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CODE OF ETHICS FOR PHARMACEUTICAL MARKETING COMMUNICATIONS

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

**Associations**
Professional organisations representing the interest of the Companies manufacturing or distributing medicinal products in Hungary: the Hungarian Pharmaceutical Manufacturers Association, the Association of Innovative Pharmaceutical Manufacturers, the “Immunity” Association of Vaccine and Immunobiological Product Manufacturers and Distributors and the Hungarian Association of Generic Manufacturers and Distributors jointly.

**Code**
Code of Ethics for Pharmaceutical Marketing Communications

**CEC**
Communication Ethics Committee of the Associations

**Company**
Any pharmaceutical manufacturer and/or distributor business organisation being signatory to the Code and part of the Associations

**Healthcare Professional**
Persons having medical qualifications, playing a role in the recommendation, prescription, procurement, selling, distribution or administering of medicinal products and in the provision of health services, including, in particular, physicians, pharmacists, healthcare professionals, members of healthcare 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 the Company irrespective of the form and means in which it is delivered, performed in order to influence the attitude and conduct of the recipient of the communication.

**Marketing practice**
Any information, activity, practice of presentation, marketing or other kinds of commercial communication intending to increase prescription, procurement, sale or consumption of a medicinal product.

**Advertisement**
Communication, information or practice of presentation intended to increase sale of a medicinal product or its use in any other way or in relation to this purpose to popularise the name, image, activity of a Company or to increase knowledge of goods or identification symbol (logo).
| **Promotion** | A commercial practice dealing with the composition, effect, and administration of a medicinal product, and performed exclusively for or by Healthcare Professionals qualified to prescribe and distribute medicinal products. Commercial communication used for consumers as well shall not qualify as promotion. |
| **Independent Event** | Independent professional and/or scientific event and programme that has not been initiated or organised by a Company, nor has it been ordered by or been in the interest of a Company, including events that are organised by Patient Organisations and of which professional programme or the contents of the programme the Company has no influence on deciding about. |
| **Company Event** | Programme, event or convention initiated or organised or ordered by a Company or for a Company or sponsored by a Company for Healthcare Professionals, organisations of Healthcare Professionals, as well as for patients, Patient Organisations and/or their members. Company Events include, in particular, promotional events for medicinal products, symposia, scientific advisory board meetings, factory visits, advanced training, meetings attended by principal investigators of clinical trials and non interventional trials. |
| **Patient Organisation** | Non-profit organisations – including so-called umbrella organs of such organisations – established usually with support of patients, their family members or caregivers, introducing, in essence, the rights of patients, the disease and the information on its treatment in a given therapeutic field, as well as representing and/or supporting the needs and interests of patients and/or their caregivers. |
| **Clinical trial** | Any trial classified as medical research conducted in human beings at a single study site or at multiple study sites, which aim to explore the  

  a) clinical, pharmacological and pharmacodynamic effects of one or more investigational medicinal products, and/or  

  b) identify any undesirable effect associated with them, and/or  

  c) studying their absorption, distribution, metabolism and elimination in order to prove the safety, efficacy, risk/benefit ratio not including non-interventional trials  

| **Non-interventional trial** | Trials classified as medical research conducted in human beings where:  

  a) the medicine is not prescribed for the purpose of the |
clinical trial, and
b) the medicine is prescribed for the patient according to usual medical practice in accordance with the terms of the marketing authorisation, and
c) enrolment of the patient in a particular treatment strategy is not defined in advance in a trial protocol but the medicine is prescribed according to current medical practice and the prescription is clearly separated from the decision to enrol the patient in the trial, and
d) no additional diagnostic or monitoring procedures are applied to the patients other than those used in usual medical practice, and
e) only epidemiological methods are used for the analysis of collected data.

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 pecuniary benefit or other material benefit not including tax credit or surety.

Affected party/parties

A natural person or a legal entity whose right or legitimate interest is affected by the procedure of the CEC or the ad-hoc Committee initiated in a particular case, or by the decision of the CEC adopted in a particular procedure, in particular the reporting party or the party reported (named in the complaint), and any other person in respect of whom the CEC decision contains a ruling.

CHAPTER 1 — Legislative background of the CODE

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

1.2. The statutory regulations governing commercial practice for medicinal products in Hungary are, with 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 Code is not intended 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 medicinal products and the conditions of the performance of their lawful and ethical activities. The commercial practice must therefore simultaneously be in accordance with the provisions of this Code and all applicable statutory regulations. 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, and only the General Assemblies are entitled to amend this Code. The Associations are entitled to amend the Code according to the rules laid down in their internal procedures.

4.1. The General Assemblies of MAGYOSZ and the Association of International Pharmaceutical Manufacturers approved the original text of the Code on the 10th of April 1995 and on the 9th of May 1995, respectively.


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 operating in the field of pharmaceutical manufacturing, trade, advertising and communication in Hungary. Any pharmaceutical market stakeholder or their 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: “CEC”) and lay down its procedural regime as part of this Code, providing that the CEC evaluates submissions filed with the CEC or its Chair by applying the provisions of the Code.

CHAPTER 3 - Scope of the CODE
1.1. The scope of this Code shall cover the commercial practice with medicinal products undertaken by Companies in accordance with the 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 organisations that are not member companies of any Association, if they recognize the provisions of this Code as binding on themselves,
   c) persons and organisations engaged in commercial practices as commissioned by or with the approval of business organisations referred to in sub-paragraphs a) and b),
   d) persons and organisations 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 behalf.

1.3. For the purposes of the application of section 1.2 of 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 ceased, shall also qualify as a Company's approval.

1.4. The scope of this Code shall cover, but shall not be limited to the following commercial communication activities regardless of whether they target patients/consumers (advertisement for medicinal products) or Healthcare Professionals (promotion of medicinal products):
   a) word of mouth;
   b) printed materials;
   c) electronic data carriers;
   d) advertisements (the press; electronic media; advertisements in public places);
   e) printed materials for Healthcare Professionals;
   f) audiovisual advertising materials;
   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) product information of medicinal products,
   b) factual, informative announcements relating, for example, to packaging changes or adverse-reaction warnings,
   c) information supplied in commercial price lists, provided they include no product claims with regard to the effect or the application 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 authorisation

1.1. No commercial practice with a medicinal product shall be performed unless the medicinal product has been granted a marketing authorisation in Hungary.

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

1.3. New scientific knowledge relating to pharmaceutical 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 provided information is not part of the marketing authorisation of any specific medicinal product.

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) authorised name – including strength and dosage form –, active ingredient (international non-proprietary name);
      ab) approved indication(s);
      ac) dosage and method of administration;
      ad) contraindications;
      ae) 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 authorisation holder’s agent in Hungary, who is available to provide more information on the application of the medicinal product;
   e) the internal ID of the printed material;
   f) date on which the document was finalized or last updated.

   Instead of the information presented in subparagraphs ab)-ae) and c), the website address link that leads to the entry in the medicine database of the pharmaceutical public authority or the competent EU authority that refers to the medicine presented can be indicated on the promotional material. In addition to the website address, a QR code pointing to the same web address can also be displayed.

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
section 2.1 of this Chapter need not be presented.

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

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 commercial practice related to medicinal products shall be accurate, balanced, fair, objective and sufficiently complete to enable the addressee of the 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 shall reflect such evidence clearly. The information provided must not be exaggerated or misleading by the distortion of verity, undue emphasis, omission, or in any other way.

3.2. Commercial practice should facilitate the rational use of a medicinal product by presenting its properties objectively. Information provided in the course of commercial practices may only declare that a medicinal product/active ingredient has any special merit, property, or capability if such claims are well founded and scientifically proven. Qualifiers such as unique or outstanding should only be used if and when 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 ingredient must be proven by the person asserting such fact.

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

3.4. In the course of commercial practice, no differentiation shall be made between originator and follow-on medicinal products (generic or biosimilar medicinal products) unless the difference is scientifically demonstrated. The originator or follow-on nature of a medicinal 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 indicated and they must be consistent with the summary of product characteristics.

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

a) the source must be clearly specified;
b) the original information must be faithfully reproduced; except where adaptation or modification is necessary in order to comply with any applicable legislation or ethical code, in this case this fact must be clearly stated;

c) particular care must be taken to ensure that the artwork is not misleading as to the nature of a medicine (e.g. whether it is appropriate for use in children) or is not misleading 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. Generalisations shall not be Comparatives or superlatives shall only be used to describe specific and sufficiently substantiated facts.

3.8. The word “safe” or any of its derivatives may only be used with the accurate definition of its meaning (e.g. “its plasma concentration will not be higher even in patients with renal insufficiency”), referring to the proper source and avoiding any exaggerated generalisations (such as “proven safety”).

3.9. The word “new” may only be used to describe any medicinal product for 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 a wholesaler for the purpose of sale in Hungary.

3.10. It must not be stated that a medicinal 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 serving as the basis for comparison shall be objective. The comparison should be relevant and it should compare one or more essential, dominant, characteristic and verifiable properties of the medicinal products in an objective way. Only comparable aspects are permitted 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 also 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. To the request of Healthcare Professionals, competitors, competent authorities or the CEC, literature used for substantiating the promotion of a medicinal product must be provided within ten (10) working days from such request. Only scientific findings that have been communicated in literature should be used for substantiation, including, as a minimum requirement, written abstracts of lectures delivered or posters presented at local or international conferences. Further substantiation in relation to the contents of the summary of product characteristics is not needed.

4. Use of quotations

Quotations from scientific publications and quotes from professional disclosure statements shall be faithfully reproduced in promotional and advertisement materials delivered as part of the commercial practice, and their authors, place of publication and source must be precisely indicated. Where adaptation or modification is required due to ethical or legal reasons, it must be clearly stated that the quotation has been adapted and/or modified.

5. Acceptability of commercial practice

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

a) never be such as to bring discredit upon the pharmaceutical industry or jeopardize confidence in the Companies;

b) be carried out paying attention to the special nature of the medicinal product and to the professional standing of the recipient of the commercial practice;

c) not be abusive, assaultive, decisive or aggressive;

d) reflect in its texts precision and they shall be consistent with the grammatical rules and orthography of the language used, and with the rules of proper style;

e) be easily understandable for patients and/or for consumers to whom the advertisements and publicity are addressed;

f) be subject to reasonable self-control and moderation.

6. Recipients of commercial communication

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

6.2 Distribution lists of recipients of commercial communication shall fully comply with data protection regulations. Registers and distribution lists shall be kept up-to-date. Requests of the recipients of commercial communications for being removed from the registers and distribution lists and for the modification of data being managed 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 recipients’s prior provable consent or at their explicit request, and in accordance with statutory regulations on data protection and all other relevant and applicable regulations.

7. Transparency of commercial communication

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

7.2. If a Company has documents or other written materials that have been used in the course of its commercial communication, published in any journal, such documents or materials must not resemble independent professional, scientific publication or editorial content. To this end, the names of both the author and the sponsor(s) must be indicated.

7.3. Information published related to medicinal products and their use, 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. Commercial practice should not pose as medical research (such as non-interventional studies including retrospective studies) in the form of post marketing surveillance of side effects, 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 reproduced prescription forms containing the name of a medicinal product, or the use of promotional or advertising materials that are confusingly similar to prescription forms, shall not be allowed in commercial practice. The use of pre-made, pre-printed, stamped or otherwise reproduced other forms (e.g. referrals, recommendations) containing the name of a prescription-only medicinal product or which is reimbursable due to social insurance, shall be prohibited in commercial practice.

7.6. Advertisements should be distinguished from other content and clearly display their advertising nature. It shall clearly appear from the advertisement that it advertises 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 as commercial communication. Sponsoring of media services or programmes and product presentation in programmes shall not qualify as advertising.

8.2. With the exception of vaccination campaigns authorised by the competent public administration organisation, the following shall not be advertised:

   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) refers to or suggests that a medical consultation, treatment or surgery is unnecessary or omissible;
b) suggests that the medicinal product is unaccompanied by adverse reactions or suggests that by the application of the medicinal product the recovery is guaranteed;
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 only;
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 the medicinal product on the human body or on any parts thereof in a frightening or untrue manner;
g) refers to recommendations by scientists, Healthcare Professionals or well-known personalities;
h) suggests that human health will be impaired if the medicinal product is not used.

8.4. For the purposes of subsection 8.3 g) of this Chapter
a) a well-known personality is a natural or fictitious person who, especially owing to his/her general reputation, 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 behaviour of a reasonably well-informed consumer proceeding with the generally expected care and attention, including, in particular, the consumer’s decision related to the purchase of a certain product,
b) in evaluating a recommendation, all 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”, “he/she recommends”, “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 and/or treatment options 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 medicinal product. The information provided in such publications should not be promotional in nature and must comply with the official summary of product characteristics. Their purpose should be to convey knowledge on the condition for which
the product is intended to be applied, to provide advice on administering the product and to 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 as prohibited 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 may only be given to patients whose physician has prescribed the medicinal product named……………… to them.”

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

8.10. The health education campaign raising health awareness shall be aimed primarily at enabling patients and laypersons to learn more about diseases, their prevention and symptoms and possible treatment. 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 laypersons 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 during business events

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

9.2. No company should organise or sponsor any event that takes place outside of Hungary and no participation at any Independent Event that takes place outside of Hungary shall be sponsored unless:
   a) most of the participants are from abroad and it makes greater sense professionally and logistically to organise 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 organise the event in a country outside of Hungary, or;
   c) for the Hungarian participants invited to an independent, professional-scientific event organised abroad, the Company organises
      ca) an event related to such event,
cb) an event hosted during such event,
cc) a supplementary professional/scientific event.

The supplementary professional/scientific event may not provide an opportunity for the unjustified extension of the stay abroad.

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 pertaining to the promotion and the advertising of medicinal products. Promotion of medicinal products may be conducted in the professional-scientific programmes of Independent Events sponsored by the Company in the event that the direct and indirect promotion (including for instance lectures on the administration of a certain product, conducting of product presentations, leasing of exhibition stands) is clearly separated within the programme of the professional-scientific event.

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

9.5. When sponsoring Independent Events, either directly or indirectly, the sponsoring Company shall be responsible to ensure that the offered sponsorship is used for the purposes and in the manner as allowed by the legislation in force and by this Code. To this end the sponsoring Company 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 that are contrary to statutory provisions in force or to the provisions of the Code.

9.6. If the Company purchases a service at a market price from the organiser of the Independent Event (including, in particular, setting up its own stand or banner), this shall not qualify neither as a direct nor as an indirect sponsorship.

9.7. Events for Healthcare Professionals shall be organised solely with professional, scientific or educational purposes (promotional events of medicinal products, trainings, professional events, symposia, congresses).

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

9.9. If an event lasts for several days and is organised outside of Hungary, maximum one day may be provided for travel before and after the event, respectively if it is logistically justified. In the case of organised events taking place abroad the registration of Healthcare Professionals for
the event is a prerequisite for invitation or sponsorship. At the event, comprehension of the congress language must be ensured.

10. **Restrictions concerning gifts and inducements**

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 or promised to Healthcare Professionals.

10.2. The prohibition of gifts does not apply to the provision of low-value benefit in kind, as specified the applicable statutory legislation, which facilitates the healthcare activity of the Healthcare Professional, is intended for training purposes and/or contributes to the improvement of patient care.

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 the items for medical or training purposes that has been handed over as referred to above (including for example the Company’s name, the medical product’s name, logo and/or other information).

10.5. Prize items offered in professional quiz games or drawing lots as parts of medicine promotion, events or any other activities must comply 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 of low-value, as specified in the applicable statutory legislation and do not induce the consumption or use of a specific medicinal product or the products of a specific marketing authorisation holder or make this

11. **Donations and grants**

11.1. Donations and grants to research institutions, organisations or associations comprised of Healthcare Professionals or providing healthcare services or to research institutions, organisations, associations, healthcare service providers, to professional organizations of Healthcare Professionals or to other organisations in connection with healthcare system (such as patient organisations, registered foundations, non-profit companies, charity organisations) shall be allowed only if:

- they are given for the purpose of supporting healthcare or research;
- they are given unconditionally, i.e. do not constitute an inducement to recommend, prescribe, purchase, supply, distribute or administer a specific medicinal product or medicinal products of a specific Company or make this a precondition or do not influence decisions on reimbursements; and
11.2. Apart from the reporting obligation as regulated in specific legislation, donors may disclose information on their other donations and grants to the public.

11.3. Participation of Healthcare Professionals in professional, scientific and educational events organised as commercial 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 When 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 to Healthcare Professionals as compensation 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 institutions, organisations and associations of Healthcare Professionals under which such institutions, organisations or associations provide any type of service to the Companies are allowed only if the subject matter of such service is healthcare or research and the remuneration 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: experts), either individually or in groups, only for services provided to the Company that involve honorarium or trips, such as, holding lectures, chairing meetings, participating in medical research or clinical trials, holding trainings, taking part in advisory board meetings or market research. The contract must meet the following criteria:
   
   a) even before the contract, the Company had a genuine, legitimate and documented need for the service and for the conclusion of a contract for that service;
   
   b) the number of experts and the scope of the service cannot be greater than what is reasonably expected to satisfy the genuine need;
   
   c) the criteria for selecting experts are specified by the requirements of the nature of the service and the persons responsible for selecting the experts have the expertise necessary to decide whether a particular Healthcare Professional meets these criteria;

   d) a written contract between the Company and the Healthcare Professional must concluded prior to the commencement of the service, specifying the subject matter of the service to be provided and with a view to subsection e) the calculation method and extent of the fee for the service;
e) remuneration of the service must be proportional with the fair market value of the service provided. False contracts concluded with experts are not allowed;

f) the Company must keep proper records of completion and make appropriate use of the result of the service.

13.3. Companies are recommended to

   a) put down in their written contract concluded with the experts that the experts are required to disclose that they work for the Company whenever they express in public their professional opinion either orally or in writing about a matter that is the subject matter of the contract or any other issue relating to the Company;

   b) ensure that practicing Healthcare Professionals working part time at a Company as experts 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 the remuneration for the service provided shall not exceed the monthly amount of the prevailing minimum wage in a year.

13.5. If a Healthcare Professional attends an event as an expert, Section 9 of this Chapter on events and hospitality during business events shall apply.

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 organisation, arrangement, and evaluation of clinical trials or non-interventional trials (hereinafter: trial), and particularly, in the selection of the trial sites and investigators. 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 commercial practice.

14.2. Healthcare Professionals may receive remuneration from the Company for their involvement in a trial. The remuneration must be proportional to the fair market value of the work performed. Prior to the trial, a written contract must be concluded with the Healthcare Professional or health service provider conducting the trial, in which the tasks, the responsibilities and the remuneration of the participants shall be specified. Payment by the Company shall always be made upon invoice or performance certificate, by bank transfer.

14.3. The study results shall be evaluated and their summary – where specific other legislation so requires – submitted to the regulatory authority within the required time frame. A summary of the study results - irrespective of whether they are favourable or unfavourable to the medicinal
products of the sponsoring Company, must be published within one year of the completion of the trial.

14.4. In addition to the aforesaid, non-interventional trials shall meet the following criteria:
   a) the trial is conducted for scientific purposes;
   b) a written trial protocol is drawn up;
   c) the trial does not constitute an inducement to recommend, prescribe, purchase, dispense, sell or use a specific medicinal product;
   d) the protocol must be approved and supervised by the scientific organisational unit of the Company where a physician or a pharmacist is employed, who is in charge of supervising the non-interventional trial (including the work of medical sales representatives). This person certifies that it has reviewed the protocol of the non-interventional trial and found it compliant with the applicable regulations.

14.5. The Company sponsoring a trial shall present the documents proving the authorisation of the trial at the request of the CEC.

15. Medicine samples and medicine 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, distribute, 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 shall be governed by the applicable legislation.

16.2. Companies shall ensure that their personnel or other people in employment relationship with them, engaged in pharmaceutical marketing communication (such as medical sales representatives, commercial representatives, marketing staff, agencies):
   a) besides the 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:
   a) refrain from disseminating information which is unsubstantiated or based on non-verifiable facts;
b) refrain from taking part in any enterprise or transaction that violates applicable legislation or is unethical;

c) refrain from resorting to deceptive or manipulative methods;

d) refrain from giving unsubstantiated, false or misleading information about any Company or otherwise discredit it or its reputation;

e) refrain from using any inducement or subterfuge to gain an interview with Healthcare Professionals;

f) take care that the frequency, timing and duration of a visit causes no inconvenience to the person visited;

g) upon the request of the Healthcare Professional being visited they furnish him/her with the summary of product characteristics for the medicinal product being promoted, in a form that is suitable for the Healthcare Professional;

h) report to the Company any feedback on the medicinal product with due regard to adverse reactions.

16.4. Each Company shall employ an adequately qualified specialist in charge of running a scientific information service, who will also be responsible for approving commercial communication. Such person shall certify with his/her signature that he/she has examined the final form of the promotional/advertisement material and found it consistent with the summary of product characteristics, the legislation in force and the 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 organisations 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 organising press events Companies must take it into account who is the “target group” for the press release or the event. To this end:
   a) exclusively when briefing journalists and editors of restricted-circulation publications that are intended for Healthcare Professionals and unavailable to the general public, Companies may act as if they were briefing the audience of scientific events or symposia, therefore in the course of such briefing may name prescription-only medicinal products;
   b) when providing written or verbal briefing to commercial or lay media, any information suitable for identifying a specific medicinal product according to subsection 8.1 of this Chapter, shall be qualified as advertisement. 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 identified from an indirect reference to them. No briefing, either written or verbal, that names or otherwise identifies a prescription-only medicinal product shall be provided to the correspondent or employee of the lay media. Any representative of the lay media requesting specific therapeutic information about a medicinal product may be refused to be given such information with reference to the applicable legislation, or be reminded, in a documented form, of the relevant legislation thereof.

17.1.6. For Companies listed on the stock exchange, company statements shall include the name of any prescription-only medicinal product. Cases when following stock exchange statements, a prescription-only medicinal product or an active ingredient is named 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. Communication 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. Organisers of press briefings and media events shall select the venue and programme of such events with a view to ensure that the value of the news, and not the venue itself, shall be the main attraction for the members of the press.

17.2.3. The only case Companies are allowed to 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 the journalist 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 programme 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 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 Organisations**

18.1. Events for Patient Organisations shall be organised predominantly with patient education or health education purposes that relate to the activity of the Patient Organisation or qualify as public social responsibility. Invitation and hospitality shall only be extended to those members of a Patient Organisation who attend the event in their own right. In exceptional cases, where there is an obvious health need (particularly in the case of persons with disabilities) the costs of travel, accommodation and meals as well as the registration cost may be paid in part or in full for the caregiver 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 Organisations or their members shall not include entertainment (e.g. cultural, sport, or leisure) programmes. 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 organised by the Company or the Patient Organisation.

18.3. As regards the selection of the venue, subsections 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 Organisation, it shall be based on a written agreement. For the purposes of this Code, significant support shall mean any contribution that is given occasionally and whose gross amount exceeds two months’ worth of the prevailing minimum wage. The written agreement should include the purpose of sponsorship, the name and type of the sponsored activity, the amount of the monetary support and a description and value of the significant direct/indirect non-monetary support as well as the role and responsibilities of any third parties involved.

18.5. Besides support provided for a certain purpose, the Company may also provide Patient Organisations with general, untied support, but in this case the contract must stipulate that the organisation shall use the support solely for the purposes stated in its deed of foundation and in compliance with all applicable legislation.

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

   a) guarantee to always clearly acknowledge any support/sponsorship and make this fact apparent from the onset; and

   b) agree to apply the provisions of this Code to their contractual cooperation and that the contracting parties shall undertake to observe these provisions.

18.7. The public use of the symbol (logo), trademark, and/or proprietary material of the Patient Organisation by the Company requires written permission from the organisation in question. In
the permission, the specific purpose and the way in which the logo, trademark and/or proprietary material can be used must clearly be stated.

18.8. The Company shall always maximally respect editorial freedom in their dealings with Patient Organisations. In no way shall a Company attempt to influence the content of a press or other material and publication made by or with the involvement of a sponsored Patient Organisation to make it favour their own commercial interests. However, this ban does not preclude the Company 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 of the Patient Organisation the Company may – in a scientifically impartial and balanced manner – take part in drafting such materials and publications.

18.9. In order to ensure transparency the Company shall publicly disclose with regard to the year preceding the disclosure the list of Patient Organisations to 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 acting with generally reasonable attention, shall be able to form their opinion on the significance of the support;
   c) for significant non-monetary supports whose monetary value cannot be established, the non-financial benefit the Patient Organisation receives 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 the Company shall make publicly disclose the amounts it had paid as a consideration in the previous year for the services of the Patient Organisations, in a breakdown according to Patient Organisation. The published data should include the description of the service the Patient Organisation had provided to the Company based on the contract, this description has to be sufficiently detailed and free of any confidential data and made in such a way that people acting with generally reasonable attention, shall be able to understand the nature of the cooperation between the Company and the Patient Organisation.

18.11. Contracts between the Company and Patient Organisations, under which these organisations provide any service to the Company are allowed if the service intends to promote healthcare or research. The Company may contract the Patient Organisation in the capacity of expert or consultant for the purpose of 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 genuine, legitimate and documented need for the service and for the conclusion of a contract for that service;
   b) the number of experts 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 Organisation meet those criteria;

d) a written contract between the Company and the Patient Organisation must be concluded 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 and extent of the fee for the service;

e) remuneration of the service must be proportional with the fair market value of the service provided. False contracts with experts shall not be concluded. Payment by the Company shall always be made upon invoice or performance certificate, by bank transfer. False expert contracts between the Company and the Patient Organisation to justify benefits for the Patient Organisation for other purposes are prohibited;

f) the Company must keep proper records of completion and make appropriate use of the result of the service;

g) the contract between the Patient Organisation and the Company may not be concluded with the purpose of the inducement to recommend a specific medicinal product.

18.12. Companies are strongly encouraged to put down in their written contract with Patient Organisations that the experts 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 shall be the sole sponsor of a Patient Organisation or any of its major programmes. For the purposes of this subsection, major programmes are those that have a budget of over two months’ worth of the gross amount of the minimum wage or those that are made for or involve a target audience of more than 40 (forty) people.

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

19.1. In order to ensure transparency of the origin, content and purpose of a website each website that is maintained or supported by the Company directly or indirectly in any other way must clearly indicate the following:

   a) name, registered office, and electronic contact information of the operator and all supporters (sponsors) of the website;

   b) the source of the information and the date of publication of the source for web surfaces sponsored or maintained by the 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 others, display the following information:

      aa) general information relating to the Company,
(a) the website may include information that is of interest for investors, the media and the general public, including financial data, description of research and development programmes,
(b) information on the issues of regulatory changes with impact for the Company and its products, and information for prospective employees;
(c) if the information is related to health education:
   (a) the website may also include health education information of non-advertisement nature, on the characteristics, prevention, screening and treatment methods of diseases;
   (b) as well as other information posted with the purpose of improving public health;
(d) the website may also include information on alternative treatment methods including surgery, change of diet, change of behaviour or other interventions not requiring the use of any medicinal product. Websites containing health educational information should always include the recommendation to the visitor to turn to a Healthcare Professional for more advice;
(e) on prescription-only medicinal products only the following information may be posted:
   (a) label, patient information leaflet, and summary of product characteristics as approved by the authority;
   (b) factual, informative announcements or informative materials relating to packaging changes of the medicinal product or to adverse reactions associated with the medicinal product;
   (c) commercial price lists provided they include no product claims with regard to the effect of the medicinal product;
(f) 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.

19.3 Inquiries received via e-mail

The website may offer Healthcare Professionals, patients and the general public the possibility to ask for more information via e-mail about the products of the Company and on other matters. The Company may answer e-mail inquiries the same way as it answers inquiries received by post, telephone or other means. Communication with patients and the lay public should avoid discussing personal medical matters. The answer should recommend to the person making the enquiry to contact a Healthcare Professional for more advice. Personal health information received should be kept confidential.

19.4 References (links)

19.4.1. Websites sponsored by third parties may refer to the website sponsored by the Company but Companies shall not place links on surfaces accessible by the general public that refer to websites intended for Healthcare Professionals and sponsored by the Company. Similarly, links referring to other websites may also be placed on the website, including websites sponsored by the Company or third parties. In general the links should refer to the home page of the website or should be managed in a way to enable the visitor to identify the website.
19.4.2. The title of a website might be included on the label in compliance with relevant legislation.

**19.5. Professional Control**

19.5.1. Companies must ensure that every piece of information on the website maintained by them and in the case of sponsored websites the commercial communication presented on that website complies with the provisions of this Code. If a sponsored or maintained website fails to comply with the provisions of this Code, the sponsorship or maintenance shall be discontinued.

19.5.2. The name or international non-proprietary name of a prescription-only medicinal product or a medicinal product included into social security subsidy as a domain name or part of a domain name shall only be used if the maintainer of the website ensures that the information posted on the website is available to Healthcare Professionals only.

**CHAPTER 5 – Rules pertaining to the operation of the CEC**

1. **Procedural rules**

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

1.2. For conducts conflicting with current legislation any proceeding initiated and/or conducted 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 current legislation.

2. **Bylaws of the Communication Ethics Committee**

2.1. **Composition of the CEC and the election of its members**

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

2.1.2. The Associations shall delegate four (4) members each to the CEC. Among the candidates of Companies, which considered as joint ventures, not more than one (1) member can be elected, irrespective of which association or associations they are members of. Each Company may have only one (1) elected CEC member, regardless of their simultaneously standing membership in the Associations.

2.1.3. Each year, the Associations shall elect members to be delegated to the CEC within their own competence. The chairpersons of the Associations shall notify each other and the CEC in writing about the names of the members elected, and about any conflict of interests between any
of the elected members and any of the joint ventures as specified in subsection 2.1.9. of this Chapter, within a maximum of eight (8) days from the date of election. The Associations shall have the right to recall their elected members in accordance with their respective operational 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 CEC is terminated for any other reason. The CEC members shall be mandated from 1 July each year and they may be re-elected every year, in accordance with the statutes of the associations.

2.1.4. Members delegated to the CEC
   a) may request that their 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 CEC 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 CEC meeting,
   c) shall initiate ethics proceedings upon learning of any suspicion of conduct breaching the rules set out in the Code;
   d) are obliged to participate in the work of the CEC.

2.1.5. The chairman of the CEC shall be elected and recalled by the respective executive bodies or by the Boards of the Associations. Two-third of the CEC members are required to propose the recall of a CEC 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 CEC chairman or person assisting the CEC’s work. The chairman of the CEC shall be appointed for two (2) years and can be reappointed every two years.

2.1.7. If a CEC chairman is incapacitated in attending to their duties, the CEC members shall elect an interim chairman from among themselves. The interim chairman shall attend to the duties of the CEC chairman for the duration of the incapacitation. If such incapacitation continuously persists for over three (3) months, a new CEC chairman shall be appointed in accordance with 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 CEC;
   b) in cases where it is ethically justified considering the nature of the case, inviting the parties independent from pharmaceutical companies to a CEC meeting;
   c) professional and ethical drafting, documenting and transmitting CEC resolutions to the parties concerned;
   d) monitoring the implementation of the decision(s);
   e) overseeing observance of the provisions of this Code;
   f) representing the CEC.

2.1.9. Any CEC member, who is employed by a party that is interested in or affected by a case being heard by the CEC, 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. Cases of affection are
to be reported to the CEC by any affected member or chairman and by any person that has knowledge of such interest or affection. In doubtful cases CEC shall decide on cases of interest or affection without a debate. If the CEC does not have a quorum as a result of an exclusion, the quorum must be established on the basis of the number of CEC members without the excluded ones.

2.2. Meetings and procedure of the CEC

2.2.1. Companies shall endeavour to resolve their disputes amicably between themselves before submitting it to the CEC.

2.2.2. The CEC shall initiate 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 initiated by a member of the CEC. Requests may be submitted by any natural or legal person that has information on any conduct or action violating the provisions of this Code.

2.2.3. Complainants may ask for confidential handling of their data by the CEC. In such cases the CEC shall handle the data of the complainant confidentially in the course of the procedure and following its termination. If it is requested by the complainant, their identity shall not be revealed by the chairman even to the members of the CEC. In such cases the identity of the complainant may only be revealed if the investigation could not be carried out without doing so.

2.2.4. If the complainant seeks a ruling from another authority before, or simultaneously with filing a complaint with the CEC or if the CEC initiates a procedure by the competent authority before making its decision on the issue, the CEC shall not commence its proceedings until the other authority’s final ruling is issued or shall suspend proceedings already in progress as the CEC 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 initiated or continued if the requested authority itself requests that the CEC should conduct the proceedings.

2.2.5. Reports filed with the CEC anonymously shall not be investigated by the CEC but even such notifications shall be sent to all CEC members for their information.

2.2.6. When the chairman of the CEC receives a complaint, he/she shall send a copy to the party named in the complaint by way of registered mail, mail with acknowledgement of receipt or hand delivery within ten (10) days of the receipt of the complaint, irrespective of whether the complainant has done so, and request such other party to present their standpoint on the matter to the CEC within ten (10) days. The CEC may only hear the case on the merits after the above deadline has expired, regardless of whether the responding party has communicated their standpoint within the deadline. If the CEC opens a proceeding ex officio, it shall notify the relevant party or parties of the conduct it has identified as presumptively violating the provisions of the Code. Otherwise, ex officio proceedings shall be conducted the same way as proceedings that are opened upon request.
2.2.7. Complaints submitted to the CEC must include all data and evidence necessary for the evaluation of a case. If the complaint fails to include these data and evidence, the CEC shall call upon the complainant to have the missing information submitted by a specified deadline only once in the course of the proceedings. In such cases, procedural deadlines shall start on the date on which the missing information is received by the CEC. If the requested party does not supply the missing information by the deadline, the CEC shall
   a) terminate the proceedings 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 initiated 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 the CEC shall treat strictly confidential any data, information and documents that they accessed or otherwise became aware of in connection with a CEC proceeding and that are not in the public domain, and shall retain them and ensure that they are not disclosed to any third party during or after the proceeding. The same applies to the chairpersons of the Associations and to the assistant that assists in the operation of the CEC. Members of the CEC and its chairman as well as the assistant assisting in the operation of the CEC shall sign a declaration of confidentiality approved by the CEC, which shall be preserved among the CEC’s documents for a period of five (5) years from the discontinuation of membership or the mandate.

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

2.2.11. Unless otherwise provided in this Code a CEC meeting has a quorum if at least nine (9) members are present. If an orderly convened CEC 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 CEC meeting has a quorum.

2.2.12. The CEC shall hold closed meetings which shall be attended by the members, the chairman, the person performing administrative tasks, and the invited persons and independent external experts only.

2.2.13. The CEC shall pass its resolutions by the simple majority of the votes of the members present. The chairman, the invitees concerned who are independent from pharmaceutical companies may attend CEC meetings with consultation right. If, for the Chairman's incapacitation, the interim chairman chairs a CEC meeting, the interim chairman shall have voting right in the decision making. In the event of a tied vote, the vote of the Chairman or the interim chairman shall be decisive.
2.2.14. In cases received by the CEC, it shall pass its resolutions within sixty (60) days of the initiation of the proceeding. The chairman of the CEC may extend this deadline once for another thirty (30) days and at the same time inform all parties concerned.

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

2.2.16 When adopting its decisions, the CEC is obliged to take into account the decisions, arguments and correlations elaborated in its previous resolutions, in order to comply with the spirit of the Code and ensure its uniform application.

2.3. Decisions of the CEC

2.3.1. The CEC shall pass a resolution or ruling at the end of every proceeding initiated and send it to the parties concerned in writing within fifteen (15) days from the date of the adoption of the decision, via registered mail with acknowledgement of receipt or by hand delivery.

2.3.2. The CEC shall immediately make its decision by ruling if:
   a) the complaint shall be rejected without material investigation in the following cases:
      aa) the CEC 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 CEC has already adjudicated the complaint on the merits;
      ae) the proceeding was not initiated against a Company covered by the personal scope of the Code and the party specified in the complaint does not voluntarily submit to the proceeding. In such cases the contents of the ruling shall be identical with those of the resolution with the difference that in the ruling the CEC informs the Company that if the conduct adopted by the party referred to in the complaint, has breached a statutory regulation as well, the CEC shall notify the competent authority thereof.
   b) the proceeding is terminated in the following cases:
      ba) the complaint could have been refused without investigation but the reason for refusal came to the knowledge of the CEC after the proceeding was launched;
      bb) the proceeding has become devoid,
      bc) the proceeding had initiated upon request and the complainant had withdrawn the request, except if the CEC conducts the procedure ex officio or the case had several complainants but not all of them withdrew the complaint;
      bd) the proceeding has become devoid due to the fact that any of the parties concerned had ceased without legal successor;
      be) the circumstance justifying the proceeding no longer exists;
if the parties concerned conclude an agreement in the course of the proceeding, which is not contrary to the provisions of this Code.

2.3.3. The CEC 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 CEC shall:
   a) give a brief description of the investigated case;
   b) establish whether or not an ethical violation has taken place;
   c) provide reasoning for its decision;
   d) if it has established that an ethical violation had taken place, communicate the sanctions;
   e) indicate the number of the previous decision of the CEC and/or ad-hoc committee, if, in adopting the resolution, reference is made to the previous CEC and/or ad-hoc committee resolution;
   f) provide information on whether an appeal may be submitted against the resolution, as well as where such appeal may be filed and within what deadline;
   g) provide information on the matter that the parties concerned are entitled to personal hearing in the appeal procedure;
   h) provide information on whether a counterclaim may be filed against the appeal, which the party submitting the counterclaim is entitled to file no later than the ad hoc committee meeting when presenting the personal position.

2.3.4. Where an ethical violation is established, the CEC shall
   a) warn the offender in writing;
   b) call upon the offender to stop the violation;
   c) require the offender to immediately withdraw the promotional/advertisement material or to immediately collect those that have been issued and to submit a written report on the fulfilment of the obligations set out in the resolution;
   d) in the case of an ethical violation of communicational nature where the deceptive communication may lead to the inappropriate use of a medicinal product or pose any other risk to patients/consumers, it may order the offender to distribute a circular letter for the rectification to the Healthcare Professionals involved in commercial communication.

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

2.3.6. The CEC 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 CEC is not competent to do.

2.3.7. The CEC shall send its resolutions to the Associations within 30 days from the date on which they become final, and the Associations shall make them available to the member companies.
2.3.8. The CEC shall prepare a summary report of its final and definitive resolutions annually without naming the company and the medical products concerned, and shall publish it through the Associations.

**2.4. Course of the procedure relating to appeals filed against a CEC resolution**

2.4.1. The parties concerned may file an appeal against the resolutions of the CEC, according to subsections 2.4.2. to 2.4.5. In the appeal procedure filed against the CEC resolutions, a four-member ad hoc committee shall proceed. Each Association delegates one expert to the ad hoc committee. The operation of the ad hoc committee shall be governed by the rules regulating the operation of the CEC with the differences regulated in the Code. The preparation of the meeting of the ad hoc committee, convening the meeting, and laying down the committee’s decisions shall be the tasks for the chairman of the CEC. The CEC members may not participate in the ad hoc committee meeting. The members of the ad hoc committee shall elect a chairman at the start of each session to represent the decision of the ad hoc committee.

2.4.2. Appeals against a CEC resolution may be filed within fifteen (15) days from the date on which the resolution was passed. Besides informing the CEC members, the chairman of the CEC shall also inform the Presidents of the Associations about an appeal and invites them to delegate, in agreement with their respective Boards, one person each to the ad hoc committee. The Associations shall endeavour to have due consideration to each other’s delegates when setting up the ad hoc committee; where possible, they shall ensure the expertise necessary for adopting the decision through the simultaneous presence of experts with legal, medical or pharmaceutical degree. The chairman of the CEC convenes a meeting of the ad hoc appeals committee on a date and time agreed with the ad hoc committee members delegated by the Associations. The ad hoc appeals committee session shall have a quorum if all the four delegates are present. The Presidents of the Associations shall be informed within seven (7) days, the members of the ad hoc appeals committee shall be informed within fifteen (15) days, and the committee shall meet and make a decision within fifteen (15) days from the date of receipt of an appeal.

2.4.3. The parties affected by the CEC resolution are entitled in the appeal procedure to appear before the ad hoc committee, and the ad hoc committee is obliged to hear the affected parties at their request in the appeal procedure. In its resolution, the CEC shall inform the affected parties on their right to be heard personally. The ad hoc committee procedure is fixed; in the appeal procedure, it is authorised to review and reverse the part of the CEC resolution that was challenged by the appeal. The ad hoc committee is not authorised to review the part of the CEC resolution that has not been challenged; however, in accordance with subsection 2.2.2 of the Code, it may file a report to the CEC.

2.4.4. The final decision of the committee – upholding, annulling or amending the CEC decision – shall be adopted following the perusal of the case documents, the hearings and debates if any, through simple verbal majority of the committee members. In case of tied votes the CEC decision remains in effect, and the deadlines for the execution of the tasks set out therein shall run from the date of the delivery of the decision of the ad hoc committee. The decision of the ad hoc committee shall be communicated by the Committee to the parties concerned, the CEC 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.

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

2.5. The CEC’s position statement

2.5.1. Issuing a CEC position statement may be requested by:
   a) any member of the CEC,
   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 CEC 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. The CEC shall publish the position statements on its website, and they shall become effective on the 30th following its publication on the website.

3. Rules related to the enforcement of this Code, final provisions

3.1. The CEC, the chairman of the CEC and the Boards 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 held liable 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 CEC.

Budapest, 17/05/2017.

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Chairman
MAGYOSZ

Thomas Straumits
Chairman
Association of Innovative Pharmaceutical Manufacturers

Péter Gaszner
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