CODE OF ETHICS FOR PHARMACEUTICAL MARKETING COMMUNICATIONS

The meanings of terms and abbreviations frequently used in the Code of Ethics of Drugs Communication **(*in order of appearance*) are as follows:**

Associations	Professional and trade interest representing organizations of the Companies manufacturing or distributing drugs in Hungary: The Hungarian Pharmaceutical Manufacturers Association and the Association of Innovative Pharmaceutical Manufacturers, "Védettség" Association of Vaccines & Immunbiological Product Manufacturers & Distributors and the Hungarian Association of Generic Manufacturers and Distributors jointly.
Code	Code of Ethics for Pharmaceutical Marketing Communication
KEB	Communication Ethics Committee run by the Associations
Company	Any pharmaceutical manufacturer and/or distributor economic organization being signatory to the Code
Healthcare Professional	Persons having medical qualifications, playing a role in the recommendation, prescription, procurement, selling, distribution or administering of drugs and/or in the provision of health services, including, in particular, a doctor, pharmacist, healthcare assistant, member of health service provider staff or any other specialist working in health care.
Marketing communication	Any activity and provision of information with direct relevance to the business of a Company irrespective of the form and means in which it is delivered, performed in order to influence the attitude and conduct of the addressee of communication.
Marketing practice	Information, activity, practice, marketing or other kinds of marketing communication intending to increase prescription, procurement, sale or consumption of a medicinal product
Advertisement	Communication, information or practice of presentation aimed to increase sale of a medicinal product or its use in any other way or to popularize the name, image, activity of a Company or increase knowledge of goods or logos for the same very purpose
Promotion	A marketing practice dealing with the composition, effect, administration of a medicinal product, and performed only for and by Healthcare Professionals qualified to prescribe and sell medicinal products. Marketing communication used for consumers as well shall not qualify as promotion
Independent Event	Independent professional-scientific events and programs initiated or organized by or in the interest of other than a Company or for

	other than a Company including events organized by Patient Organizations for which companies have no influence on deciding about the professional program or the contents of the program
Company Event	Programs, events or conventions initiated or organized by a Company or for a Company or sponsored by a Company for Healthcare Professionals, organizations of Healthcare Professionals, patients, Patient Organizations and/or their members. Company Events include, in particular, promotional events, symposia, scientific meetings, factory visits, advance training, meetings attended by principal investigators of clinical trials and non interventional studies.
Patient Organization	Non-profit organizations – including so-called umbrella organs of such organizations – established usually with support from patients, their family members or careers, representing, in essence, the rights of patients, diseases and treatment information in some therapeutic field, representing and/or promoting the needs and interests of patients and/or their careers
Clinical trial	Investigations classified as medical research carried out in human beings in one or more centers with one or more medicinal products with the aim to *a)* explore their clinical, pharmacological or pharmacodynamic effect, and/or *b)* identify any undesirable side effect associated with them, and/or *c)* studying their absorption, distribution, metabolism and elimination in order to prove the innocuousness, effectiveness, risk/benefit balance of the preparation not including non-invasive trials
Non-interventional trial	Trials classified as medical research carried out in human beings where: *a)* prescription of a medicine is not related to the patient's participation in the clinical trial, and *b)* the medicine is prescribed for the patient according to normal medical practice in accordance with the marketing authorization, and *c)* enrolment of the patient in a given treatment strategy is not defined in advance in a treatment plan but the medicine is prescribed according to current medical practice and prescription is clearly distinguished from the decision to enroll the patient in a trial, and *d)* the patient is not subjected to any supplementary diagnosis or monitoring in addition to the regular medical practice, and *e)* collected data are analyzed only by epidemiological methods.

Donation	Sponsorship provided without consideration in exchange, along with movable objects handed over partly or fully free of charge, and services provided partly or fully free of charge
Sponsorship	Provision of a sum of money or other pecuniary benefit not including tax credit or surety

CHAPTER 1 – Legislative background

1.1 The Associations and Companies acknowledge their responsibility in devising and implementing ethical pharmaceutical marketing communication, in their effort to provide right and broad ranging information that truly reflects the role of industry and trade in the Hungarian healthcare system, in the interest of public health.

1.2 The statutory regulations governing marketing practice for medicinal products in Hungary are, in regard to the Code, background rules from which it is only possible to deviate in the course of the interpretation or application of any provision comprised in the Code if such deviation stems from the rules of the Code.

1.3 The purpose of the Code is not to repeat legal norms but to supplement the text of statutory regulations and thus to regulate, together with the statutory regulations, the commercial practices of Companies and – in a broader sense – of Healthcare Professionals in relation to drugs and the conditions of the performance of their lawful and ethical activities. Marketing practice must therefore simultaneously satisfy the provisions of this Code and all applicable legal statutes. Hence in doubtful cases the activity must be undertaken with adherence to the stricter rules that apply to that activity.

2. The Code complies with the minimum requirements of the European Federation of Pharmaceutical Industry Associations (EFPIA) European Code of Practice.

3. This Code has been approved by the respective decision making bodies of the Associations. Only the General Assemblies have the right to amend this Code and the General Assemblies shall authorize the Board of MAGYOSZ / AIPM Executive Committee to amend and align the Code as necessary in their own authority whenever changes to relevant legislation occur.

4.1 The General Assemblies of MAGYOSZ and AIPM approved the original text of the Code on 10 April 1995 and 9 May 1995, respectively.

4.2 Current amended text of this Code became effective after the ally of Association of the Hungarian Generic Pharmaceutical Manufacturers and Distributors Interest and “Immunity” Vaccine and Immunobiology Product Manufacturers, 1 March 2012. The provisions shall apply to cases started after the effective day.

4.3 The amendments to the Code adopted as specified in subsections 4.1 and 4.2 in this Chapter and the consolidated text of such amendment were adopted by the General Meeting of the Hungarian Pharmaceutical Manufacturers` Association on 10 June 2014, by the General Meeting of the Association of Innovative Pharmaceutical Companies on 12 May 2014, the

General Meeting of the 'Immunity' Association of Manufacturers and Distributors of Inoculants and Immunobiological Products on 26 May 2014, the General Meeting of the Hungarian Association Manufacturers and Distributors of Generic Drugs on15 April 2014. The consolidated text of this Code including its amendments will enter into force on 1 July 2014.

5. The Companies shall consider the provisions set out in this Code and the spirit of the Code as binding upon them. They recommend compliance with and use of this Code for all non-member natural persons and legal entities active in the field of pharmaceutical manufacturing, trade, advertising and communication in Hungary. Any pharmaceutical market stakeholder or association is free to join the signatories to this Code.

CHAPTER 2 – Enforcement of the CODE

In order to identify cases of violation of this Code and to publish position statements to promote enforcement of this Code, the Associations set up an executive body functioning in the form of a committee, called Communication Ethics Committee (hereinafter: 'KEB') and lay down its procedural regime as part of this Code, providing that the KEB evaluates submissions filed with the KEB or its Chair by applying the provisions of the Code.

CHAPTER 3 - Applicability of the CODE

1.1 The scope of this Code shall cover marketing practice undertaken with by Companies medicinal products as regulated in Act XCV of 2005 on Medicinal Products for Human Use and Amendments to Other Regulations on Medicinal Products.

1.2 The scope of the Code shall apply to

a) the Companies,
b) business entities that are not member companies of any Association, recognizing the provisions of this Code as binding on themselves,
c) persons and organizations engaged in commercial practices as commissioned by or with the approval of business entities referred to in sub-paragraphs *a)* and *b)*,
d) persons and organizations engaged in commercial practices without being commissioned by business entities referred to in sub-paragraphs a) and b) but with their knowledge and in their interests.

1.3 For the purposes of the application of subsection 1.2 in this Chapter, cases where the beneficiary of the commercial practice does not, in a proven way, call on the entity pursuing commercial practices in a way that is in breach of the rules set out in the Code to stop such activities and it does not use its best efforts to make sure that the conduct that is contrary to the Code is put an end to, shall also qualify as a Company's approval.

1.4 The scope of this Code shall cover, but not be limited to the following marketing communication activities whether or not they target consumers/patients (advertisement) or Healthcare Professionals (promotion):

a) word of mouth;
b) printed materials;
c) electronic data carrier media;
d) advertisements (the press; electronic media; outdoor advertisements);
e) printed materials for Healthcare Professionals;

f) audiovisual systems;
g) conferences and congresses;
h) medicine samples, gifts;
i) internet:
j) telecommunication.

2. The scope of the Code shall not cover and therefore its provisions shall not apply to:
a) accompanying documents for medicinal products,
b) factual, informative announcements relating, for example, to packaging changes or adverse-reaction warnings,
c) information supplied in trade catalogues or price lists, provided they include no product claims with regard to the effect or use of a medicinal product,
d) information given to answer unsolicited, specific questions about a particular medicinal product.

CHAPTER 4 – Provisions of the CODE

1. Marketing authorization

1.1 No marketing of a medicinal product shall be performed unless the medicinal product has been granted a marketing authorization in Hungary.

1.2 All information presented during marketing practice must be consistent with the summary of product characteristics.

1.3 New scientific knowledge relating to drug research may be disclosed at professional-scientific conferences or in professional publications if the provision of such information does not qualify as commercial practice according to existing legislation. Even in communicating such information it must be clearly pointed out that the information made available in this way is not part of the marketing authorization of any specific drug.

2. Information to be provided

2.1 In the interest of providing detailed and balanced information on medicinal products, all written promotional materials presented to Healthcare Professionals must, include the following information, in a clear and legible form:
a) the medicinal product's
aa) authorized name – including dosage form and strength –; active pharmaceutical ingredient (international non-proprietary name); approved indication(s);
ab) dosage and method of administration;
ac) contraindications;
ad) most important adverse reactions;
b) the following warning: *"For more information, please read the summary of product characteristics";*
c) the date on which the summary of product characteristics was last approved;
d) name and address of the marketing authorization holder's agent in Hungary, who is available to provide more information on the use of the medicinal product;
e) the internal ID of the printed material;
f) date on which the document was finalized or last updated

2.2 If it can be used in the course of the health service providing activities, only the following shall be displayed on the item handed over in the course of commercial practice – including in cases referred to in subsections 10.1–10.3 of this Chapter :

a) the name of the drug, or
b) its international non-proprietary name, or
c) the name, or trade mark/identifying symbol (logo) of the Company,

the information referred to in subsection 2.1 of this Chapter need not be presented.

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

2.3 If information qualifying as promotion is presented on the item referred to in subsection 2.2 of this Chapter, the rules set out in subsection 2.1 of this Chapter shall be applied as appropriate.

3. Validation and substantiation of the information presented

3.1 Information and documents provided during marketing practice with medicinal products shall be accurate, balanced, fair, objective and sufficiently complete to enable Healthcare Professionals receiving such information to form their own opinion of the therapeutic value of the medicinal product in question. The information shall be based on an up-to-date evaluation of scientific evidence and reflect that evidence clearly. It must not mislead by distortion, undue emphasis, omission, or in any other way.

3.2 Marketing practice should encourage rational use of a medicinal product by presenting its properties objectively. Information imparted in the course of commercial practices may only declare that a medicinal product/active pharmaceutical ingredient has any special merit, quality or property unless such claims are well founded and scientifically proven. Unique, outstanding attributes should only be used when and where they can clearly be proven. In the case of doubt, any special merit, property or capability or any unique or outstanding feature of the medicinal product/active pharmaceutical ingredient must be proven by the person asserting such fact.

3.3 Clinical conclusions from data gleaned from in vitro and animal experiments and/or from healthy volunteers shall not be drawn unless the relevance and significance of such data is verified.

3.4 In the course of marketing practice, no differentiation shall be made between original and follow on products (generic or biological drugs) unless the difference is scientifically demonstrated. The original or follow on nature of a product shall not be presented as a special merit, value, advantage or disadvantage, deficiency or risk of that product.

3.5 If the information being communicated refers to research results published in a way that is accessible for the Healthcare Professional, such references must be clearly presented and they must be consistent with the instructions on the administration of the product.

3.6 The entire presentation of the information being communicated must be in line with the following principles, including charts, figures, photographs borrowed from published studies:

a) the source must be clearly specified;

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

c) particular care must be taken to ensure that the artwork does not mislead about the nature of a medicine (e.g. whether it is appropriate for use in children) or about a claim or comparison, particularly by using incomplete or statistically irrelevant information or unusual scales;

d) data published in the referenced publication(s) in tabular or textual form may be displayed graphically under the following conditions:

da) all data being relevant for the substantiation of the claim shall be displayed;

db) if only part of the data of a table is displayed this fact shall clearly be indicated;

dc) scales shall be displayed accurately and non-continuous scales must be marked as such;

de) „n" values (number of items) and significance values shall be provided;

dd) the text of a graph should legibly and clearly indicate that it is based on data which were used in the publication – page number and/or figure number provided.

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

3.8 The word "safe" or any of its derivatives must never be used to describe a medicinal product without proper definition of its meaning (e.g. "plasma concentration will not rise even in the case of renal insufficiency", etc.), referring to the proper source and avoiding any exaggerated generalizations (such as "proven safety").

3.9 The word "new" must not be used to describe any medicinal product for longer than one year from its introduction to the market, from the product's general commercial availability on the Hungarian market. This period runs from the first delivery of the medicinal product to the wholesaler for the purpose of sale in Hungary.

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

3.11 In the case of comparing two or more medicinal products in any commercial communication, all claims relating to the medicinal product compared should be objective. Comparison should be relevant and based on one or more essential, dominant, characteristic and verifiable properties of the products. Only comparable aspects are to be compared. In the course of comparing products to each other:

a) the comparison must not be misleading;

b) competitors' products must not be discredited;

c) no unfair advantage may be obtained by misuse of the reputation of a competitor's product or trademark;

d) advertisement materials or other materials containing information produced by other Companies must not be promoted, even in imitation, and/or published as own work,

e) price comparison in any advertisement material shall qualify as pharmaceutical advertisement, and therefore such comparisons should use specific data and precise references to the source.

3.12 The provisions in subsection 3.11 *e)* of this Chapter shall also apply to comparisons made during promotion.

3.13 Scientific literature to be used for substantiating a promotion must, on request, be provided within ten (10) working days, to Healthcare Professionals, competitors or the competent authorities. Only published studies should be used for substantiation, including, as a minimum requirement, written abstracts of lectures delivered or posters presented at local or international conferences. Substantiation need not be provided, however, in relation to the contents of the summary of product characteristics.

4. Use of quotations

Quotations from scientific publications and professional disclosures shall be faithfully reproduced in promotional and advertisement materials delivered as part of the marketing practice, and their authors and place of publication and precise source must identified. Where adaptation or modification is required in order to comply with any applicable legislation or ethical code, it must be clearly stated that the quotation has been adapted and/or modified.

5. Acceptability for marketing practice

Companies shall maintain the highest ethical standards at all times. Marketing practice shall:

a) never be such as to bring discredit upon the pharmaceutical industry or jeopardize confidence in the Companies;
b) shall be carried out paying attention to the special nature of a medicinal product and the professional standing of the recipient;
c) not be abusive, offending, decisive or aggressive;
d) be succinct and consistent with the grammatical rules and orthography of the Hungarian or any other language used, and with the rules of proper style;
e) be easily understandable for consumers and/or patients to whom the advertisements are addressed;
f) be subject to reasonable self-control and moderation.

6. Recipients of marketing communication

6.1 Professional marketing practice shall only be directed at those whose need for, or interest in that particular piece of information can reasonably be assumed.

6.2 Mailing lists of persons receiving marketing communication shall fully comply with data protection regulations. Mailing lists shall be kept up-to-date. Requests of the addressees of commercial communications for getting removed from the mailing list and for the modification of data being controlled must be complied with.

6.3 Commercial practices may be conducted with the aim of direct business acquisition through any communication channel only with the addressee’s prior proven consent or at its express request, in accordance with statutory regulations on data protection and all other relevant and applicable regulations.

7. Transparency of marketing communication

7.1 Commercial practices shall not be concealed and any concealed communication intended to appear as neutral information (including particularly covert advertisements or promotion) shall be prohibited.

7.2 Where a Company pays for or otherwise secures or arranges the publication in any journal of documents or other written material it had used during marketing communication, such material must not resemble independent professional or scientific publication or editorial content. To this end, the names of both the author and the sponsor(s) must be attached.

7.3 Information published on medicinal products and their uses, be it scientific information, promotion or advertisement, which is sponsored by a Company, must clearly indicate the fact of sponsorship and provide the name of the Sponsor.

7.4 Marketing practice should not pose as medical research (such as non-interventional studies including retrospective studies) in the form of post marketing surveillance, training, market research or other non-commercial data collection. Such activity shall be carried out in accordance with applicable legislation and as provided for in Section 14 herein.

7.5 The use of pre-made, pre-printed, stamped or otherwise duplicated prescription forms containing the name of a medicinal product, or the use of promotional or advertising materials that closely resemble prescription forms, shall not be allowed in marketing practice. The use of pre-made, pre-printed, stamped or otherwise duplicated other forms (e.g. referrals, recommendations, etc.) containing the name of a prescription-only or reimbursable medicinal product shall be prohibited in marketing practice.

7.6 Advertisements should be distinguished from other content and clearly display their advertising nature. It should clear that these advertisements advertise medicinal products.

8. Advertisements targeting patients and consumers

8.1 Any publicly disseminated information containing the name of a medicinal product or any reference identifying such a product shall be deemed marketing communication. Sponsoring of media services or programs and product presentation in programs shall not qualify as advertising.

8.2 The following shall not be advertised apart from vaccination campaigns authorized by the competent public administration organization:

a) medicinal product available on medical prescription only;
b) Medicinal product included in the scope of the health insurance system;
c) other substances prohibited by law.

8.3 Advertisements targeting patients / consumers shall not contain any comparison, claim, reference or expression that:

a) gives the impression that a medical consultation, treatment or surgical operation is unnecessary or omissible;

b) suggests that the effects of taking the medicine are guaranteed or are unaccompanied by adverse reactions;
c) implies that the medicine is a cosmetic or a food product;
d) attributes the safety or efficacy of the medicinal product to its natural origin;
e) by description or detailed presentation of a case history, may result in inaccurate self-diagnosis;
f) presents any alteration or condition caused by a disease or an injury, or any effect exerted by a medicine on the human body or on any parts hereof in a frightening or untrue manner;
g) refers to recommendations by scientists, Healthcare Professionals or celebrities;
h) suggests that human health will be impaired if the medicine is not used.

8.4 For the purposes of subsection 8.3 *g)* of this Chapter,

a) a well-known person is a natural or fictitious person who, owing to his/her general popularity, widely recognized professionalism, good reputation or credibility, is suitable to influence – through his/her appearance or a reference to him/her, particularly a reference to his/her name – the behavior of a reasonably well-informed consumer proceeding with the generally expected care and attention, including, in particular, the consumer's decision on whether or not to buy a certain product,

b) in evaluating a recommendation, all of the elements of an advertisement must be taken into account, particularly the messages carried by its text, sound effects and visual elements to the average consumer. Recommendations include, in particular:

ba) advertisements including any of the words "I recommend/suggest", "he/she recommends/suggests", "with the recommendation of" or similar expressions;

bb) certain movements or gestures made by the person appearing in the advertisement that are clearly indicative of handing over, offering, or holding out the product,

bc) all elements of an advertisement carrying messages of positive evaluation of the product's efficacy or effectiveness.

8.5 In the event patients or consumers ask for advice on personal medical matters, they should be advised to consult their physician.

8.6 Patient information brochures and educational materials containing particulars of prescription-only medicinal products may only be given to patients for whom a Healthcare Professional had previously prescribed the product. The information provided in such publications should not be promotional in nature and must reflect the official administration instruction as closely as possible. Their purpose should be to transfer knowledge about the condition for which the product is intended, provide advice on administering the product and improve patient compliance.

8.7 The Company must verifiably ensure that the publications referred to in subsection 8.6 of this Chapter reach only those patients whose Healthcare Professional has already made a therapeutic decision on the administration of the medicinal product concerned. Publications referred to in subsection 8.6 of this Chapter containing the name of a prescription-only medicinal product or any reference identifying such a product shall be regarded illegal medicine advertisement if they are handed over in a way that they can also be accessed by patients not using that product.

8.8 The publications referred to in subsection 8.6 of this Chapter must, in a prominent and legible manner, display the following warning: "This information material is only intended for patients whose physician has prescribed …… to them."

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

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

9. Events and hospitality

9.1 Company events must be held in an appropriate venue that is consistent with the main objectives of the event. In selecting venues those renowned for their entertainment establishments or extravagant venues offering extraordinary experiences that are not compatible with the Company event's key objectives shall be avoided.

9.2 No company should organize or sponsor any event that takes place outside Hungary and no participation at any Independent Event that takes place outside Hungary shall be sponsored unless:

a) most of the participants are from abroad and it makes greater sense professionally and logistically to hold the event in another country, or;
b) given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country, or;
c) the Company organizes a program for the Hungarian participants of an independent professional/scientific event hosted abroad, which program is
ca) related to the event,
cb) hosted during that event,
cc) a supplementary professional/scientific program.

A supplementary professional/scientific event shall not be an opportunity to prolong the duration of the stay abroad without due justification.

9.3 At international events, Independent or Company Events hosted in Hungary any information displayed at exhibition stalls or information pertaining to medicinal products delivered in any way to the participants must conform to the regulations on drug promotion and on the advertising of drugs. Drug promotion may be conducted in the professional or scientific programs of Independent events sponsored by the Company if the direct and indirect promotion (including for instance presentation on the administration of a concrete product, holding of product presentations, leasing of exhibition stands) is clearly separated within the program of the scientific or professional event.

9.4 Sponsorship granted in kind for participation at an Independent Event or at a Company Event held with professional and advance training purpose and not qualifying as promotion shall strictly be limited to travel, meals and accommodation during the event and to the genuine registration fees. Sponsorship shall not exceed what the sponsored would normally be prepared to pay for him. Sponsorship granted for participation at an Independent Event or a Company Event held with professional and advance training purpose and not qualifying as promotion shall only be extended to persons that qualify as participants in their own right.

9.5 When sponsoring Independent Events, either directly or indirectly, sponsoring Companies shall be responsible to ensure that the sponsorship offered is used for the purposes and in the manner as allowed by existing legislation and this Code. To this end sponsoring Companies shall be required to conclude a written sponsorship contract with the party to be sponsored in which the sponsor guarantees that the sponsorship shall not be used for purposes and in manners else than allowed in this Code.

9.6 The Company's purchasing of a service (including, in particular, setting up its own stand or banner), at market price, from the organizer of the Independent event, shall not qualify as sponsorship.

9.7 Events for Healthcare Professionals shall be organized solely with professional, scientific or educational purposes (promotional events, advance trainings, conferences, symposia, congresses).

9.8 Sponsorship extended by a Company in connection with events held for Healthcare Professionals shall not include entertainment (e.g. cultural, sport, or leisure) programs.

9.9 If the event in a foreign country lasts for more than one day, one extra day each may be provided for travelling there and back, provided it is logistically justified. In the case of organized events taking place abroad the registration of Healthcare Professional for the event is a prerequisite for invitation or sponsorship. Arrangements shall be made to ensure that the presentations and contributions delivered during the conference are understood by all, regardless of language proficiency.

10. Restrictions concerning gifts and inducements[1]

10.1 In the framework of promotion of prescription only medicine no gift or pecuniary advantage (in cash or benefit in kind) may, neither directly or indirectly, be supplied, offered of promised to a healthcare professional.

[1] *EFPIA HCP Code bans any promotional gifts and allows transfer of items of medical utility and educational items in two separate articles to clearly distinguish the nature of the two phenomena. In accordance with the definition specified in the Act XCVIII of 2006 on the General Provisions Relating to the Reliable and Economically Feasible Supply of Medicinal Products and Medical Aids and on the Distribution of Medicinal Products in subsection 8 of Section 3 any items allowed to be given to HCPs qualify as a gift. In respect to implement the principle of EFPIA code while not compromising Hungarian legislation this Article bans promotional gifts in connection with prescription-only medicine, while allows gifts for OTC products as well as items of medical utility. (Editorial remark – not part of the approved text).*

10.2 The prohibition of gifts does not apply to the provision of items of medical utility or educational items which are inexpensive, as specified by the applicable statutory regulation, relevant to the medical practice of the Healthcare Professional or beneficial to the care of patients.

10.3 Only inexpensive – as specified in the applicable statutory regulations – gift or pecuniary advantage may be provided for a Healthcare Professional in the context of promotion relating to non-prescription medicinal products, that is relevant to the medical practice of the Healthcare Professional. The provisions set out in subsection 9.5 shall apply to the responsibility of the Company in this case, as well.

10.4 The rules set out in subsection 2.2 of this Chapter shall apply to information displayed on an item for medical or training purposes that has been handed over as referred to above (including among others, the Company's name, the medical product's name, logo and/or other information).

10.5 Prizes offered in technical/professional quiz games or drawing lots as parts of drug promotion or organized events or any other activities shall be in line with the provisions set out in subsections 10.1–10.3 of this Chapter.

10.6 No gifts shall be given to patients or consumers except if they are inexpensive according to applicable legislation and don't encourage consumption or use of a specific medicinal product or the product of a specific marketing authorization holder or make this a precondition.

11. Donation and grants

11.1 Donation and grants to institutions, organizations or associations comprised of Healthcare Professionals (e.g. health service providers, trade bodies) or providing healthcare or conducting research or to other organizations with relevance to healthcare (e.g. patient organizations, registered foundations, non-profit companies, charity organizations) shall be allowed if:

a) they are given for the purpose of supporting healthcare or research;
b) they are unconditionally given, i.e. do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a specific medicinal product or a medicinal product of a specific Company or make this a precondition or to influence decisions on reimbursements; and
c) they are documented and kept on record by the donor/grantor.

11.2 Apart from the reporting obligation as regulated in specific legislation, donors may make information on their other donations and grants publicly available.

11.3 Participation of Healthcare Professionals in professional, scientific and educational Events organized as marketing practice may be sponsored in accordance with the provisions set out in Section 9 of this Chapter.

11.4 No donation or grant shall be given to Healthcare Professionals in their capacity as private individuals.

12 Sponsorship awarded to Healthcare Professionals

12.1 Whenever awarding sponsorships to Healthcare Professionals, Companies must avoid using unfair influence or the impression of attempting to unfairly influence the recipients.

12.2 Sponsorship must not be offered as compensation merely for attending an Event. Hospitality extended to participants must comply with the provisions in subsection 9.1 and 9.4 of this Chapter.

13 Use and remuneration of services

13.1 Contracts between Companies and Healthcare Professionals, their institutions, organizations and associations under which such institutions, organizations or associations provide any type of service to the Companies are allowed if the subject matter of such service is healthcare or research and the payment does not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a specific medicinal product.

13.2 Companies may contract Healthcare Professionals as experts or consultants (hereinafter: consultants), either individually or in groups, for services that involve honoraria or trips, such as, holding lectures, chairing meetings, participating at medical research or clinical trials, holding trainings, taking part in advisory board meetings and market research. The contract must fulfill the following criteria:

a) a legitimate need for a service and for the conclusion of a contract for that service has existed on the part of the Company already prior to the contract;
b) the number of consultants and the scope of the service cannot be greater than what is reasonably expected to satisfy the genuine need;
c) the criteria for selecting consultants are directly related to the nature of the service and the persons responsible for selecting the consultants have the expertise necessary to decide whether a particular Healthcare Professional meets those criteria;
d) a written contract between the Company and the Healthcare Professionals must be in place prior to the commencement of the service, specifying the subject matter of the service to be provided and with a view to paragraph *e)* the calculation method of the payment and its extent;
e) remuneration of the service must reflect the fair market value of the service provided. False consultancy contracts are not allowed;
f) Companies must keep proper records of the service provided and make appropriate use of the result.

13.3 Companies are strongly encouraged to

a) put down in their written contract concluded with the consultants that consultants are required to disclose that they work for the Company whenever they write or speak in public about a matter that is the subject matter of the contract or any other issue relating to that Company;
b) ensure that practicing Healthcare Professionals working part time at a Company as consultants are required to disclose that they work for the Company whenever they write or speak in public about a matter that is the subject matter of the contract or any other issue relating to that Company.

13.4 Limited market research such as ad hoc telephone interviews, or questionnaires sent by post/e-mail or posted on the Internet shall not fall under the scope of subsection 13.3 of this Chapter, provided that the participation of the Healthcare Professional is not recurrent (regarding the frequency of inquiries in general or in the given research in particular) and remuneration for the service provided does not exceed one monthly amount of the prevailing minimum wage in a year.

13.5 Where a Healthcare Professional attends an event as consultant, Section 9 of this Chapter applies to the event and to hospitality.

14. Studies, research activity

14.1 In order to avoid conflicts of interest, the use of unfair influence or the impression thereof, any personnel directly involved in sales (medical sales representatives, sales and marketing staff) shall not be allowed to take part in the organization, arrangement, and evaluation of clinical trials or trials not entailing intervention (hereinafter: trial), and particularly, in the selection of the trial sites and the professionals carrying out the trials. Purely logistical duties, such as distributing and collecting data sheets, may be an exemption from this rule. Participation of medical sales representatives in such duties shall not be linked to marketing practice.

14.2 Healthcare Professionals may receive remuneration from the Company for their involvement in a study. The remuneration must be commensurate with the usual market value of the work performed. Prior to the study, a written contract must be concluded with the Healthcare Professional or health service provider performing the study, the contract specifying tasks, responsibilities and remuneration for the participants. Payment by a Company shall always be made against invoice or after verification of performance, by bank transfer.

14.3 The findings of a study shall be evaluated and their summary - where specific other legislation stipulates it - submitted to the regulatory authority within the stipulated time frame. A summary of the study findings - irrespective of whether they are favorable or unfavorable to the medicinal products of the sponsoring Company, must be published within one year of the completion of the study.

14.4 Apart from the aforesaid, non-interventional studies shall meet the following criteria:

a) he study is conducted for scientific purposes;
b) a written study plan (protocol) is in place;
c) the study does not constitute an inducement to recommend, prescribe, purchase, dispense sell or use a specific medicinal product;
d) the protocol is to be approved by the scientific organizational unit of the Company and supervision of the study also carried out by that scientific organizational unit where a doctor or a pharmacist is employed, who are in charge of supervising the non-interventional study (including the work of medical sales representatives). This person certifies that it had reviewed the protocol of the non-interventional trial and found it compliant with applicable regulations.

14.5 The Company sponsoring a trial shall present the documents proving the authorization of the trial at the request of the KEB.

15. Medicine samples and donations

15.1. Medicine samples and medicine donations shall be provided in accordance with applicable regulations with the proviso that no free medical sample of any prescription-only medicinal product shall be given for a period of two years after commencement of its sale in Hungary.

15.2. Medicine samples and medicine donations shall not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a medicinal product.

15.3. The purpose of giving free medical samples is to enable Healthcare Professionals to study the new medicine and obtain experience with its use.

16. Pharmaceutical company staff

16.1 The personal conditions applicable to medical sales representatives are to be governed to existing regulations.

16.2 Companies shall ensure that their personnel and agents engaged in pharmaceutical marketing communication (medical sales representatives, commercial representatives, marketing staff, agencies):

a) besides professional requirements, know and observe the applicable laws and regulations and the provisions of this Code;
b) carry out their duties lawfully, ethically and responsibly.

16.3 Medical sales representatives shall refrain from:

a) disseminating information which is unfounded and based on non-verifiable facts;
b) taking part in any enterprise or transaction that violates applicable legislation or is unethical;
c) resorting to deceptive or manipulative methods;
d) giving unfounded, false or misleading information about any Company or otherwise defame it or tarnish its reputation;
e) using any inducement or subterfuge to gain an interview with Healthcare Professionals;
f) they shall take care that the frequency, timing and duration of a visit causes no inconvenience to the person visited;
g) upon request they furnish the Healthcare Professional being visited with the usage instructions for the drug being promoted, in a form that is suitable for the Healthcare Professional;
h) report to the Company any feedback on a medicinal product with due regard to adverse reactions.

16.4 Every Company shall employ an adequately qualified specialist in charge of running a scientific service, who will also be responsible for approving marketing communication. Such person shall certify that it has examined the final form of the promotional/advertisement material and found it consistent with the summary of product characteristics, existing legislation and ethical requirements and to be a fair and truthful presentation of the facts about the medicinal product.

16.5 Each Company shall appoint a senior executive who will be responsible for ensuring compliance with the provisions of this Code.

17. PR activities and press relations

17.1 Public Relations (hereinafter: PR) activity:

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

17.1.2 During their PR activities Companies shall respect editorial freedom to the maximum extent and shall not, in any way whatsoever, attempt to influence the contents of any article, interview or broadcast. They however may seek the possibility for peer review to correct factual inaccuracies.

17.1.3 Companies shall not be allowed to pay journalists or media organizations for any articles, interviews or broadcasts that are based on information supplied by the Company if such news items are presented as editorial matter, or indicating the name of the journalist or the phrase "from our correspondent".

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

17.1.5 When preparing press releases or organizing press events Companies must bear in mind who is the "target group" for the press release or the event. In this context:

a) exclusively when briefing journalists and editors of restricted-circulation publications that are intended for Healthcare Professionals and unavailable to the general public, Companies might name prescription-only medicinal products just as they do when briefing the audience of scientific events or symposia.

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

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

17.2 Relations with the Press

17.2.1 No gift, hospitality or benefit shall be provided to members of the press if the gift, hospitality or benefit is suitable to influence them or seen as an attempt at influencing them.

17.2.2 Organizers of press briefings and media events shall select the venue and program of such events with a view to ensuring that the news value, and not the venue itself, is the main attraction for the members of the press.

17.2.3 The only case Companies can sponsor foreign trips for journalists to attend press briefings, media events or scientific symposia is when the information or imagery material presented there could not be obtained without being personally present at the site. The duration of the trip or the level of accommodation or hospitality shall not serve, or be seen as a means of influencing a journalist. If the venue or the program so requires, Companies may also cover the cost of accommodation and meals for maximum one day before and after the event. Companies shall neither directly nor indirectly sponsor any travel and accommodation expenses or meals for any family member or any other person accompanying such a journalist.

17.2.4 Any Company sponsoring a trip may reimburse a journalist for the costs of travel, accommodation and meals, but shall not provide any per diem allowance to any member of the press for the duration of their stay abroad.

18. Relations between pharmaceutical industry and Patient Organizations

18.1 Events for Patient Organizations shall be organized predominantly with patient education or health education purposes that relate to the Patient Organization's activity or qualify as corporate social responsibility. Invitation and hospitality shall only be extended to those members of a Patient Organization that attend the event in their own right. In exceptional cases, where there is obvious health need (particularly in the case of persons with disabilities) the costs of travel, accommodation and meal as well as the registration cost may be paid in part or in full for the care-giver of such person accompanying him/her.

18.2 Hospitality extended by a Company or for a Company in connection with events held for patients, Patient Organizations or their members shall not include entertainment (e.g. cultural, sport, or leisure) programs. Hospitality shall not exceed the level applying to Healthcare Professionals by law and shall be subordinate to the main purpose of the event irrespective of the event being organized by the Company or the Patient Organization.

18.3 As regards the selection of the venue, subsection 9.1 and 9.2 of this Chapter shall apply as appropriate.

18.4 Whenever a Company provides monetary support or significant direct or indirect non-monetary support to a Patient Organization, it must have a written agreement in place. For the purposes of this Code, significant support shall mean any contribution that is given infrequently and whose gross amount exceeds two months' worth of the prevailing minimum wage. The written agreement should include the type of sponsorship, the name and type of the sponsored activity, the amount of the monetary support and a description of the significant direct/indirect non-monetary support and its value as well as the role and responsibilities of any third parties involved.

18.5 Besides purpose-linked support, Companies may provide Patient Organizations with general, free use support, but in this case the contract must stipulate that the organization shall use the support solely for the purposes stated in its deed of foundation and in compliance with all applicable legislation.

18.6 Companies shall have an approval process in place for contracts to be concluded with Patient Organizations. Companies and parties to these contracts shall not conceal the fact of support/sponsorship. The Company and the sponsored Patient Organization in their written agreement shall

a) pledge to always clearly acknowledge any support/sponsorship and make this fact apparent from the start;
b) warrant to apply the provisions of this Code to their contractual cooperation and that the contracting parties shall undertake to observe these provisions.

18.7 Public use of a Patient Organization's logo, trademark and/or proprietary material by a Company requires written permission from that organization. In seeking such permission, the specific purpose and the way the logo, trademark and/or proprietary material are to be used must clearly be stated.

18.8 Companies shall always maximally respect editorial freedom in their dealings with Patient Organizations. In no way shall a Company attempt to influence the text of a press or other material made by or with the involvement of a sponsored Patient Organization to make it favor their own commercial interests. This ban does not however preclude Companies from seeking possibilities for peer review and correcting factual inaccuracies, whenever needed in order ensure that the requirement of the reasonably expected professional care is met. Upon request by a Patient Organization the Company may – in a scientifically neutral and balanced manner – take part in drafting such materials and publications.

18.9 To ensure transparency the Company shall make publicly available the list of Patient Organizations for which it provides monetary support and/or significant non-monetary support. Such disclosure shall include:

a) the value of the monetary support or the costs invoiced by a third party to the Company;
b) description of the support in such a way that people in general can form their opinion on the importance of the support;
c) for significant non-monetary supports whose monetary value cannot be established, the non-financial benefit the Patient Organization gets by way of the support.

The information referred to in this subsection may be published nationally or at the European level, with the date of the last update being indicated. This information should be updated at least once a year.

18.10 At least once a year Companies shall make public the amounts they had paid in the previous year for services bought from Patient Organizations, in a breakdown according to Patient Organization. The published data should include description of the service the Patient Organization had provided to the Company by contract, this description has to be sufficiently detailed and free of confidential data and made such a way that people in general can understand the nature of the cooperation between the Company and the Patient Organization.

18.11 Contracts between Companies and Patient Organizations, under which these organizations provide any service to Companies are allowed if the service intends to promote healthcare or research. Companies may contract Patient Organizations in the capacity of experts or consultants for taking part in advisory body meetings or holding lectures. The contract must meet the following criteria:

a) even before the contract, the Company had a legitimate need for the service and for the conclusion of a contract for that service already;
b) the number of consultants and the scope of the service cannot be greater than what is reasonably expected to satisfy the genuine need;
c) the criteria for selecting service providers or services are directly related to the need to be met by that service and the persons responsible for selecting the service provider or the service have the expertise necessary to decide whether the experts or consultants available at a particular Patient Organization meet those criteria;
d) a written contract between the Company and the Patient Organization must in place prior to the commencement of the service, specifying the subject matter of the service to be provided, and with a view to paragraph e) the calculation method of the payment and its extent;
e) remuneration of the service must reflect the fair market value of the service provided. False consultancy contracts are not permitted. Payment by a Company shall always be made against an invoice or after verification of performance, by bank transfer. False contracts between Companies and Patient Organizations to justify benefits for a Patient Organization for other purposes are disallowed;
f) the Company must keep proper records of the service provided and make appropriate use of the result;
g) a contract between a Patient Organization and a Company cannot be an inducement to recommend a specific medicinal product.

18.12 Companies are strongly encouraged to put down in their written contract with Patient Organizations that the consultants are obliged to disclose that they work for the Company whenever they write or speak in public about a matter that is the subject matter of the contract or any other issue relating to that Company.

18.13 No company shall require that it be the sole funder of a Patient Organization or any of its major programs. For the purposes of this subsection, major programs are those that are made for or involve a target audience of 40 (forty) or more people and have a budget of over two months' worth of the minimum wage.

19. Rules governing Internet websites open to Healthcare Professionals, patients and the general public

19.1 To ensure transparency of the origin, content or purpose of a website every website that are maintained by a Company or supported directly or indirectly in any other way must clearly indicate the following:

a) name, address, and electronic accessibility of the maintainer and the sponsor(s) of the website;
b) source of the information and the date of publication of the source for web surfaces sponsored or maintained by a Company;
c) audience targeted by the website, if restricted (e.g. Healthcare Professionals).

19.2 Website content

Websites must clearly show the date on which the information was last updated, and

a) websites with contents for patients and the general public shall – among other things – display the following information:
aa) general information relating to the Company,
ab) the website may include pieces of information that are of interest for investors, the media and the general public, including financial data, description of research and development programs,
ac) information on regulatory issues with impact for the Company and its products, and information for prospective employees;

b) as information on health education:
ba) the website may include health education information of non-advertisement nature, dedicated to disease characteristics, prevention, screening and treatment methods,
bb) as well as other information posted with the purpose of improving public health;

c) the website may also include information on alternative treatment methods including surgical interventions, change of diet, change of behavior and other interventions not requiring the use of any medicinal product. Websites containing health educational information should always include a suggestion for the visitor to turn to a Healthcare Professional for more advice;

d) prescription-only medicinal products shall include the following information:
da) label, patient information leaflet, and summary of product characteristics as approved by the authority,
db) factual, informative announcements or informative materials relating to packaging changes or adverse-reaction warnings,
dc) commercial price lists provided they include no product claims with regard to the effect of a medicinal product.

e) as regards the information intended for Healthcare Professionals it shall be pointed out that they are provided exclusively for Healthcare Professionals and it shall be ensured that they can only be accessed by Healthcare Professionals.

19.3E-mail inquiries

Websites should offer Healthcare Professionals, patients and the general public the possibility to ask for more information in e-mail about products of a Company and other matters. Companies may answer e-mail inquiries the same way as they answer inquiries received by post, telephone or other means. Communication with patients and the lay public should avoid discussing personal medical matters. The answer should suggest for the enquirer to contact a Healthcare Professional for more advice. Personal health information received should be kept confidential.

19.4References (links)

19.4.1 Websites sponsored by other companies may refer to websites sponsored by the Company but Companies shall not be allowed to post links on surfaces intended for the general public to refer to websites intended for Healthcare Professionals and sponsored by the Company. Similarly, websites may have links referring to other websites, including websites sponsored by the Company or others. The link in general should refer to the starting page of the website or should be such as to enable the visitor to identify the website.

19.4.2 The title of a website might be included on the label with adherence to applicable legislation.

19.6 Professional Control

19.6.1 Companies must ensure that every piece of information on a website they maintain and in the case of sponsored websites the marketing communication presented on that website conforms to the provisions of this Code. If a sponsored or maintained website falls short of meeting the provisions of this Code sponsorship or maintenance shall be discontinued.

19.6.2 Using the name or international non-proprietary name of a prescription-only or a reimbursable medicinal product as a domain name or part of a domain name is allowed only if the maintainer of the website guarantees that the posted information is available to Healthcare Professionals only.

CHAPTER 5 – Rules pertaining to the operation of the KEB

1. Procedural rules

1.1 Ethics complaints and disputes shall be evaluated by the KEB in accordance with its own bylaws pursuant to the provisions of this Code.

1.2 For conducts conflicting with existing legal statutes any proceeding opened and/or completed pursuant to the provisions of this Code shall be without prejudice to the right to open market or advertising pre-vetting procedures, other administrative or court actions under the above legal statutes.

2. Bylaws of the Communication Ethics Committee

2.1 Composition of the KEB and the election of its members

2.1.1 The KEB shall consist of sixteen (16) members and a chairman. Members of the KEB shall participate in the work of the KEB as representatives of their respective associations; they shall have equal rights and obligations, and they shall perform their activities with a view to enforcing the principle of self-regulation. Members of the KEB shall not be instructed or held accountable in relation to their duties linked to specific issues of ethics.

2.1.2 The Associations shall delegate four (4) members each to the KEB. Among the candidates of an Enterprise which considered as joint companies, one (1) member can be elected, irrespective of which association or associations they are members of.

2.1.3 Each year, the Associations shall elect members to be delegated to the KEB in their own competence. The chairpersons of the Associations shall notify each other and the KEB about the members elected, and about any conflict of interests between any of the elected members and any of the affiliated undertakings as specified in subsection 2.1.9 of this Chapter, within a maximum of eight (8) days of the date of election. The Associations shall have the right to recall their elected members in accordance with their respective procedural rules, but a new member must be immediately delegated to replace the recalled member. This rule also applies to cases in which a person’s membership in the KEB is terminated for

whatever reason. The KEB members shall be mandated from 1 July each year and they may be re-elected every year, in accordance with the charters of the associations.

2.1.4 A member delegated to the KEB

a) may request that his opinion concerning a concrete issue be specifically entered in the minutes, and such request shall be carried out on a mandatory basis;
b) may propose that the KEB should discuss a case not qualifying as an issue of ethics but falling in the scope of its competence, which must be submitted to the next KEB meeting,
c) shall initiate ethics proceedings upon learning of any suspicion of conduct breaching the rules set out in the Code,
d) shall participate in the work of the KEB.

2.1.5 The chair of the KEB shall is to be elected and recalled by the respective executive bodies or the Boards of the Associations. 2/3 of the KEB members are required to propose recall of a KEB chairman.

2.1.6 Any person that has no employment relationship with any pharmaceutical company under or outside the scope of this Code may be appointed KEB chairman or person assisting the KEB's work. The KEB's chairman shall be appointed for two (2) years and can be reappointed every two years.

2.1.7 If a KEB chairman is incapacitated in attending to his/her duties, the KEB members shall elect an interim chairman from among themselves. The interim chairman shall attend to the duties of the KEB chairman for the duration of the incapacitation. If incapacitation persists for over three (3) months, the presidents of the Associations shall appoint a new KEB chairman as specified in subsection 2.1.5 of this Chapter.

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

a) convening and chairing the meetings of the KEB;
b) whenever a case ethically warrants, inviting parties – not related to pharmaceutical companies – to a KEB meeting;
c) drafting, documenting and transmitting KEB resolutions to the parties concerned;
d) overseeing the implementation of the decision(s);
e) overseeing observance of the provisions of this Code;
f) representing the KEB.

2.1.9 Any KEB member, who is employed by a party that is interested in or affected by a case being heard by the KEB, shall not participate in the adjudication of that case. Adjudication of a case is understood to mean participation in making decision on the starting of the proceeding and in the proceeding itself, actual decision-making and any appeals procedure. Any chairman that is interested in or affected by a case being heard by the KEB shall not take part in the proceeding or in the appeals procedure during the adjudication of the case. Cases of interest or affection are to be reported to the KEB by any interested or affected member or chairman and by any person that has knowledge of such interest or affection. In doubtful cases KEB shall decide on cases of interest or affection without a debate. If the KEB does not have a quorum as a result of an exclusion, the quorum must be established on the basis of the number of KEB members without the excluded ones.

2.2 KEB meetings and their procedure

2.2.1 Companies shall endeavor to resolve their disputes amicably between themselves before submitting it to the KEB.

2.2.2 The KEB shall open a procedure upon receiving a request/complaint (hereinafter: complaint) or open any ex officio proceedings at its own initiative for issues it has become aware of. A procedure is started ex officio if it has been proposed by a member of the KEB. Complaints are to be submitted by any natural or legal person that has information on conduct or actions violating provisions of this Code.

2.2.3 Complainants may ask for confidential handling of their data by the KEB. In such cases the KEB shall handle complainant data in confidence during and after the procedure. If it is requested by the complainant, his or her identity shall not be shared even with the KEB members. In such cases the identity of the complainant may only be disclosed if the investigation could not be carried out without doing so.

2.2.4 If a complainant seeks a ruling from another authority before, or simultaneously with filing a complaint with the KEB or if the KEB initiates a procedure by the competent authority before making its decision on the issue, the KEB shall not commence its proceedings until the other authority's final ruling is issued or shall suspend proceedings already in progress for the KEB does not wish its own decisions or resolutions to influence other authorities in their decision-making. In such cases all deadlines specified in this Code shall be suspended until decision is taken by the authorities concerned. The proceedings shall be started and/or continued if the relevant authority itself requests that the KEB should conduct the proceedings.

2.2.5 Reports filed with the KEB anonymously shall not be investigated by the KEB but even such notifications shall be sent to in the way of information, to every KEB member.

2.2.6 When the chairman of the KEB receives a complaint, it shall send a copy to the party named in the complaint by way of registered mail or hand delivery within ten (10) days of receipt, irrespective of whether the complainant has done so, and request such other party to present its standpoint on the matter to the KEB within ten (10) days. The KEB may only hear the case on the merits after the above deadline has expired, regardless of whether the responding party has communicated its standpoint within the deadline. Where the KEB opens an ex-officio proceeding, it shall notify the relevant party or parties of the conduct or action it has identified as presumably violating the Code. Otherwise, ex officio proceedings are conducted the same way as proceedings that are opened upon request.

2.2.7 Complaints submitted to the KEB must include all data and evidence necessary for the evaluation of a case. If a complaint is incomplete, the KEB may once call upon the complainant to have the missing information furnished by a specified deadline. In such cases, procedural deadlines start on the date on which the missing information arrives to the KEB. If the responding party does not supply the missing elements by the deadline, the KEB shall

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

2.2.8 No proceedings shall be launched if at least one (1) year has already elapsed since the date on which the violation of the Code took place.

2.2.9 The chairman and the members of KEB shall treat strictly confidential any data, information and documents that they accessed or otherwise became aware of in connection with a KEB proceeding and that are not in the public domain, and shall retain such data, information and documents and ensure that they are not disclosed to any third party during or after the proceeding. The same applies to the presidents of the Associations and to the assistant that assists the work of the KEB. Members of the KEB and its chairman as well as the assistant helping the KEB's activities shall make out a declaration of confidentiality approved by the KEB, which shall be preserved among the KEB's documents for a period of five (5) years from the discontinuation of membership or the mandate.

2.2.10 The KEB shall hold meetings as often as required, but at least once a month. The Chairman shall convene the meetings of the KEB by a written invitation posted at least three (3) days in advance. In the case of a new report the chairman shall convene the KEB meeting within thirty (30) days of the deadline specified in the communication sent to the party involved in the petition.

2.2.11 Unless otherwise provided in this Code a KEB meeting is a quorum if at least nine (9) members are present. If a regularly convened meeting does not have a quorum, the Chairman shall convene a new meeting again within seven (7) days and repeat this as long as the meeting has a quorum.

2.2.12 The KEB shall hold closed meetings which shall only be attended by the members, the chairman, the assistant, and any invited person and independent external expert.

2.2.13 The KEB shall pass its resolutions with simple majority of votes. The chairman, the invitees and the independent experts attend KEB meetings with consultation right. Where, for the Chairman's incapacitation, the interim chairman chairs a KEB meeting the interim chairman shall have voting right in decision making. In the event of a tie vote, the vote of the Chairman or the interim chairman shall be decisive.

2.2.14 In cases received, the KEB shall pass its resolutions within sixty (60) days of the opening of a procedure. The Chairman may extend this deadline once for another thirty (30) days and at the same time inform all affected parties.

2.2.15 During its proceedings, the KEB shall examine the necessary documents and other materials before deciding on a case, initiate hearing of the affected parties or independent experts or hear a party if any of the affected parties so requests. The KEB does not rely on the assistance of attorneys, it hears only the representatives of the Companies in question. Legal representatives of the Companies will not be allowed to participate in the hearing. The KEB will pass its resolutions regardless of any failure or delay by any party to reply letters, answer an inquiry or attend a hearing.

2.3 KEB decisions

2.3.1 The KEB shall pass a resolution or ruling in the end of every procedure it has opened and send it to the affected parties within fifteen (15) days from date of decision, via registered mail or by hand delivery.

2.3.2 The KEB shall immediately make its decision if:

a) the complaint is rejected without material investigation of the case because:
aa) the KEB is not competent to conduct a proceeding,
ab) the complaint calls for the investigation of an obviously impossible matter,
ac) the complaint was filed late,
ad) the KEB has already adjudicated the complaint,
ae) the procedure was not started against a Company covered by the Code's personal scope and the party specified in the report does not voluntarily submit to the procedure. In such cases the contents of the ruling are identical with those of the resolution with the difference that in the ruling the KEB informs the Company that it will turn to the competent authority if it is assumed from the report that the conduct adopted by the party specified in the report breached some statutory regulation as well.

b) the proceeding is terminated because:
ba) the complaint could have been refused without investigation but the reason for refusal came to the notice of the KEB after the proceeding was launched,
bb) the case is no longer relevant,
bc) the proceeding had opened upon request and the complainant had withdrawn the request, except if the KEB conducts the procedure ex officio or the case had several complainants but not all of them withdrew the complaint,
bd) the proceeding is no longer relevant for the complainant had ceased without legal successor,
be) the circumstances warranting the proceeding no longer exist,
bf) if the affected parties make a deal during a procedure, which deal is not contrary to the provisions of this Code

2.3.3 The KEB shall pass its resolutions on the merits of the case after examining all relevant facts and circumstances of a case. In its written resolutions the KEB shall:

a) give a brief description of the case under investigation;
b) establish whether or not an ethical violation has taken place;
c) explain its decisions; and
d) communicate sanctions if it established that an ethical violation had taken place.

2.3.4 Where an ethical violation is established, the KEB shall impose the following sanctions on the offender:

a) warn it in writing,
b) call upon the offender to stop the violation,
c) oblige it to immediately withdraw the promotional/advertisement material or to immediately collect those that have been issued and to submit a written report on the fulfillment of the obligations set out in the resolution,
d) in the case of a communication ethics violation where deceptive communication might lead to inappropriate use of a medicinal product or pose any other risk to patients/consumers, it may order the offender to distribute a correcting circular letter to the Healthcare Professionals involved in commercial communication;

2.3.5 In the event of a particularly severe ethical violation, the KEB may propose temporary suspension of the membership of the member company condemned in the relevant pharmaceutical association or termination of its membership by expulsion, through the presidency of the competent association.

2.3.6 The KEB may turn to the competent authority in cases where grounds for doing so exist, particularly when it learns of a suspected ethical violation and the procedure had to be

terminated by the ruling referred to in 2.3.2 *ae)* of this Chapter in connection with a Company outside the scope of this Code or adjudication of a case requires procedures that the KEB is not competent to do.

2.3.7 The KEB shall transmit its resolutions on the Associations and shall make them accessible for the member companies within 30 days from the date on which they become binding.

2.3.8 Once a year the KEB shall produce a summary report of its final and definitive resolutions establishing the fact of the code of ethics was breached, without naming the Companies and the medical products concerned, and shall publish it with the participation of the Associations.

2.4 Review of the KEB's resolutions

2.4.1 Resolutions of the KEB are appealable. If an appeal is filed, an ad-hoc committee consisting of four-members will review the resolution. Each Association delegates one experts each to the ad hoc committee. The operation of the ad hoc committee shall be governed by the rules regulating the operation of the KEB with the differences regulated in the Code. The preparation of the meeting of the ad hoc committee, convening the meeting, chairing it and laying down the committee's decisions shall be tasks for the chairman of the KEB. The chairman of the KEB shall attend the meetings of the ad hoc committee with a consulting right.

2.4.2 Appeals against a KEB resolution may be filed within fifteen (15) days of the date on which the resolution was passed. In addition to the KEB members the Chairman informs the Presidents of the Associations about an appeal and invites them to delegate, in agreement with their respective Boards, 1 person each to the ad-hoc appeals committee. The Chairman convenes a meeting of the ad-hoc appeals committee on a date agreed with the ad hoc members delegated by the Associations. The ad-hoc appeals committee session is a quorum, if all the four delegates present. From the date of receipt of an appeal, there will be seven (7) days available to inform the Presidents of the Associations, a further fifteen (15) days to appoint the members of the ad-hoc appeals committee and another fifteen (15) days for the committee to meet and make a decision.

2.4.3 The ad-hoc appeals committee, where necessary, may hear the affected parties at its own initiative or do so at the request of either of the affected parties. The committee make the final decision by simple voting – either upholding or rejecting or amending the original resolution – after review of the documents of the case, any hearing and debate. In case of equal votes the KEB decision remains in effect, and the deadlines for the execution of the tasks set out in it shall run from the date of the delivery of the decision of the ad hoc committee. The committee's resolution shall be communicated by the Committee to the affected parties, the KEB and the Boards in writing within fifteen (15) days. The decision of the ad hoc committee shall be signed by the member designated by the committee.

2.4.4 The rules set out in subsection 2.2.9 of this Chapter on secrecy shall be applied to the members of the ad hoc committee as well, as appropriate, providing that they shall not be obliged to make out the declaration.

2.5 The KEB's position statement

2.5.1 Issuing a KEB position statement may be requested by:

a) any member of the KEB,

b) the Boards of the Associations.

2.5.2 Issue of a position statement and adoption of its full text requires a majority vote of two third of the members present at the KEB meeting.

2.5.3 The publication of the text of the position statement shall be governed by the provisions set out in subsection 2.3.8 of this Chapter. Position statements shall apply to forms of behavior or conduct adopted thirty (30) days after the date of their publication.

3. Enforcement of this Code, closing provisions

3.1 The KEB, the chairman of the KEB and the Presidents of the Associations shall be responsible for overseeing compliance with the provisions of this Code.

3.2 Member companies of the Associations that violate the provisions of this Code shall be sanctioned according to the rules set forth herein.

3.3 Companies that violate the provisions of this Code shall be obliged to implement the resolutions of the KEB.

Budapest,..... 2014