value required to be disclosed pursuant to Section 14.4.1 or 14.4.2 hereof, is made to an individual healthcare professional indirectly via healthcare organisation, such transfer can be only published once. Such Transfer of Value shall only be required to be disclosed once. To the extent possible, such disclosure shall be made on an individual healthcare professional named basis pursuant to Section 14.4.1 (2) hereof.

14.4.4 Research and Development Transfers of Value

Research and development Transfers of Value in each Reporting Period shall be disclosed by each Member Company on an aggregate basis. Costs related to events that are clearly related to activities covered in this Section 14.4.4, can be included in the aggregate amount under the “Research and Development Transfers of Value” category”.

14.4.5 Methodology

Each Member shall publish a note summarising the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category described in Section 14.4.1 hereof. The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Transfers of Value for purposes of this Code, as applicable.

14.5 Enforcement

14.5.1 Enforcement through EFPIA Member Associations

Each EFPIA Member Association shall adopt implementation and procedure rules which will be binding upon its members and set forth the framework for the implementation of Section 14 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

14.5.2 Disclosure Requirements Different from this Code

If the applicable national law or regulation, the relevant national code or other industry self-regulation prescribes equivalent or more stringent disclosure requirements, the relevant Member shall comply with such equivalent or more stringent requirements in a manner as consistent as possible with the substantive disclosure requirements of this Code.

14.5.3 Sanctions

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

14.5.4 Reporting

The AIFP Ethics Working Group together with AIFP Ethical Committee shall produce, at least annually, reports summarising adherence to obligations set out in Section 14 hereof (the first such report is expected to be produced in September 2016).

14.6 Amendments and Guidance Concerning Compliance with Provisions on Disclosure

14.6.1 Compliance with Provisions on Disclosure

The AIFP Ethics Working Group together with AIFP Ethical Committee shall assist the Members to comply with their obligations under Section 14 hereof.

14.6.2 Amendments of Provisions on Disclosure

The AIFP Ethics Working Group together with AIFP Ethical Committee shall regularly review adherence to Section 14 hereof and to all instructions issued in relation to compliance

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.

with Section 14 hereof. Proposed amendments to Section 14 hereof shall be submitted to the Supervisory Board for review and to the General Meeting for approval.

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			
	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 number	Aggregate HCPs number	Aggregate HCPs number	Aggregate HCPs number		
	Number of Recipients in aggregate disclosure						N/A	N/A	number	number	number	number		
	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed						N/A	N/A	%	%	%	%		
	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 number	Aggregate HCOs number	Aggregate HCOs number	Aggregate HCOs number	Aggregate HCOs number	Optional		
	Number of Recipients in aggregate disclosure						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		
	AGGREGATE DISCLOSURE													
	Transfers of Value re Research & Development as defined - Article 14.4.4 and Annex No. 1											TOTAL AMOUNT	OPTIONAL	

14.7 Implementation and procedure rules

14.7.1

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.

14.7.2

By adaptation of an original text and wording of the EFPIA Code and its approval by the General Meeting of AIFP these provisions (Section 14) shall 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, shall be adequately applicable thereto.

ANNEX NO. 1 TO THE ETHICAL CODE

GLOSSARY

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 in accordance with 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) stipulated in the Section 9 hereof.

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 product.

“**Product Information**” means a document containing information about the 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:

- 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).

“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 with a view to making 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, a use for the purpose of 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.

“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.

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 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. 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 previous breach” means the situation where the same or similar breach is repeated in the promotion of a particular product of a company, which had been found in breach in the preceding 24 months.

“Authorised person” includes a person authorised to prescribe medicinal products and a person authorised to dispense medicinal products.

P

“**Breaches after 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 on behalf of 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 a healthcare professional or healthcare organisation as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in the Slovak Republic.

R

“**Reference manual**” is a serial or monographic publication designed by its publisher to provide information in classified sequence for the purposes of 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 marketing of a medicinal product in the Slovak Republic.

“**Promotion**”, “**Promotional**”, or “**Promotional claim**” means presentation of a medicinal product in any form whatsoever with the aim 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 efficacy, rate of adverse reactions or other cautionary aspects of the product and comparative information.

“Promotional material” means any representation concerning the attributes of a medicinal product conveyed by any means whatsoever for the purpose of encouraging the prescription, dispensing, sale or consumption of a medicinal product.

S

“SmPC” means the applicable Summary of Product Characteristics of a medicinal product.

“Correct” means 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 in accordance with 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 medical condition 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 medicinal product among healthcare professionals.

“Reasoning” means giving reasonable grounds in order 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 a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society 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.

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 on a voluntary basis as a prerequisite of their membership in AIFP.

Conduct of the Ethical Committee is not legally binding and should be understood as a 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 shall 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 shall confirm in writing that they will not initiate any legal steps against AIFP, the Ethical Committee or particular members of the Ethical Committee on based on a decision issued by the Ethical Committee in a specific matter.

Subject to an approval by the Supervisory Board of AIFP (hereinafter referred to as the “**Supervisory Board**”), the Ethical Committee shall be entitled to disclose details of its decisions to professional as well as 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) shall, at the same time, be always an internal member of the Ethical Committee. Another three internal members shall be nominated by the AIFP Ethics Working Group from among its members. The nominees shall be appointed by the Supervisory Board.

2.2 External Members

External members of the Ethical Committee may be:

- physician with active ambulant or hospital practise,

- representative of the Pharmaceutical or Medicine Faculty,
- 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 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 shall 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 it required.

5. Terms of Office

Term of office of internal elected members of the Ethical Committee is two 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 shall be elected for a one year term and two member shall be elected for a two years term. Internal elected members of the Ethical Committee appointed in the following years shall 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 shall 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 shall appoint a new member of the Ethical Committee until the end of the elective period of the member whose office shall 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 shall appoint a new member of the Ethical Committee until the new member or Chairman of that working group is elected in a regular manner.

6. Termination of the Office

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

- expiration of the office term of 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 internal member being the Chairman of the AIFP Ethics Working Group shall 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 shall 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 shall 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 shall be adopted if more than a half of all members of the Ethical Committee had voted for it. *Per rollam* voting shall 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 shall follow this Code. The Code of Practice on the Promotion of Medicines of European Federation of Pharmaceutical Industries and Associations (EFPIA Code) is a base for 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 shall 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 shall be also excluded in the event of a complaint filed against the Member he/she represents.

External member shall be excluded from the reviewing process too provided that, with regards to his/her relation to the reviewed matter, or to 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 shall be also excluded if he/she challenges his/her impartiality him/herself with respect to the reviewed matter, or to the Member filing the complaint, or to the Member against which the complaint is aimed.

In the event of 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 shall be adopted if more than a half of all members of the Supervisory Board had voted for it. *Per rollam* voting shall 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 shall be excluded from reviewing and arbitrating on such complaint. Concurrently, that member of the Appellate Body shall be excluded against which the complaint is filed, and shall also be excluded in the event of a complaint filed against the Member he/she represents.

12. Providing Information to the public

Pharmaceutical industry, healthcare professionals as well as the general public shall be informed that the Statute on 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, in order 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.

1.1 Plaintiff and Defendant

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

1.1.2 A defendant, for the purposes of 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) government official or state authority;
- e) patients organisation.

1.2.2 In the event where no formal complaint about 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 (compulsorily) in English language as a copy thereof and 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 legal entity, 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), including e-mail address.
 - d) Name of a medicinal product or medicinal products, if affected by the complaint.
 - e) Reference material which shall be used as an evidence of the alleged breach of the Code.
 - 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 the alleged breach of the Code.
 - h) The date of filing of the complaint.
 - i) A specific reference to the part of the Code under which the complaint is being made (section and paragraph number(s)).
 - 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 whether via post or electronically.

2. Procedure for Filing Complaints concerning the Code

2.1 Validation and Referral of the Complaint

- 2.1.1. A complaint shall be filled with the Ethical Committee by the Member after a negotiation with the alleged Code's violator 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 and
 - 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. In any event, the Ethical Committee is entitled to express its opinion concerning the behaviour of the non-member company.

- 2.1.5. The Ethical Committee will inform the plaintiff and the headquarters and responsible Regional Managers of the defendant if the complaint was accepted for further proceeding. Final decision of the Ethical Committee will be send to the plaintiff and the defendant.

2.2 Time Limits

- 2.2.1 Upon receiving the copy of the complaint from the Ethical Committee, the defendant shall 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 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) shall be provided by the defendant to the Ethical Committee.
- 2.3.3 The defendant shall 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 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 shall process the complaint during its next meeting. The plaintiff and the defendant shall be invited to this meeting to present their statements.
- 2.4.2 The Ethical Committee shall rule whether the Code was breached. Provided that it rules that the breach had occurred, it shall concurrently detect one of the following level 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 (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 previous breach” means the situation where the same or similar breach is repeated in the promotion of a particular 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 shall 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, the defendant has fifteen working days following the delivery of that ruling to provide the Ethical Committee 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 shall 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 to present their statements.
- 2.6.3 Where the Appellate Body rules that there is a breach of the Code, the defendant shall be advised in writing on such ruling and shall be given the reasons of 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 and the defendant are advised on the ruling in writing.
- 2.6.5 The decision of the Appellate Body is final.
- 2.6.6 In the event a Member does not accept the ruling and does not fulfil the required actions, the Appellate Body has to submit a proposal for expelling the respective Member from AIFP at the next General Meeting.

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 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 shall 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 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 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.*

If a Member's parent company does not agree with the ruling of the Ethical Committee it shall have the right to appeal and present its case directly to the meeting of the Appellate Body.

3. General Provisions

3.1 Enforcing of the Code

- 3.1.1 The enforcing of the Code shall be supervised by the Ethical Committee which shall be responsible to the General Meeting of AIFP. Expert advice may be sought externally by the Ethical Committee in reaching a decision as to whether or not a breach of the Code has occurred.
- 3.1.2 Unless otherwise provided herein, the terms and expressions contained herein shall have the meaning defined or assigned to them in the Code.

3.2 Issuing of an Annual Report

- 3.2.1 The Ethical Committee shall prepare an annual report and distribute it to all Members. The Ethical Committee can recommend to publish this report. This report shall contain the following information:
 - a) sections of the Code which were breached and the reasons of 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 shall be obliged to ensure to publicise all final decisions issued in particular cases in their full wording, or if only selected information are made public, to such extent of information which reflect 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) together with the details on the case shall 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 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 of the precedential character or are of an 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 in accordance with 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.

3.3.4 The schedule of fines for breaches under the Code shall 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 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 shall become effective on 19 September 2014.

Date of the last text revision: 15 March 2018



Name: MUDr. Branislav Budke
Office: Chairman of the Supervisory
Board of AIFP
Date: 19/4/2018



Name: Marianthi Psaha
Office: Vice-Chairman of the
Supervisory board of AIFP
Date: 11/5/2018