Code of Conduct

VERSION 18.09.2014

Amendments adopted on 18th September 2014 are coming into force on 1st October 2014.

aifp

Asociace inovativního farmaceutického průmyslu

TABLE OF CONTENTS

PREFACE

The pharmaceutical industry promotes the concept of good health, and a positive, health-oriented approach to daily living. Recognizing that medicines play a vital role in the prevention, amelioration and treatment of disease states, the industry undertakes:

- to provide medicines that conform to the highest standards of safety, efficacy and quality;
- to ensure that medicines are supported by comprehensive technical and informational services in accordance with currently accepted medical and scientific knowledge and experience;
- to use professionalism in dealing with healthcare professionals, public health officials and the general public.

The industry is committed to the quality use of medicines and rationale prescribing, and supports that its products are used in accordance with the directions and advice of healthcare professionals. To ensure that the information is available upon which to make informed prescribing decisions, it is necessary for the manufacturer to disseminate to healthcare professionals the specialized product information gained during the research and development process, and from experience gained in clinical use. In doing so, the manufacturer draws attention to the existence and nature of a particular product by appropriate educative and promotional measures.

With the full cooperation of the industry, there is now adequate legislation designed to safeguard the public by ensuring that all products marketed meet standards of quality, effectiveness and safety which are acceptable in the view of present knowledge and experience.

While it is possible to legislate satisfactorily for the testing, manufacture and control of Medicinal Products, appropriate standards of marketing conduct cannot be completely defined by the same means. For this reason, responsible manufacturers, members of AIFP (the “Members”) have concurred in the promulgation of the Code of Conduct and submitted to its constraints.

Members of AIFP commit to market and promote their products within the strictest ethical principles. Promotion (as is defined below) must (i) never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry, (ii) be of a nature which recognizes the special nature of medicines and the professional standing of the recipient(s), and (iii) not be likely to cause offence. The Members commit particularly not to implement any practice or activity that will ‘lock’ prescribers in schemes aiming at generating prescriptions in exchange of incentives (goods, services or financial). Grants, scholarships, subsidies, support, consulting contracts, invitations for congresses or educational or practice related items must not be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing may be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional’s prescribing practices.

SCOPE AND APPLICABILITY OF THE AIFP CODE

A Member of the AIFP undertakes to comply with valid EU and national legislation (namely the laws specified herein), the European Federation of Pharmaceutical Industries and Associations Code of Practice on the Promotion of Medicines (the "EFPIA Code"), the AIFP Statutes and this AIFP Code of Conduct (the "AIFP Code"), where the latter do not conflict with the former.

AIFP encourages compliance with the letter and spirit of the provisions of the European Federation of Pharmaceutical Manufacturers Associations Code of Pharmaceutical Marketing Practices where applicable.

The AIFP Code covers the promotion to and advertising aimed at healthcare professionals of prescription-only medicinal products. "Promotion", as used in the AIFP Code, includes any activity undertaken, organized or sponsored by a pharmaceutical company, or with its authority, which promotes the prescription, supply, sale, administration or consumption of its medicinal product(s), including advertising and sponsoring activities defined in the Act No. 40/1995 Coll., as amended, on regulation of advertising. "Medicinal Products", as used in the AIFP Code, has the meaning set forth in Article 2 of the Act No. 79/1997 Coll., as amended, on pharmaceuticals (the "Law") which implemented into Czech legislation the respective provisions of Council Directive 2001/83/EC, as amended, relating to medicinal products for human use (the "Directive"). The AIFP Code covers promotional activity and communication directed at any person who in the course of his or her professional activities prescribe or supply a Medicinal Product (a "Healthcare Professional") and any member of the medical, dental, pharmacy or nursing professions or any other person (including but not limited to governments, hospital, insurers, patient organizations) who in the course of his or her professional activities may determine the access to, prescribe, purchase, supply or administer a medicine, or provide healthcare services .

The AIFP Code covers all methods of promotion including, but not limited to, oral and written promotional activities and communications, journal and direct mail advertising, the activities of medical sales representatives, internet and other electronic communications, the use of audio-visual systems such as films, video recordings, data storage services and the like, and the provision of samples, gifts and hospitality.

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

The AIFP Code does not cover the following:

- the labelling of Medicinal Products and accompanying package leaflets, which are subject to the provisions of Article 26c of the Law and its implementing Regulation of the Ministry of Health No. 288/2004 Coll., as amended, relating to registration of Medicinal Products;
- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular Medicinal Product;
- factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general precautions, trade catalogues and price lists, provided they include no product claims;
- non-promotional information relating to human health or diseases;
- activities which relate solely to non-prescription only 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 programs, and discussion of regulatory developments affecting the company and its products.

Attached to the AIFP Code are: Annex A, Processing of complaints and the initiation or administration of sanctions by member associations, Annex B, the "Guidelines for Internet Websites Available to Healthcare Professionals, Patients and the Public in the EU" which provide guidance to Members and companies with respect to the content of websites containing information on medicinal products subject to prescription, and Annex C - Declaration of acceptance of the AIFP Code of Ethics

Promotion which takes place within Europe must comply with applicable laws and regulations. In addition, promotion which takes place within Europe must also comply with each of the following "applicable codes":

(a) (i) in the case of promotion that is undertaken, sponsored or organized by a company located within Europe, the member association national code of the country in which such company is located; or (ii) in the case of promotion that is undertaken, sponsored or organized by a company located outside of Europe, the EFPIA Code; and

(b) the member association national code of the country in which the promotion takes place.

In the event of a conflict between the provisions of the applicable codes set forth above, the more restrictive of the conflicting provisions shall apply, except for the application of Section 10.01, where the monetary threshold set in the country where the event takes place (i.e. the "host country") shall prevail. For the avoidance of doubt, the term "company" as used in this AIFP Code, shall mean any legal entity that organizes or sponsors promotion which takes place within Europe, whether such entity is a parent company (e.g., the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organization.

GENERAL PROVISIONS

General Manager of each Member will confirm acceptance of the current version of the AIFP Code by his / her signature at the beginning of each calendar year.

The Code shall be supervised and administered by the Ethical Committee of AIFP (the "AIFP EC") which may issue determinations from time to time for the purpose of interpretation of certain sections of the AIFP Code. Complaints concerning alleged breaches of the AIFP Code should be reported to the AIFP EC.

Complaints against any activity of any Member should be made to the AIFP EC as provided for in the AIFP Code (Operating Procedures).

Failure to comply with the AIFP Code will result in sanctions being applied under the provisions of operating procedures. Adherence to the AIFP Code in no way reduces Members' responsibilities to comply with the Czech legislation and the EFPIA Code. Promotion of prescription-only products to the general public is prohibited by the law.

The AIFP Code is open to adoption by all pharmaceutical companies, regardless of whether they are companies involved in research and development of new pharmaceuticals or production and distribution of generic pharmaceuticals. The AIFP Code is also open for adoption by all other organisations, institutions and persons involved in the production, distribution and sale of pharmaceutical products as well as to other entities within the healthcare system in the Czech Republic. Adoption of the Code shall become effective upon signing of the Declaration of adoption of the AIFP Code. Each signatory pledges by signing that during his/her activities he/she will abide by and promote the rules and principles of the AIFP Code, comply with valid EU and Czech legislation and support the principles of the anti-corruption strategy highlighted by the Czech Ministry of Health. By adopting the AIFP Code, each signatory bears in mind the seriousness of the rules outlined in the AIFP Code as well as their enforceability by competent AIFP bodies, including the possibility of sanctions for their breach. Unless otherwise specified, the provisions of Annex A to the AIFP Code shall be used for handling complaints regarding alleged breaches of the AIFP Code by a signatory.

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/technical advisers to ensure that medical content included in all promotional materials is correct, fully supported by the valid version of the Czech summary of product characteristics (the "SPC"), literature or "data on file", where the latter do not conflict with the former. Activities of company representatives must comply with the AIFP Code at all times. This responsibility is objective and the company could not be exempted from it.

EXPLANATORY NOTES

This responsibility relates not only to the product being promoted, but to any information given or claims made about other products. Of importance is that any claim made must be consistent with the Czech SPC document, irrespective of the source on which the claim is based.

1.2 Provision of Substantiating Data

Further to the information supplied or generally available, the manufacturer will, upon reasonable request, provide Healthcare Professionals with additional accurate and relevant information about its marketed products.

Substantiating information should be based mostly on publications in scientific journals or oral presentations on an international scientific congress and must not rely solely on data on file.

Data cited in promotional material in support of a claim, including "data on file" or "in press" must be made available to Healthcare Professionals and industry companies upon request within 10 working days. Substantiation need not be provided, however, in relation to the validity of elements approved in the SPC.

EXPLANATORY NOTES

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

(b) Evaluated data contained in an application for marketing in accordance with the Czech Guidelines for the Registration of Drugs or preceding Guidelines as the basis of the registration of the product by the State Institute for Drug Control - SUKL 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" will not be accepted.

(c) If the information on which a claim is based may not be released, e. g. because are part of "`in press" article which is subject to confidentiality provisions, then that 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 all provisions of this Code.

1.3 False or Misleading Claims

Information, medical claims and graphical representations about products must be valid, accurate, balanced and must not mislead either directly, by implication, or by omission and must not be able to cause deceptive imagination of an addressee.

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

(c) clearly indicate the precise source(s) of the artwork;

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

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

Information, claims and graphics must be capable of substantiation. Such substantiation must be provided within 10 working days at the request of Healthcare Professionals or a pharmaceutical company.

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

EXPLANATORY NOTES

The majority of found breaches of the Code concern this section. The following are examples of situations where promotional material may breach the Code. This list is not exhaustive and is based on the experience of the AIFP EC.

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

(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 SPC not approved by SUKL or by EMEA.

(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, to the casual reader could produce an incorrect perspective. The type size of small fonts used for qualifying statements must not be less than 2mm. 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 altering the original author's meaning.

(j) Use of foreign product information to support a claim where that information is inconsistent with the Czech SPC.

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

(l) Lack of 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.

(m) Use of preliminary results without clear indication of its preliminary nature.

It should be noted that 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.

1.4 Unapproved Products and Indications

Medicinal Product, or its unapproved indication, must not be promoted prior to their registration under the national rules (i.e. with SUKL) or via the centralized EU authorization procedure (i.e. with EMEA).

Promotion must be always consistent with the particulars listed in the SPC of the relevant Medicinal Product.

1.5 Good Morals

Promotion and promotional materials (including graphics and other visual presentations) must conform to generally accepted standards of good morals and taste and recognize the professional standing of the recipients. Promotion must not be discriminatory, deceptive or disparaging.

1.6 Unqualified Superlatives

Promotion must encourage the rational use of Medicinal Products by presenting them objectively and without exaggerating their properties. 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 words as “safe”, “standard” etc. must never be used to describe a Medicinal Product without proper qualification.

It must not be stated that a product has no side-effects, toxic hazards or risks of addiction or dependency.

1.7 New Products

The word “new” must not be used to describe any Medicinal Product or presentation, which has been marketed, or any therapeutic indication which has been generally promoted for more than one year in the Czech Republic

1.8 Comparative Advertising

Comparative advertising is advertising that directly or indirectly identifies any other manufacturer or Medicinal Product of any other manufacturer.

Comparative advertising must not be deceptive or disparaging, but must be factual, fair and capable of substantiation and referenced to its source. It must compare only relevant, substantial, verifiable and representative elements and compare in more than one element. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by used scale, by used doses, by undue emphasis or in any other way. "Hanging" comparatives - those which merely claim that a product is better, stronger, more widely prescribed etc. must not be used.

"Data on file" when used to substantiate comparative statements must comply with the requirement of Section 1.2 hereof.

EXPLANATORY NOTES

Where a claim of comparative efficacy or safety is made, it must not be based solely on a comparison of product information documents that does not reflect the general literature, as those documents are based on different databases and are not directly comparable. This applies to Czech as well as foreign product information documents.

Claims of comparative efficacy or safety must be substantiated with respect to all aspects of efficacy or safety. 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 generalize or to indicate superiority or inferiority*

The statement that the claim 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 2mm.

1.9 Imitation

Promotional information must not imitate the devices, copy, slogans or general layout adopted by other manufacturers in a way that is likely to mislead or confuse. Promotional information must not infringe or be able to infringe intellectual property rights, trademarks, patents or similar rights of other person or entity.

1.10 Medical Ethics

Healthcare Professionals´ names or photographs must not be used in any way that is contrary to medical ethics or provisions on the protection of personal data, privacy and personhood.

1.11 Distinction of Promotional Material

Promotion must not be disguised or based on the subliminal perception. Promotion and promotional materials must be clearly distinguishable as such. Materials relating to Medicinal Products and their uses, whether promotional in nature or not, which is sponsored by a Member, must clearly indicate that it has been sponsored by that Member.

EXPLANATORY NOTES

Advertisements in a journal should not be designed so as to resemble editorial matter unless clearly identified as an advertisement.

2. PRODUCT INFORMATION

2.1 Full Product Information

All promotional materials relating to Medicinal Products, including journal advertisements must be accompanied by either full or abridged product information according to the SPC („Product Information“).

Wherever required, Product Information must appear in a type size of small fonts not less than 2 mm (for format A4) on a background sufficiently contrasting for legibility. For smaller format of promotional material it is possible to decrease the size of fonts of Product Information accordingly with maintaining of good readability. Major headings should be easily identifiable. The date on which the last version of Product Information was approved by SÚKL or for centrally-registered products by EMEA must be included.

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

EXPLANATORY NOTES

In case the fonts in the Product Information are smaller than 2 mm the good readability will be judged by the AIFP EC.

2.2 Abridged Product Information

Abridged Product Information must accurately reflect the full Product Information but may be a paraphrase or precise of the full Product Information.

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

(e) Brand name of the product

(f) The INN of the active ingredient (s)

(g) Approved indications for use

(h) Contra-indications

(i) Clinically significant warnings

(j) Clinically significant precautions for use

(k) Clinically significant adverse events and interactions

(l) Available dosage forms

(m) Dosage regimens and routes of administration

(n) Dependence potential of clinical significance

(o) Reference to special groups of patients

(p) Name and address of the registration holder

(q) Registration number

(r) Storage conditions

(s) Latest revision of SPC

Where the full Product Information does not include items under aforementioned headings, such headings are not required to be included in the document.

2.3 Changes of Clinical Significance

Where a change of clinical significance relating to product safety 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 small fonts not less than 2mm: "Please note change(s) in product information".

The full text of the changed section should be included in any abridged Product Information during this period.

3. PROMOTIONAL MATERIAL

3.1 Journal Advertisement

Promotion of Medicinal Products aimed at Healthcare Professionals may not be carried out through information channels and communication means other than those dedicated mainly to Healthcare Professionals (e.g. professional magazines and journals, professional audiovisual documents etc.).

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

Journal advertising must conform to the requirements of one or other of the following categories. The information required shall appear in each publication in a type size of small fonts not less than 2 mm, and should appear on a background sufficiently contrasting for legibility.

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 of small fonts not less than 2 mm to the effect of the following statement: "Please review product information before prescribing. In this publication, product information can be found ...." At the point ..., insert the page number in the publication where the information can be found or reference to an adequately referenced Product Information section or advertisers index. Product Information must form a fixed part of the journal. Loose leaf inserts will not satisfy the requirements of this section.

EXPLANATORY NOTES

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 Content of Journal Advertisement

A journal advertisement must contain the following within the body of the advertisement.

(t) The brand name of the Medicinal Product

(u) The INN of the active ingredient (s)

(v) The name of the registration holder and a mailing address in the Czech Republic

(w) The full or abridged Product Information

(x) Other data required by legal provisions.

EXPLANATORY NOTES

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

3.3 Reminder

A reminder is designed to remind a prescriber of a Medicinal Product‘s existence, and must not contain any promotional claims. The sole use of a reminder within any one issue of a publication is not permitted before 12 months from first advertising of a new Medicinal Product.

Reminder gimmicks must be in accordance with Article 10.2 of the AIFP Code.

3.4 Content of Reminder

A reminder can contain only the brand name of the Medicinal Product approved in the registration decision, or its INN, or trade-mark.

3.5 Member Commissioned Articles

Member commissioned articles must be identified as such in a type size of the small fonts not less than 2 mm.

The Member which is responsible for the insertion of the commissioned article must be clearly identified at either the top or the bottom of the article in a type size of the small font not less than 2 mm. Member commissioned articles must conform to all relevant provisions of Article 1 of this AIFP Code.

EXPLANATORY NOTES

Sponsoring companies should ensure that statements by third parties which are quoted in Commissioned Articles comply with all requirements of this Code.

Independently edited supplements which publish the proceedings of a recognized congress are not considered as Commissioned Articles. It is recommended that if a company sponsors such a supplement this must be stated clearly in the supplement*

3.6 Materials for Use by Medical Representatives

A major guiding principle of the AIFP Code is that, whenever a promotional claim is made for a Medicinal Product, it shall be accompanied by either full or abridged Product Information. Where multiple forms of Promotion items are intended to be distributed at one time, the Product Information must appear at least once.

3.7 Printed Promotional Materials

All Member printed promotional material must include the following information:

(y) The brand name of the Medicinal Product

(z) The INN of the active ingredient(s)

(aa) The name of the registration holder and its mailing address in Czech Republic

(bb) Full or abridged Product Information

(cc) Reimbursement status and classification of the Medicinal Product

(dd) Other data required by legal provisions.

EXPLANATORY NOTES

This section applies to detail aids, leaflets, posters and other materials prepared by companies based on the available literature and intended for distribution to Healthcare Professionals, which contain promotional claims.

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

The Product Information must be contained within the promotional material a must form a fixed part of the promotional material. Loose leaf inserts will not satisfy the requirements of this section.

3.8 Audiovisual Promotional Material

All audiovisual promotional material must be accompanied by a document which contains the following information:

(ee) The brand name of the Medicinal Product

(ff) The INN of the active ingredient(s)

(gg) The name of the registration holder and its mailing address in Czech Republic

(hh) Full or abridged Product Information

(ii) Other data required by legal provisions

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

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

EXPLANATORY NOTES

This section applies to audiotapes and videotapes for private use by Healthcare Professionals or for demonstration purposes to groups of Healthcare Professional.

3.9 Computer Based Promotional Material

Computer based promotional material must comply with all relevant provisions of the AIFP Code.

Where an individual Medicinal Product is being promoted the appropriate Product Information 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.

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

EXPLANATORY NOTES

Promotional material designed by companies to promote their products directly to Healthcare Professionals and includes such promotional tools as software programs used by Medical Representatives during interchanges with Healthcare Professional.

The use by Members of external computer generated programs to promote their products and includes such programs as prescribing and dispensing software.

The use by Members of messages on the Internet. Member companies considering the use of the Internet must refer to Czech law which prohibits the promotion of prescription products to the general public.

3.10 Mailings

Mailings must comply will all relevant provisions of Section 1 of this Code.

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

Mailings should only be sent to those categories of Healthcare Professionals whose need for, or interest in, the particular information can be reasonably assumed. Mailing lists must be kept up-to-date. Requests to be removed from promotional mailing lists must be complied with promptly and no name restored except at specific request or with written permission.

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

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

Items suggesting a requirement for urgent attention are not acceptable for promotional purposes.

EXPLANATORY NOTES

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

Envelopes must not be used for dispatch of promotional material if they bear words implying that the contents are non-promotional.

Unsolicited reprints of journal articles must be consistent with the Product Information, and any covering letter should comply with Article1.

3.11 Document Transfer Media

Unsolicited telegrams, telexes and electronic transmissions, or replicas thereof, must not be used for promotional purposes.

3.12 Promotional Competitions

Promotional competitions must fulfill all of the following criteria:

(jj) The competition is based on medical knowledge or the acquisition of medical knowledge. Medical knowledge must correspond to background of Healthcare Professionals.

(kk) The prize is directly relevant to the practice of medicine or pharmacy.

(ll) Individual prizes offered must be in accordance with Article 10.2 of the AIFP Code.

Entry into a competition must not be dependent upon prescribing or recommending of a product and no such condition shall be made or implied.

The conduct of competitions shall comply in all respects with relevant Czech legislation.

4. MEDICAL REPRESENTATIVES

Each Member shall ensure that its sales representatives, including personnel retained by way of contract with third parties, and any other company representatives who call on Healthcare Professionals, pharmacies, hospitals or other healthcare facilities in connection with the Promotion of Medicinal Products (each, a "Medical Representative") are familiar with the relevant requirements of the applicable code(s), and all applicable laws and regulations, and are adequately trained and have sufficient scientific knowledge to be able to provide precise and complete information about the Medicinal Products they promote.

Medical Representatives must comply with all relevant requirements of the applicable code(s), and all applicable laws and regulations, and companies are responsible for ensuring their compliance.

Each member company is required to ensure that its medical representatives, including their line managers, undergo instruction in the basics of pharmacology, pharmaceutical law and ethics, which is available on the website at www.certifikat-aifp.cz, and subsequently pass an examination verifying the acquired knowledge. Detailed rules for certification of medical representatives are determined by the implementing guideline by the Board of Directors. AIFP shall ensure conditions for the timely and smooth implementation.

Medical Representatives must approach their duties responsibly and ethically.

During each visit, and subject to applicable laws and regulations, Medical Representatives must give the persons visited, or have available for them, SPC for each Medicinal Product they present.

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

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

Medical Representatives must not use any inducement or subterfuge to gain an appointment. 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 company they represent.

All company staff of a Member, and any personnel retained by way of contract with third parties, who are concerned with the preparation or approval of promotional material or activities must be fully conversant with the requirements of the applicable code(s) and relevant laws and regulations.

Every Member must establish a scientific service in charge of information about its Medicinal Products. This scientific service must include a doctor or, where appropriate, a pharmacist who will be responsible for approving any promotional material before release. Such person must certify that he or she has examined the final form of the promotional material and that in his or her belief it is in accordance with the requirements of the applicable code(s) and any applicable advertising laws and regulations, is consistent with the SPC and is a fair and truthful presentation of the facts about the medicine.

Each Member must appoint at least one senior employee who shall be responsible for supervising the company and its subsidiaries to ensure that the standards of the applicable code(s) are met.

5. PRODUCT SAMPLES

Care should be exercised by Members that the distribution of samples is carried out in accordance with the applicable laws, and regulations issued by SUKL.

Samples of Medicinal Products may only be supplied to Healthcare Professionals who are qualified to prescribe those products for gaining familiarization and acquiring experience in dealing with them. Each Healthcare Professional should receive not more than 4 samples of a particular new Medicinal Product he/she is qualified to prescribe per year. Sampling of a particular Medicinal Product is allowed only for two (2) years after the first Healthcare Professional first requested samples of such Medicinal Product ("4x2" standard).

For the purposes of this Article, a new Medicinal Product is a product for which a new marketing authorisation (MA) has been granted, either following an initial MA application or following an extension application for new strengths / dosage forms that include a new indication, as well as a Medicinal Product for which a new group of prescribing Healthcare Professionals has been authorized. Extensions of the MA to additional strengths / dosage forms for existing indications or pack sizes (number of units in the pack) cannot be considered as new Medicinal Products.

Members must have adequate systems of control and accountability for samples which they distribute and Medical Representatives must take adequate precautions to ensure the security of samples in their possession. Members must develop an appropriate recording system so that, if a product recall is necessary, relevant samples will be included in the recall. This system shall also clearly establish, for each Healthcare Professional, the number of samples supplied in application of the "4x2" standard.

On request, Members must promptly accept the return of samples of their Medicinal Products.

Samples of Medicinal Products must not be given as an inducement to recommend, prescribe, purchase, supply, sell or administer specific Medicinal Products, and shall not be given for the sole purpose of treating patients.

Without prejudice to the ban on medical sampling of medicines containing psychotropic and narcotic substances, medical samples can only be given in response to a written request from health professionals qualified to prescribe that particular medicine. Written requests must be signed and dated by the recipient.

EXPLANATORY NOTES

The "4x2" shall be interpreted such that the 2-year period applies to the sampling of the particular Medicinal Product in general, i.e. on the entire market and not to individual Healthcare Professionals individually.

For new Medicinal Products launched after 31 December 2011, the "4x2" standard shall apply immediately. For Medicinal Products launched before 31 December 2011, no samples shall be distributed after 31 December 2013, i.e. for such products, the 2-year period commences on 1 January 2012.

6. TRADE DISPLAYS

Trade displays are important for the dissemination of knowledge and experience to the Healthcare Professionals. The prime objective in organizing such displays must be the enhancement of medical knowledge.

Trade displays must comply with the law with a special consideration to promoted products (prescription only, OTC).

A trade display must include, in a prominent position, the name of the sponsoring company.

Product Information for products being promoted must be available from the display stand. No alcohol and game of chance are accepted at trade displays

EXPLANATORY NOTES

Information regarding such products must be consistent with the approved Product Information as registered in the Czech Republic. Such Product Information must be available and distributed as per the AIFP Code of Conduct.

7. TRAVEL AND MEETING SPONSORSHIP

7.1 Members support events for purely professional and scientific purposes, such as scientific meetings, scientific congresses within or outside the Czech Republic (the „Meetings"). Sponsorship of Meetings, that do not satisfy this principle, is not allowed. This support must comply with the following principles:

(a) Purposes of the Meetings must be purely professional and scientific.

(b) Sponsors must be publicly disclosed and mentioned in all documents relating to the Meetings and proceedings.

Sponsorship cannot be undertaken by any Member to the exclusion of any other Member willing to sponsor the particular Meeting.

7.2 Sponsorship of Healthcare Professionals attending Meetings organized by third parties must comply with the following principles:

(a) Sponsorship must be reasonable in level and strictly limited to the main scientific purpose of the meeting.

(b) The meeting must be directly related to the Healthcare Professional's area of expertise.

(c) Sponsorship cannot be extended to spouses or traveling companion(s).

(d) Sponsorship cannot be linked to prescribing behavior or volume of sales.

(e) Costs for travel, accommodation, meals and registration can be covered by the sponsor. Hospitality provided by Members cannot include sponsoring or organizing entertainment (e.g., sporting or leisure) events.

(f) Arrival at the venue of the meeting can occur within 24 hours before start of the Meeting and departure must occur within 24 hours after the Meeting finishes. If attendees elect to arrive earlier or stay longer, any expenses associated with the additional time must be paid by the attendee and may not be reimbursed by the sponsoring Member.

(g) Members must report every sponsorship according to this section in the database of the Association.

7.3 Member sponsored Meetings / Stand alone Meetings

(a) Members can organize Member sponsored Meetings/Stand alone Meetings for Healthcare Professionals in accordance with the AIFP Code.

(b) Approved Medicinal Products in accordance with marketing authorization can only be promoted at these Meetings.

(c) Hospitality at the Meetings must be reasonable in level and strictly limited to the main purpose of the Meetings.

(d) Costs for travel, accommodation, meals can be covered by the sponsor. Hospitality shall not include sponsoring or organizing entertainment (e.g., sporting or leisure) events. Members should avoid using venues that are renowned for their entertainment facilities.

(e) Hospitality at promotional meetings cannot be extended to persons other than Healthcare Professionals.

(f) No spouses, other family members or friends of Healthcare Professionals can be sponsored.

(g) Domestic Meetings cannot take more than 3 days including travel. At least 75 % of usual working hours must be allocated to the scientific program. Invitation to the event cannot be linked to an agreed level of prescriptions.

(h) No Member may organize or sponsor a Meeting or other event that takes place outside its home country unless:

Venue must be located in:

Major corporate, manufacturing, or research sites of the sponsoring company within Europe (with exception of visit to HQ site if located outside of Europe).This rule does not apply to stand alone meeting organized by the HQ function (European or World Wide HQ).

Invitation to the event must not be linked to an agreed level of prescriptions

At least 75% of usual working hours must be allocated to the scientific program.

The Meeting cannot last more than 4 days including travel.

(i) Investigator meetings can be held only for participants of clinical trials which are conducted consistent with Good Clinical Practice and which were either approved by or notified to SUKL.

(j) Reimbursement for expenses associated with Member-sponsored Meeting or travel must be made by check, bank transfer or money order and not by cash or other cash equivalent, and must be associated with itemized receipts for all reimbursed expenses.

(k) This section applies also to cases when a Meeting or other event is organized by a third party but is funded wholly or partially by a Member.

EXPLANATORY NOTE

If company sponsored meeting is organized during weekend or holidays the same principles apply. Travel time is part of usual working hours.

8. OTHER SPONSORSHIPS

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 morals and taste.

Sponsorships are not to be based upon the number of prescriptions written, nor are to be used to influence a Healthcare Professional's judgment.

Equipment or other tangible items cannot be provided to individual Healthcare Professionals under this Article.

Equipment or other tangible items (e.g., TV sets, printers, PCs, furniture) are appropriate forms of sponsorship for hospitals or institutions when the equipment or item is used as a means of diagnosis/evaluation, or improves medical quality or patients care. In the case of equipment or other tangible items, such equipment must to remain within property/site of the hospital or institution at all times, and must not be used for personal use of individual Healthcare Professional at any time.

All requests for sponsorship must be unsolicited, and based on a written request by hospital or institution. Each Member should establish internal procedures to review sponsorship requests for appropriateness.

9. RESEARCH

The following provisions apply to Non-interventional Studies and Market Research, whether carried out directly by the manufacturer or by organization acting under its direction.

This section does not apply to evaluations being carried out as clinical trials (consistent with Good Clinical Practice) according to Act on Pharmaceuticals.

9.1 Non-interventional Studies

Non-interventional studies (the „NIS“) must be carried out in line with the applicable laws and SUKL regulations.

NIS must concern regulatory approved products used in approved indications and can include, but not only, non-interventional trials, observational trials, Post-Marketing Surveillance and Post-Authorization Safety Studies.

NIS must have a scientific purpose.

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

The NIS must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product.

The written study protocol must be approved by the company’s scientific service and the conduct of the study must be supervised by the company’s scientific service

The study results must be analysed by or on behalf of the member company and summaries thereof must be made available within a reasonable period of time to the company’s scientific service which service shall maintain records of such reports for a reasonable period of time. The company must send the summary report to all healthcare professionals that participated in the study and must make the summary report available to industry self-regulatory bodies and/or committees that are in charge of supervising or enforcing Applicable Codes upon their request.

If the study shows results that are important for the assessment of benefit-risk, the summary report must be immediately forwarded to the relevant competent authority.

Medical Sales Representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the company's scientific service that will also ensure that the representatives are adequately trained. Such involvement must not be linked to the promotion of any medicinal product.

Every NIS has to be notified to AIFP Executive Director before start. Members have to submit the Protocol of the NIS and study report forms including the written agreement with the Healthcare Professional. These documents are filed in NIS AIFP Database. The following information from the submitted studies will be made available to all Members on the AIFP intranet: study sponsor, studied product, name of the study and timeline for observation. AIFP Executive Director ensures the confidentiality of the submitted documentation.

In case of a complaint by a Member regarding NIS performed by another Member the Executive Director makes available all study documentation submitted to the Ethical Committee.

AIFP EC will randomly check up to 20% of the submitted NIS whether they fulfill criteria described in the AIFP Code. If a particular NIS is selected for review, the sponsoring company is invited to the review meeting. Company is represented by Medical Director. Ethics Committee decides whether the study is compliant with the Code. In case of a breach of the AIFP Code the AIFP EC may penalize the Member according to the Complaint procedure.

In order for the NIS to be in line with the AIFP Code, the study must live up to the following criteria in the chart below.

EXPLANATORY NOTES

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

The Ethics Committee will primarily review the NIS from the point of view whether the particular NIS could be considered disguised advertising or promotional tool. For this purpose the Ethics Committee will primarily look at the following: timing within the life cycle of the product, number of patients, content of protocol, amount of compensation, duration of the study etc.

Non-interventional studies have to be structured in a following way:

Issue	Task	Characteristic	Comments
1. Name of program		Must describe the nature of the study and product studied	The nature of the study can be one of many describing non-interventional studies; PMS, non-interventional trial, Post-Authorization Safety Study etc.
2. Introduction to Study		Written introduction to the study must be prepared and handed to all physicians included in the study	The introduction must provide a clear understanding of the purpose and nature of the study as described in section 2.1 to 2.7

	2.1 Objective	Must provide a clear understanding of what the sponsor expects to gain from the study	Main purpose must be to gain useful data of clinical experience related to the medicine studied in accordance with approved indication
	2.2 Product included	Which product(s) is(are) observed in the study	
	2.3 Timeline for observation	Time for start of the observation period and deadline for collection of study records/protocols must be clearly stated	
	2.4 Study record/protocol	The type of data collected must be described, how are physicians expected to complete the study records/protocols and how to record Adverse Events	Data can be medical, epidemiological, pharmaco-economical, safety, QoL etc.
	2.5 Patient Inclusion	Patients included should be patients who would have the product prescribed independent of the study	Patient selection, prescribing, monitoring and other treatment decisions remains the full responsibility of the treating physician
	2.6 Data analysis and evaluation	How and by whom will data be analyzed and evaluated	Will data be analyzed internally or externally and will external or internal people/department be responsible for evaluation of data
	2.7 Use of Data	What is the primary use of data, how and when will results be published.	Will publication of data be pursued, used for presentation at company sponsored or external meetings etc.
3. Studied products		Products must be prescribed by the treating physician and the study cannot facilitate usage outside the approved indication	As samples would promote usage of the studied product, sampling can't be used during the study period.
4. Adverse event reporting		There is no special requirement apart of rules and laws specifying spontaneous AE reporting. Company can add in "patient form" field for AE reporting/ safety /tolerability description.	To use standard reporting via standard channels to SUKL
5. Agreement With Physician		A clear contract must be signed with each physician included specifying, program, medicine related to data collection and remuneration. Physicians can only be paid for data records/protocols collected	DPP (Dohoda o provedení práce) is one possibility as within it must be specified characteristic of the work, who will overtake data and how much is paid. We can only demand the physician to complete records/protocols in accordance

		which are sufficiently completed.	with what is normal practice for the physician
6. Ethical committee approval		Not required	
7. Data privacy		All patients are coded. No source data verification	
8. Data collection/data management		Data collection is part of documentation for health care professional's payments. Collected data can be statistically processed if their amount is reasonable. Usually in accordance with statistical plan	No monitoring is performed only data completeness. Data collection will usually be retrospective. Health care professionals will be paid only for sufficiently completed forms.
9. Payment		Physicians can only be paid for sufficiently completed data. Payment can't be done directly by sponsor employees but must be transferred from the sponsors financial department or by similar method The amount must be disclosed in protocol of the NIS and must represent a fair market value for the provided services	
10. Documentation		The sponsoring company must document all above mentioned issues.	

9.2 Market Research

Market Research studies must be clearly identified as such when the initial approach is made.

Any payment must be kept to a minimum and should not exceed a level commensurate with the work involved.

Promotion must not be presented as market research or research of any type.

Market research is not to be carried out be Medical Representatives or any other position involved in sales activities, unless there is no payment to the physician who is taking part in the research. Members carrying out Market Research must practically utilize its results.

10. RELATION WITH HEALTHCARE PROFESSIONALS

10.1 Hospitality

Hospitality offered to Healthcare Professionals in connection with promotion should be appropriate, secondary to the professional content and in proportion to the occasion.

Limits for hospitality offered or provided to the health care professionals in connection with the promotional activities or organizing of meetings in the Czech Republic or abroad are determined by the implementing guideline by the Board of Directors.

If a different limit for hospitality is valid in the country where the event takes place (determined by generally binding legal regulations or ethics codes of the local industry association), the AIFP member company shall respect the local limit.

Lunch/Dinner meetings can be hold for maximum 10 physicians. The hospitality is limited to lunch or dinner. No travel and accommodation should be provided.

10.2 Gifts and Inducements

Providing, offering or promising of gifts, pecuniary advantage or benefit in-kind to a healthcare professionalis forbidden.

The same rule applies to any member of the medical, dental, pharmacy or nursing professions or any other person (including but not limited to a person from the governments, hospital, insurers, patient organizations) who in the course of his or her professional activities may determine the access to, prescribe, purchase, supply or administer a medicine, or provide healthcare services.

Providing of informational or educational materials is permitted provided it is inexpensive, directly relevant to the practice of medicine or pharmacy and directly beneficial to the care of patients.

Items of medical utility aimed directly at the aducation of healthcare professionals and patient care can be provided if they are inexpensive and do not offset routine business practices of the recipient.

Permitted materials and items shall not be provided as an inducement to recommend, prescribe, sell, dispense or supply a Medicinal Product.

The scope of Informational or educational materials and items of medical utility considered may not constitute a circumvention of the prohibition on gifts defined in this Article.

Explanatory Note:

Permitted items shell not replace or influence proper healthcare services (lege artis) provided by a recipient.

Gifts of medical literature are acceptable of up to 1,500 CZK per piece. The total value of all items provided to a single Healthcare Professional cannot exceed 1,500 CZK a year.

Explanatory Note:

Reprints of professional articles are considered as the Member companies' own promotion which is not limited by the threshold of CZK 1,500. However, this would not apply in case that the Member company purchases number of copies of a particular professional magazine as originally published and then distributes these copies to individual HCPs without further processing.

10.3 Medical Educational Material

Materials supplied for medical education must include the name of the manufacturer and its mailing address in the Czech Republic.

Material supplied for medical education may include promotional claims and/or statements, but must comply with Section 3 of the Code of Conduct.

10.4 The use of consultants

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, fulfill all the following criteria:

a written contract or agreement is agreed in advance of the commencement of the services which specifies the nature of the services to be provided and, subject to terms below, the basis for payment of those services;

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

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;

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

the member company maintains records concerning, and makes appropriate use of, the services provided by consultants;

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

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.

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 the company 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 company. Similarly, companies 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 company 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 company. The provisions of this section apply even though the AIFP Code does not otherwise cover non-promotional, general information about companies .

If a healthcare professional attends a Meeting (an international Meeting or otherwise) in a consultant or advisory capacity the relevant provisions of Article 7 shall apply.

11. COMMUNICATION TO THE PUBLIC

Where Members assist or are directly involved in the conduct of public/patient disease awareness programs to meet growing demands of society for more information and enhance public understanding

of disease prevention, signs and symptoms of medical conditions, illnesses, and available treatments, such activities must adhere to the highest standards of accuracy and support the role of the healthcare provider.

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

Communications may include the provision of patient package inserts and other leaflets and booklets, etc., made available to inform patients about products prescribed or recommended by Healthcare Professional.

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

In the case 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. ETHICS COMMITTEE OF AIFP

The AIFP EC consists of eleven members.

The Chairman – preferentially non-industrial - of the AIFP EC is nominated by the AIFP Board and approved by the General Assembly

Other members of the AIFP EC would be AIFP Member representatives. Preferentially 4 members are General Managers, 2 members are Medical Directors and 1 member is Marketing Director. Two committee members should be non-AIFP members preferably one being a pharmacologist or pharmacist and the other a medical doctor. A lawyer is a member of the ethics committee.

These members are nominated by the AIFP Board, based on member companies proposal, and approved by the General Assembly.

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

An AIFP member company may have only one representative in the AIFP EC.

ANNEX A

AIFP' CODE OF ETHICS DIRECTIVE – COMPLAINTS PROCEDURE

1. Application of complaints procedure

Procedure for submitting complaints according to this AIFP´ Code of Ethics is available to every member of medical profession, company or public, acting in good faith and within the form and purposes of this Code.

1.1. Claimant and subject of the complaint

1.1.1 For purposes of this Code shall an individual or a Member submitting a complaint be regarded as a claimant.

1.1.2 Member against which a complaint is filled (company allegedly breaking rules of this Code) shall be, for purposes of this Code, regarded as a defendant.

1.2. Submitting of a complaint

1.2.1. Complaints must be submitted in a written form and it must include:

- Identity of claimant – full name (as registered in the Commercial Register at the relevant court) with whole address (including fax no. and e-mail, if possible
- Identity of defendant – full name (as registered in the Commercial Register at the relevant court) with whole address (including fax no. and e-mail, if possible)
- For every complaint name of product/products concerned or description of activities to which the complaint refers
- Relevant material which should be used as a proof of breach of the Code (in case of activity)
- For every case particular reference to the resource of commercial/activity which is subject to such complaint and/or printed material or other proof
- Date when alleged breach was discovered
- Date of submission of complaint
- Particular reference to the part of Code which was breached (article and section number)

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

Etická komise AIFP (AIFP EC)
Attention : Executive Director
IBC Pobřežní 3
186 00 Praha 8

2. Procedure for submitting complaints

2.1. Verification and Appeal

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

- Whether exist adequate information enabling to examine the complaint

2.1.2. One complaint may comprise more than one case, e.g. complaint may apply to more than one advertisement concerning various subjects of complaint and/or to various products. Ethics Committee of AIFP shall authorize one of its members to administer the "Book of complaints". This member then administer every case individually, according to main references of complaint.

2.1.3. Initial step with every complaint shall be:

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

2.1.4. Ethics Committee is obliged to undertake the complaint within 45 working days from the day it was delivered by the claimant. The Ethics Committee is obliged to inform the defendant about the complaint within 15 working days after handling the complaint.

2.2. Time limits

2.2.1. After receiving information by Ethics Committee the defendant has 15 working days to deliver it's statement in writing to AIFP Ethics Committee. Ethics Committee or EC Chairman may extend such period as an exception upon agreement of both parties involved

2.2.2 Provided that the defendant acknowledges acting in contradiction with the Code, it shall inform the Ethics Committee about steps taken/to be taken in order to ensure redress, e.g. amicable settlement of dispute between interested parties.

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

2.3. Complaint discussion and decision

2.3.1. After the reception of the defendant's response, AIFP Ethics Committee shall deal with the issue at its next meeting. Both interested parties shall be about such meeting informed in time and invited at least 15 calendar days before a meeting in a written form to pronounce their opinion. Company at the meeting is represented by the General Manager.

2.3.2. Ethics Committee shall decide whether a breach of the Code occurred a how such breach shall be defined (for the reasons of enlisting to the list of various Code's infringements, see section 4 Definitions). The Ethics Committee votes about each breach of the Code. Ethics Committee decision is valid if at least 4 members of the EC are present at the meeting. These members are Chairman, lawyer, one General Manager and one Medical Director. The decision is valid if the single majority of present Ethics Committee members votes for the decision. In case of equal votes the Chairman's vote is decisive.

2.3.3. Ethics Committee informs about it's decision both parties in writing no later than 15 working days after the decision was made, The defendant shall within 15 calendar days after receipt of the decision provide a written commitment declaring the cessation of disputable activities or materials without any delay and the defendant shall take all possible steps to avoid such breach of the Code in the future. This commitment shall be signed by General Manager of the company (defendant) and must be accompanied by details of the steps that are to be taken in order to realize this commitment, including the date when such promotional material appeared/was used for the last time and/or the date when last promotional activity took place.

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

2.3.5 In the case a member of the Ethics Committee is either a claimant or a defendant or associated with them or has any interest in either of them in a particular case, he or she may not take part in any evaluation, discussion and/or decision making concerning the case.

2.3.6. Regarding the decision of the Ethics Committee, the claimant or the defendant may appeal to the Committee of Appeal.

2.4. Procedure of the Committee of Appeal

2.4.1. A function of the Committee of Appeal shall be performed by the AIFP' Board. Members of the Committee of Appeal shall not be members of Ethics Committee.

2.4.2 The term of the Committee of Appeal is the same as those of the AIFP' Board. The re-election is possible.

2.5. Decision of the Committee of Appeal

2.5.1. Appeal must be submitted within 15 working days from the receipt of the decision of the Ethics Committee and must contain reasons for which is the decision of the Ethics Committee not accepted.

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

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

2.5.4. If any party appeals against the decision on the complaint (as defined in 2.1.2) of the Ethics Committee, it shall consign a bail of 50.000 CZK to the account of AIFP.

2.5.5. If the Committee of Appeal accepts the appeal the bail will be within 15 working days after the decision, returned to the appealing party If the appeal is refused, the 50.000 CZK bail shall not be returned to the defendant but will be used to cover the costs of the appeal.

2.5.6. Committee of Appeal informs about it's decision both parties in writing no later than 15 working days after the decision was made, If the Committee of Appeal decides the Code was breached, the defendant shall within 15 calendar days provide a written commitment declaring the cessation of disputable activities or materials without any delay and the defendant shall take all possible steps to avoid such breach of the Code in the future. This commitment shall be signed by General Manager of the company (defendant) and must be accompanied by details of the steps that are to be taken in order to realize this commitment, including the date

when such promotional material appeared/was used for the last time and/or the date when last promotional activity took place

2.5.7. The decision of the Committee of Appeal is final. Members of AIFP cannot change such decision.

2.5. 8. The Committee of Appeal may change the fine amount too and return to the Ethics Committee such case where formal requirements were not met.

2.5.9. In case the company does not accept respective decision and does not take any requested steps, AIFP Board shall submit a proposal to exclude such company from AIFP at the next General Meeting. Ethics Committee monitors compliance with the decision. In relevant case the Ethics Committee informs AIFP Board which at the next GM submits proposal for exclusion from Association.

3. General Provisions

3.1. Compliance with the Code

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

3.1.2 Ethics committee opinions
Member companies may submit to the Ethics committee questions regarding explanations of the Code. Ethics committee will issue it's opinion and inform the Members about the decision. This opinion serves as guidance to Members had they similar questions.

3.2. Issue of semi-annual report

3.2.1. The Ethics Committee prepares semi-annual reports and distributes them to all Members. The Ethics Committee may advise the AIFP Board to publish such reports. Report shall include this following information:

(mm) For complaints where breach of the Code was proved names of the defendants (in case of a major breach)

(nn) Product or promotional material interfering the Code

(oo) Section of the Code that was breached and reasons of such breach

(pp) Imposed sanctions for such breach

(qq) Overall number of received complaints and totals of different industry sectors

(rr) Overall number of infringements of the Code

(ss) Overall number of appeals and their results

3.3. Fines

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

3.3.2. List of the fines that may be imposed for a breach of this Code is as follows:

- lesser breach ∗NIL and anonymous publication in semi-annual report

- minor breach∗, maximum of 200,000 CZK and anonymous publication in semi-annual report
- major breach∗, maximum of 500,000 CZK, named publication in semi-annual report and a named publication on the AIFP website
- repeated major breach∗, maximum of 1,000,000 CZK (within 24 months) Maximum of 1,000, 000 CZK named publication in semi-annual report and a named publication on the AIFP website and a press release.

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

- temporarily exclusion of a member from the Association and/or suspension of adoption of the AIFP Code of Ethics, for a definite period of time
- exclusion of a member from the Association and/or cancellation of adoption of the AIFP Code of Ethics

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

3.3.4. Based on the AIFP Articles of Association, both these sanctions must be approved by the General Meeting of AIFP, by simple majority of votes.

4. Definitions

In this Code:

"Association" means the International Association of Pharmaceutical producers (AIFP)

"Boxed Warning" is a mechanism for highlighting special warning statements in Product Information.

"Reminders" means such items of low monetary value which are intended to remind healthcare professionals of the existence of a product.

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

(a) Approved indications for use

(b) Precautions for use

(c) Contra-indications

(d) Warnings

(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)

(j) Boxed warnings

"Company representatives" are those persons authorized by a Member to disseminate information about a product to healthcare professionals, including medical representatives.

"Congress" means an event sponsored and organized by a Society, College, university or other non-company entity.

"Correct" means representing all the valuable data.

"Data on File" is that body of unpublished clinical or scientific information held by a company. It does not include evaluated data submitted to SUKL in accordance with the Czech Guidelines for the Registration of Drugs or preceding Guidelines.

"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.

"Evaluated data" means data which have been submitted as part of an application for marketing in accordance with the Czech Guidelines for the Registration of Drugs which form the basis for registration of a product by the SUKL

"General Public" are persons other than healthcare professionals.

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

"Industry" means Members of AIFP

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

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

"Lesser breach" is a breach of this Code that has no safety implications to the patient's wellbeing and/or will have no major effect on how the medical profession will prescribe the product.

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

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

"Major breach" is a breach of this Code that will have safety implications to the patient's wellbeing and/or will have a major effect on how the medical profession will prescribe the product or repeated minor breach of the same nature.

"Manufacturer" includes the manufacturer, importer or Czech distributor of a pharmaceutical product.

"Market research" is the gathering of data on the scope or dimensions of a market and its components, including the needs of the customers in that market. Market research is a study or other project which does not include any individual patient data. Every market research which contains individual patient data shall be considered as a non-interventional study.

EXPLANATORY NOTES

Individual patient data means data which is related both to the medicine and its effect on an individual patient. In particular, individual patient data is recorded in case report forms (CRF).

"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, curing or alleviating a disease, defect or injury in man;

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

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

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

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

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

"Member" means any person, firm or company holding Ordinary or Associate membership of AIFP, as defined in the Rules of the Association.

"Minor Breach" is a breach of this Code that has no safety implications to the patient's wellbeing but may have an effect on how the medical professional will prescribe the product or repeated lesser breach of the same nature.

"Non-interventional studies" means that the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorization. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data.

"Product" means any compound and/or delivery method that is approved for registration by SUKL.

"Product Information" means a document containing information about the product which is compiled in the SUKL Guidelines for the Registration of Drugs or subsequent revision.

"Promotion", "Promotional" or "Promotional claim" means any statement made by a Member or Member's representative, whether verbal or written, which conveys the positive attributes of a product which extend beyond a simple non-qualitative or quantitative description of the therapeutic category or approved indication for the purpose of encouraging the usage of that product. It includes 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 product conveyed by any means whatever for the purpose of encouraging the usage of a product.

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

"Registration" is the issue by the Ministry of Health of an Czech registration number for a product approved for marketing in Czech rep.

"Repeated major breach" means when a Member repeats major breach within a period of 24 months in the promotion of any of the Member's products.

"Samples" means a quantity of a product supplied without cost to medical practitioners, dentists and hospital pharmacists.

"Substantiation" means to give reasonable grounds in support of a promotional claim. Substantiating information should conform with the requirements of Section 1.3, and must not rely solely on data on file.

"Trade display" means a display or exhibit of promotional or educational material about a product or products.

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

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

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

ANNEX B

GUIDELINES FOR INTERNET WEBSITES AVAILABLE TO EALTHCARE PROFESSIONALS, PATIENTS AND THE PUBLIC IN THE CZECH REPUBLIC

The Guidelines for Internet Websites Available to Healthcare Professionals, Patients and the Public in the Czech Republic set forth herein are intended as a supplement to the provisions of the Code of Practice on the Promotion of Medicines (the "AIFP Code").

SECTION 1. **Transparency of Website Origin, Content and Purpose.**

Each website shall clearly identify:

- the identity and physical and electronic addresses of the sponsor(s) of the website;
- the source(s) of all information included on the website, the date of publication of the source(s) and the identity and credentials (including the date credentials were received) of all individual/institutional providers of information included on the website;
- the procedure followed in selecting the content included on the website;
- the target audience of the website (e.g., Healthcare Professionals, patients and the general public, or a combination thereof); and
- the purpose or objective of the website.

SECTION 2. **Content of Websites.**

Information included in the website shall be regularly updated and shall clearly display, for each page and/or item, as applicable, the most recent date as of which such information was up-dated.

Examples of the information that may be included in a single website or in multiple websites are: (i) general information on the company; (ii) health education information; (iii) information intended for Healthcare Professionals (as defined in the AIFP Code), including any Promotion; and (iv) non-promotional information intended for patients and the general public about specific Medicinal Products marketed by the company.

General information on the company. Websites may contain information that would be of interest to investors, the news media and the general public, including financial data, descriptions of research and development programmers, discussion of regulatory developments affecting the company and its products, information for prospective employees, etc. The content of this information is not regulated by these guidelines or provisions of medicines advertising law.

Health education information. Websites may contain non-promotional health education information about the characteristics of diseases; methods of prevention and screening and treatments, as well as other information intended to promote public health. They may refer to Medicinal Products, provided that the discussion is balanced and accurate. Relevant information may be given about alternative treatments, including, where appropriate, surgery, diet, behavioral change and other interventions that do not require use of Medicinal Products. Websites containing health education information must always advise persons to consult a Healthcare Professional for further information.

Information for Healthcare Professionals. Any information on websites directed to Healthcare Professionals that constitutes promotion (as defined in the AIFP Code) must comply with applicable code(s) (as defined in the AIFP Code) and any other industry codes of practice governing the content

and format of advertisement and promotion of Medicinal Products. Such information must be clearly identified as information for Healthcare Professionals, but need not be encrypted or otherwise restricted.

Non-promotional information for patients and the general public. Subject to any applicable national laws and regulations, websites may include non-promotional information for patients and the general public on products distributed by the company (including information on their indications, side-effects, interactions with other medicines, proper use, reports of clinical research, etc.), provided that such information is balanced, accurate and consistent with the approved summary of product characteristics. For each product that is discussed, the website must contain full, unedited copies of the current summary of product characteristics and patient leaflet. These documents should be posted in conjunction with other information about the products or be connected with that discussion by a prominent link advising the reader to consult them. In addition, the website may provide a link to the full, unedited copy of any public assessment report issued by the Committee for Medicinal Products for Human Use or a relevant national competent authority. Brand names should be accompanied by international non-proprietary names. The website may include links to other websites containing reliable information on Medicinal Products, including websites maintained by government authorities, medical research bodies, patient organizations, etc. The website must always advise persons to consult a Healthcare Professional for further information.

E-mail Enquiries.

A website may invite electronic mail communications from Healthcare Professionals and patients or the general public seeking further information regarding the company's products or other matters (e.g., feedback regarding the website). The company may reply to such communications in the same manner as it would reply to enquiries received by post, telephone or other media. In communications with patients or members of the general public, discussion of personal medical matters must be avoided. If personal medical information is revealed, it must be held in confidence. Where appropriate, replies shall recommend that a Healthcare Professional be consulted for further information.

SECTION 3. Links from Other Websites.

Links may be established to a company-sponsored website from websites sponsored by other persons, but companies should not establish links from websites designed for the general public to company-sponsored websites that are designed for Healthcare Professionals. In the same manner, links may be established to separate websites, including websites sponsored by the company or by other persons. Links should ordinarily be made to the home page of a website or otherwise managed so that the reader is aware of the identity of the website.

SECTION 4. Website Addresses in Packaging.

Subject to any applicable national laws an regulations, uniform resource locators (URLs) of company-sponsored websites that comply with these guidelines may be included in packaging of Medicinal Products.

SECTION 5. Scientific Review.

Companies should ensure that scientific and medical information prepared by them for inclusion in their websites is reviewed for accuracy and compliance with the applicable code(s). The scientific service established within the company pursuant to those provisions of the applicable code that adopt Section 1.02 of the EFPIA Code may perform this function, or it may be entrusted to other appropriately qualified persons.

SECTION 6. **Privacy.**

The website must conform to legislation and applicable codes of conduct governing the privacy, security and confidentiality of personal information.

ANNEX C

DECLARATION OF ADOPTION OF THE AIFP CODE OF ETHICS

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

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

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

Organisation name: ……
……
Organisation ID No.:…...…….
Address:……
……..
Telephone number:…… Fax: ……..
www:……..…
E-mail address of contact person …….
Contact person: ……

Date: …… Authorised representative's signature:…….