



**Hungarian
Pharmaceutical
Manufacturers
Association
(MAGYOSZ)**



**Association of Innovative
Pharmaceutical
Manufacturers**



**Hungarian Association of
Generic Manufacturers
and Distributors**



**“Immunity”
Association of Vaccine
and Immunobiological
Product
Manufacturers and
Distributors**

CODE OF ETHICS FOR PHARMACEUTICAL MARKETING COMMUNICATIONS

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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 Communications (in order of appearance) are as follows:

Definitions of frequently used terms and abbreviations

1.1. Donation

Benefit provided without consideration in exchange, along with movables handed over partly or fully free of charge, and services provided partly or fully free of charge.

1.2. 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.

1.3. Patient

Any natural person who uses or is provided with healthcare services for the preservation of the individual's health and for the prevention, early detection, establishing diagnosis and treatment of a disease, or of a life-threatening condition, or to improve a condition resulting from a disease or prevent further deterioration.

1.4. Patient Organisation

Non-profit organisation – including the umbrella organisation to which it belongs –, which is a legal person or business organisation mainly composed of

patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers (including the umbrella organisation to which it belongs) and whose business address, place of incorporation or primary place of operation is in Europe ¹.

1.5. Patient Organisation Representative

A person who is mandated to represent and express the collective views of a Patient Organisation on a specific issue or disease area.

1.6. Healthcare community

Healthcare professionals, healthcare organisations, patients and patient organisations. It includes any other person or organisation that is involved in the regulation, approval, control or supply of medicines to the public, or that communicates about medicines in a professional capacity (for example a medical journalist, but excluding member company representatives) to healthcare professionals, healthcare organisations or patient organisations.

1.7. Healthcare Professional

Natural persons having medical qualifications, participating 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 provider staff or any other specialists working in health care. In the application of this Code, the definition of healthcare professionals includes the following: (i) any officer or employee of a government, authority or other organisation (whether in the public or private sector) who may prescribe, purchase (not for their own personal use), recommend or administer Medicinal Products and (ii) any employee of a Company whose primary occupation is that of a practising Healthcare Professional, but excludes (x) all other employees of the Company and (y) wholesalers or distributors of Medicinal Products, and their employees.

1.8. Item of Medical Utility

Inexpensive item aimed directly at the education of

¹ Belgium, Bosnia Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United Kingdom.

Healthcare Professionals enhancing the provision of medical services and patient care, which does not offset routine business practices of the Healthcare Professionals and is not suitable for covering the normal operating costs of healthcare activities.

1.9. Medical Education

Includes education related to human health and diseases and specific non-promotional training related to Medicinal Products.

1.10. Healthcare Organisation/Provider

Any legal person, entity, individual entrepreneur (1) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other educational institution or scientific society (except for Patient Organisations) whose business address, place of incorporation or primary place of operation is in Europe or (2) through which one or more Healthcare Professionals provide services.

Wholesalers, distributors, and similar commercial intermediaries cannot be considered as Healthcare Organisations.

Pharmacy businesses are always considered as healthcare providers, regardless of their ownership or ownership structure.

1.11. 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.

1.12. Host Country Principle

The monetary threshold set for one meal (food and beverages) in the National Code of the country where the Event takes place prevails against the thresholds set in other national codes, in accordance with the Medicinal Products Act.

1.13. Consumer

Any natural person acting for purposes other than his or her own occupation and economic activity.

1.14. 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 the decision about the professional programme or the contents of the programme the Company has no influence on.
1.15. Medicinal Products Act	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 (Gyftv.).
1.16. Promotion	A commercial practice dealing with the composition, effect, and administration of a medicinal product, and performed exclusively for or against Healthcare Professionals qualified to prescribe and distribute medicinal products. Commercial communication used for consumers as well shall not qualify as promotion.
1.17. Position Statement	Guideline prepared for companies to help implement the Code and support the practical application of the provisions of the Code.
1.18. CEC	Communication Ethics Committee of the Associations
1.19. Commercial 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.
1.20. Commercial Communication	Any activity and provision of information with direct relevance to the business of the Company irrespective of the form and device in which it is delivered, performed in order to influence the attitude and conduct of the recipient of the communication.

1.21. 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 <ul style="list-style-type: none"> a) clinical, pharmacological and pharmacodynamic effects of one or more investigational medicinal products, and/or b) identify any adverse effect associated with them, and/or c) studying their absorption, distribution, metabolism, and elimination in order to prove the safety, efficacy, risk/benefit ratio of one or more investigational medicinal products, excluding non-interventional trials
1.22. Code	Code of Ethics for Pharmaceutical Marketing Communications.
1.23. Purchase of services ensuring appearance	Fee paid as specific compensation at an independent professional-scientific event in the context of the Company's commercial practice.
1.24. Promotional aid	Non-monetary item given for promotional purpose (which does not include promotional documents).
1.25. Advertisement	Communication, information, or practice of presentation intended to increase the sale or use in any other way of a medicinal product or in relation to this purpose to popularise the name, image, activity of a Company or to increase awareness of goods or identification symbol (logo).
1.26. Associations	Professional organisations representing the interests of the Companies manufacturing or distributing medicinal products in Hungary and signing this Code.
1.27. Informational or Educational Material	As specified in the Medicinal Products Act, an inexpensive document directly relevant to the practice of medicine or pharmacy and directly serving the interests of patient care.
1.28. Sponsorship	Monetary or other material benefit granted without consideration not including tax allowance or surety, and the sponsorship of media services and programmes.

1.29. Fair Market Value

The amount payable for services that would be expected to result from negotiation between independent and well-informed parties.

The basis for determining the consideration of the service is the fair market value that consider the prevailing rate in the country of primary practice of the individual or employer/organization, even if the service is provided elsewhere.

The principle of fair market value generally applies to collaborations with members of the healthcare community.

1.30. Sponsorship granted in kind

Support intended solely to cover expenses incurred in direct connection with attendance at events (such as, in particular, travel expenses, accommodation costs, meals (food and beverages together are referred to hereinafter as “Hospitality”), attendance (registration) fees).

1.31. Company

Pharmaceutical industry operator involved in the manufacturing or distribution of medicinal products that belongs to the Associations signing the Code or that has joined the signatories of the Code through a unilateral declaration pursuant to Chapter 1, Section 2.5. and that accepts the Code as binding to itself and any natural person or legal entity pursuant to Sections 4.1.1 and 4.1.2 of Chapter 1.

1.32. 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, investigator meetings of clinical trials and non-interventional trials.

PREAMBLE

As pharmaceutical companies, we work in collaboration with the Healthcare community, various stakeholders including Healthcare Professionals, Healthcare Organisations/Providers, Patient Organisations and their Representatives, regulatory authorities, governmental bodies, and the public with the aim of increasing and improving health and quality of life, as well as the quality of patient care.

Associations and Companies consider the consistent enforcement of the principles laid down herein during their operation as fundamental value, thus they are proud to openly undertake them, and strive to proactively share the standards set forth herein and to cooperate in their implementation with stakeholders, including Healthcare Professionals, Healthcare Organisations/Providers, Patient Organisations and their representatives, regulatory authorities, government bodies and the public at large.

First and foremost, the **PATIENTS ARE AT THE HEART OF WHAT WE DO**. We aspire to ensure that everything we do will ultimately benefit patients. Our primary contribution to society is to make high quality Medicinal Products and to promote their appropriate and rational use in patient care.

We act with **INTEGRITY**, interact in a responsible manner, and aim to ensure that our communications with stakeholders are accurate, legitimate and balanced. We are accountable for our decisions, actions and interactions and we encourage others to follow the same high ethical standards.

We interact with all our stakeholders with **RESPECT**. We commit to approach our stakeholders in an open manner, with a responsive, constructive, and learning attitude and mutual respect. We value the importance of independent decision-making by stakeholders, based on evidence and including patient interest. With respect to society, we listen to what is expected from us and adapt our way of working accordingly. We follow applicable laws and make ethical decisions when processing personal and health data.

We are committed to ensure that **TRANSPARENCY** is respected. We are open about our activities and interactions and encourage stakeholders to act with the same openness.

The Associations believe that interactions between Companies and Healthcare Professionals have a profound and positive influence on the quality of patient care and the value of future research. At the same time, the integrity of the decision of a Healthcare Professional to prescribe a Medicinal Product is one of the pillars of the healthcare system. Consequently, professional and industry associations have adopted codes and guidelines to ensure that these interactions meet the high standards of integrity that patients, governments, and other stakeholders expect.

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. As part of this kind of their activities, Associations and Companies actively strive to educate professionals and as necessary the public regarding the content and form requirements of ethical pharmaceutical communication.

- 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 and the requirements of the Medicines for Europe Code of Conduct.
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.
- 4.2. This Code has been adopted by the authorized bodies of the Associations. The consolidated text of this Code, as amended, is applicable from 1 June 2022, provided that any ethical violation committed prior to the effective date of this Code is subject to the provisions of the Code in force at the time of the breach of ethics unless the act ceases to be a breach under this Code.
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 establish conduct contrary to the provisions of the Code and to publish position statements assisting in the implementation of the Code, the Associations shall establish an executive body in the form of a Committee called the Communication Ethics Committee of the Associations (hereinafter: “CEC”) and determine its rules of procedure within the framework of this Code, provided that the CEC assesses applications submitted to it or to the CEC Chairperson in accordance with the provisions of the Code.

CHAPTER 3 – Scope of the CODE

1.1. The scope of this Code covers commercial practices carried out with medicinal products in accordance with Act XCV of 2005 on Medicinal Products for Human Use and Amendments to Other Regulations on Medicinal Products, regardless of whether it was carried out by an organisation within the personal scope of this Code or another organisation or person on its behalf or with its approval.

1.2. The scope of the Code shall apply to:

- a) Companies;
- b) Business organisations that are not member companies of any Association, if they recognize the provisions of this Code as binding on themselves.

1.3. For the purposes of the application of section 1.1 of this Chapter, it shall also qualify as the Company’s approval where the beneficiary of the commercial practice does not, in a proven way, call on the entity pursuing commercial practices on behalf of the Company without delay after becoming aware of the commercial practices in breach of the rules set out in the Code to stop such activities and it does not use all reasonable efforts to ensure that the conduct that is contrary to the Code is ceased.

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) audio-visual 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,
- e) disclosure of Benefits to Healthcare Professionals, Healthcare Organisations and Patient Organisations in respect of medicinal products.

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 of the medicinal product.*”;

- 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 finalised 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 healthcare 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 section 10 of this Chapter

- a) the name of the medicinal product, or
- b) the international non-proprietary name of the medicinal product, or
- c) the name, or trademark/identifying symbol (logo) of the Company;

the information referred to in subsection 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 must be displayed;
 - db) if only part of the data of a table is displayed, this fact must be clearly indicated;
 - dc) scales must be displayed accurately and non-continuous scales must be marked as such;
 - dd) „n” values (number of items) and significance values must be provided;
 - de) the text of the graph must legibly and clearly indicate that it is based on data which were used in the publication with the indication of page number and/or figure number.
- 3.7. Generalisations 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 may only be used with the accurate definition of its meaning (e.g. “its plasma concentration will not increase 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 publicities 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 recipient'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. No commercial practice should pose as medical research (such as non-interventional trials including retrospective trials) in the form of post-marketing surveillance of side effects, training, market research or other non-commercial data collection or activity. Such activity shall be carried out in accordance with applicable legislation and as provided for in Section 14 of this Chapter.
- 7.5. Clinical assessments, post-marketing surveillance programmes, and post-authorisation studies (including those that are retrospective in nature) must not be the subject of surreptitious commercial practice. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose.
- 7.6. Where a Company pays for, otherwise ensures by means of consideration, or arranges for commercial communications to appear in written or electronic media, such commercial communications shall not create the appearance of independent (whether lay or professional-scientific) editorial content.
- 7.7. 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. In the case of medicinal products that can be ordered under social security subsidy, or are subject to prescription, the use of pre-made, printed, stamped or otherwise reproduced other forms (e.g. referrals, recommendations) containing the name of the medicinal product shall be prohibited in commercial practice.
- 7.8. 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. Support 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 social security subsidy 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 attending 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 individuals not using that medicinal 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. Health education and health awareness campaigns should have as their primary aim to enable patients and lay consumers to learn more about diseases, their prevention and the symptoms of such diseases. Such campaigns must provide precise and certifiable information for patients and for lay consumers. The information must be balanced and must convey useful knowledge for patients and lay consumers that they can actually use. In the campaign attention must be drawn to the fact that any decision on suitable treatment must be taken by the Healthcare Professional after consultation with the patient, or the lay consumer.

9. Events, business hospitality, and purchase of services ensuring appearance

- 9.1. Company Events must be held in an appropriate venue that is consistent with the main objectives of the Company Event. 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. A venue is not considered as extravagant if it has the necessary conditions for the transfer of information for scientific or educational purposes, and which does not serve exclusively as a tourist destination and is not linked only to leisure/sports activities, and that is not capable of appreciably altering or influencing any person invited to or participating in the event in their opportunity to make independent, impartial decisions in any respect.
- 9.2. No company should organise or sponsor any Company 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 purposes and not falling within the definition of promotion of a medicinal product shall only be extended to persons eligible to participate.
- 9.5. When sponsoring Independent Events, either directly or indirectly, or purchasing services ensuring appearance, the Company shall be responsible to ensure that the offered funds are used for the purposes and in the manner allowed by the legislation in force and by this Code. To this end, the Company shall stipulate compliance with legislation and the provisions of the Code (e.g., prohibition of entertainment) in a written contract.
- 9.6. If a 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 direct nor as indirect sponsorship, but as the purchase of services ensuring appearance.

- 9.7. Company 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 or purchase of services ensuring appearance in connection with events organised for Healthcare Professionals or Patient Organisation Representatives 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.
- 9.10. Companies may only offer hospitality to members of the healthcare community if such hospitality is secondary to the purpose of the Event. Any amount of in-kind support provided for meals (food and drinks) in the framework of hospitality to Healthcare Professionals, members of Healthcare Organisations and Patient Organisation Representatives may not exceed the maximum amount prescribed by the Medicinal Products Act and the Associations. The maximum amount of hospitality offered for meals during any foreign Event is governed by the rules of the country where the Event is held – “Host Country Principle”, unless the law or national code of the participant’s own country provides otherwise.
- 9.11. Companies shall only offer hospitality to persons who attend the Event in their own right. In exceptional cases of established health needs of a Patient Organisation Representative (e.g., disability or injury), the travel, meals, accommodation, and genuine registration fee costs of accompanying person(s) may be paid.
- 9.12. In connection with the commercial practice, Companies may neither directly nor indirectly finance or support the recreational and entertainment activities of the Healthcare community members, these shall be financed by the organizers from other funds.
- 9.13. Companies must comply with the criteria set forth in this Code and the applicable local regulatory requirements governing the invitation, selection and support of Healthcare Professionals or Patient Organisation Representatives to attend trainings or Events.
- No payment must be offered to compensate merely for the time spent by the Healthcare Professional or Patient Organisation Representative in attending Events.
- 9.14. Subsections 9.1, 9.2 and 9.4 to 9.13 shall not be applied to health education programmes aimed at Consumers within the meaning of Subsection 1.13 of this Code, and to commercial practices carried out vis-à-vis Consumers related to over-the-counter (OTC) and non-subsidised medicines.

10. Restrictions concerning gifts and inducements

10.1. In the context of the promotion of prescription-only medicinal products no

- a) gift,
- b) monetary advantage or benefit in kind,
- c) cash or cash equivalents,
- d) gifts for personal benefits (such as tickets to a sporting or entertainment event, gifts given as a courtesy gesture),
- e) personal services,
- f) promotional aid,

may be given, offered, or promised to Healthcare Professionals, members of Healthcare Organisations, or Patient Organisation Representatives neither directly nor indirectly.

For the purposes of this section, personal services are any type of service unrelated to medical professional activity and that confer a personal benefit to the Beneficiary.

10.2. Promotion of prescription-only medicinal products shall only include the provision of inexpensive— specified under the Medicinal Products Act – promotional items to Healthcare Professionals, members of Healthcare Organisations, or Patient Organisation Representatives in small quantities on an occasional basis (for instance, Informational or Educational Materials, Items of Medical Utility) that

- a) are in line with the provisions of the Medicinal Products Act,
- b) are directly related to medical or pharmaceutical practice, aids the healthcare activities carried out by the Healthcare Professional or serves healthcare training purposes,
- c) directly contribute to improving patient care,
- d) do not constitute an evasion of the prohibition on gifts specified in point 10.1 of this Code, and
- e) do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a Medicinal Product.

10.3. Informational or Educational Materials and Items of Medical Utility that are provided to achieve objectives specified in subsection 10.2 a)-c) may include the Company name but must not contain the product name or the international non-proprietary name of the active ingredient unless the Medicinal Product's name or the international non-proprietary name is essential for the correct use of the material or item by the patient.

10.4. In terms of Companies subject to the Medicines for Europe Code of Conduct, promotion of prescription-only and non-prescription medicinal products to Healthcare Professionals, members of Healthcare Organisations or Patient Organisation Representatives will continue to be allowed to include the Company's name, drug name, logo, active ingredient name on

- a) Informational or Educational Materials,

- b) Items of Medical Utility, and
 - c) inexpensive promotional items (e.g., spatula, latex gloves, masks, wipes, clothing).
- 10.5. When the item of medical utility is needed in a public health emergency or during disaster relief, deviations from Subsection 10.2 are only permitted to the extent accepted by the international industry associations (EFPIA, Medicines for Europe).
- 10.6. Only inexpensive – as specified in the applicable statutory legislation – gift, monetary advantage, or benefit in kind 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. Promotional aid related to non-prescription medicinal products may be given to Healthcare Professionals.
- 10.7. Only gifts may be given to patients or consumers that are of low value, as specified in the applicable statutory legislation and do not induce or define as a prerequisite the consumption or use of a specific medicinal product or the products of a specific marketing authorisation holder.
- 10.8. The content of information on the provided inexpensive promotional items (such as the Company name, drug name, logo, active ingredient name, other information) is governed by the provisions of subsections 2.2 and 2.3 of Chapter 4 of this Code.
- 10.9. Professional quiz games as parts of medicine promotion, events or any other activities must comply with the provisions set out in subsections 10.1–10.6 and 10.8 of this Chapter.

11. Donations and grants

- 11.1. Donations and Grants provided (in cash, in kind or otherwise) to Healthcare Organisations and/or Patient Organisations are only allowed if:
- a) they are made for the purpose of supporting healthcare, research or education;
 - b) they are documented and kept on record by the donor/grantor; and
 - c) does not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.
- 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 may be provided to a Healthcare Professional in their capacity as private individuals other than a grant under Section 9 of this Chapter.
- 11.5. No Company may require to be the sole funder or sponsor of a Patient Organisation or a Healthcare Organisation or any of their programmes.

- 11.6. Companies welcome broad support and sponsorship of Patient Organisations and Healthcare Organisations from multiple sources.

12. Support provided to Healthcare Professionals and Medical Education

- 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 the time spent at an event. Hospitality extended to participants must comply with the provisions in subsections 9.1., 9.4., 9.10. and 9.11. of this Chapter.
- 12.3. Companies must not finance the attendance of individual healthcare professionals on courses certified by accredited institutions of further education (for example Masters degrees) or modules contributing to postgraduate qualifications, because they would provide a significant personal benefit to the individual. This prohibition does not apply to courses that are organised for Healthcare Professionals for educational purposes, serving continuous professional training, accredited, continuous learning points providing or to conferences.
- 12.4. The goal of Medical Education is to increase the scientific knowledge and competence of Healthcare Professionals in order to enhance medical practice and improve patient outcomes. Companies may provide different types of Medical Educations; however, such activity must be separated from promotion activities.
- 12.5. When sponsoring independent Medical Education or in organising Medical Education activities either directly or in collaboration with third parties, Companies must ensure that their participation and role is always clearly acknowledged and transparent from the outset. In case Companies have influence on the content, they are responsible for what is communicated during the activities. Such content must be fair, balanced and objective, and elaborated to allow the expression of diverse theories and recognised opinions.
- 12.6. When sponsoring Medical Education, Companies are obligated to comply with the legislative provisions in effect, with particular regard to mandatory maintenance training events.

13. Use and remuneration of services

- 13.1. Contracts between Companies and Healthcare Professionals, Healthcare Organisations, Patient Organisations or Patient Organisation Representatives under which the professional or organisation in question provides any type of service to that Company (not otherwise covered by the present Code of Practice) are only allowed if such service (i) is provided for the purpose of supporting healthcare, research or education; and (ii) does not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.

- 13.2. The entrusting of Healthcare Professionals or Patient Organisation Representatives is permitted both in groups or individually. In this context they may provide services such as taking lectures and/or chairing at meetings, involvement in medical/scientific studies, clinical trials or trainings, participation at advisory board meetings, and participation in market research, and for such services they may receive remuneration, and reimbursement for travel, accommodation, and hospitality. The arrangements that cover these consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:
- a) a written contract is agreed in advance of the commencement of the services which specifies the nature of the services to be provided and, subject to subparagraph h) below, the basis for payment of those services;
 - b) a legitimate need for the services has been clearly identified and documented in advance of requesting the services and entering into arrangements;
 - c) the criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular consultant meets those criteria;
 - d) the number of consultants retained, and the extent of the service are not greater than are reasonably necessary to achieve the identified need;
 - e) the contracting Company maintains records concerning, and makes appropriate use of, the services provided by consultants;
 - f) the hiring of the consultant to provide the relevant service is not an inducement to recommend and/or prescribe, purchase, supply, sell or administer a particular Medicinal Product;
 - g) appropriate records and supporting documents should be kept,
 - h) the compensation for the services is reasonable and reflects the fair market value of the services provided. In this regard, token consultancy arrangements should not be used to justify compensating the Healthcare Professionals or Patient Organisation Representatives.
- 13.3. Companies are strongly encouraged by the Associations to include in their written contracts with consultants provisions regarding the obligation of the Healthcare Professional to declare that they act upon the request of the given Company whenever they write or speak in public about a matter that is the subject of the agreement or any other matter relating to that Company.
- 13.4. When engaging the services of or providing support to a Healthcare Professional, Healthcare Organisation, Patient Organisation or a Patient Organisation representative from a different country, Companies must ensure that all applicable requirements of the individual's country of primary practice are met, as well as the local country requirements.
- 13.5. 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.

- 13.6. If a Healthcare Professional or Patient Organisation Representative attends an event as an (international or other) expert, Section 9 of this Chapter of the Code on events and hospitality during business events applies.

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 study 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. Non-Interventional Trials that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, Healthcare Professionals specifically for the trial must comply with all of the following criteria:
- a) There is a written study plan (observational plan/protocol) and there are written contracts between healthcare professionals and/or the institutes at which the study will take place, on the one hand, and the company sponsoring the study, on the other hand, which specify the nature of the services to be provided and, subject to subsection c) immediately below, the basis for payment of those services; Any remuneration provided is reasonable and reflects the fair market value of the service performed;
 - b) In countries where ethics committees are prepared to review such studies, the study plan must be submitted to the ethics committee for review; Local laws, rules and regulation on personal data privacy (including the collection and use of personal data) must be respected; The study must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a particular Medicinal Product;

- c) The study plan must be approved by the Company's medical department and the conduct of the study must be supervised by the Company's medical department as described in subsection 16.4.;
- d) The study results must be analysed by or on behalf of the contracting Company and summaries thereof must be made available within a reasonable period of time to the Company's medical department (as described in Section 16), and the medical department must maintain records of such reports for a reasonable period of time. If the study shows results that are important for the assessment of benefit-risk, the summary report must be immediately forwarded to the relevant competent authority;² and
- e) Medical Sales Representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the Company's medical department that will also ensure that the Medical Sales Representatives are adequately trained. The involvement of Medical Sales Representatives must not be linked to the intention of Promoting any Medicinal Product.

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.

² Companies are encouraged to publicly disclose the summary details and results of Non-Interventional Trials in a manner that is consistent with the parallel obligations with respect to clinical trials.

- 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 must establish a medical department in charge of information about its Medicinal Products and the approval and supervision of non-interventional trials. Companies are free to decide how best to establish the medical department in accordance with this section (i.e., whether there is one department in charge of both duties or separate departments with clearly delineated duties), taking into account their own resources and organisation. The medical department must include a medical doctor, a pharmacist, or an appropriately qualified person, who will be responsible for approving any promotional material before release thereof. Such person or another person appointed by the Company must certify that he or she has examined the final form of the promotional material and that he or she holds it to be in accordance with the requirements of the present Code and any relevant laws and regulations, consistent with the summary of product characteristics and a fair and truthful presentation of the facts about the medicinal product. For Non-Interventional Trials, the Company must ensure that the study personnel include a medical doctor, a pharmacist, or an appropriately qualified person who will be responsible for the oversight of any non-interventional trial (including the review of any responsibilities relating to such studies, particularly with respect to any responsibilities assumed by Medical Sales Representatives). Such person must certify that he or she has examined the protocol relating to the non-interventional trial and the remuneration for the services provided in connection with the non-

interventional trial and that he or she holds it to be in accordance with the requirements of the present Code of Practice and any relevant laws and regulations.

- 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 patients and lay consumers, 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 media and media for patients and lay consumers, any information suitable for identifying a specific medicinal product according to subsection 8.1. of this Chapter, shall be qualified as advertisement. 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 media for patients and lay consumers. Any representative of the media for patients and lay consumers

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.

- 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 conferences 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 conferences, 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. Use of social media

- 18.1. Companies should have appropriate social media policy in place for their employees to ensure that individual employee interactions with the company's social media (including forwarding, retweeting, comments and likes) do not bring content to the attention of inappropriate audiences (for example, content intended for healthcare professionals to lay people).

19. Relations between pharmaceutical industry and Patient Organisations

- 19.1. Companies must comply with the following principles, that pan-European Patient Organisations have also subscribed to:
- a) The independence of Patient Organisations, in terms of their political judgement, policies and activities, must be assured.
 - b) All partnerships between Patient Organisations and Companies must be based on mutual respect, with the views and decisions of each partner having equal value;
 - c) Companies must not request, nor shall Patient Organisations undertake, the Promotion of a particular Prescription-only medicine;
 - d) The objectives and scope of any collaboration must be transparent. Monetary and non-monetary support provided by Companies shall always be clearly documented.
- 19.2. 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.
- 19.3. 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.
- 19.4. As regards the selection of the venue, subsections 9.1. and 9.2. of this Chapter shall apply as appropriate.
- 19.5. 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. The contract must also include a description of significant indirect support (e.g., the sponsorship of public relations agency's time and the nature of its involvement) and significant non-monetary support.

- 19.6. 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.
- 19.7. 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.
- 19.8. 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.
- 19.9. 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.
- 19.10. 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.

- 19.11. 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.
- 19.12. 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.
- 19.13. 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.
- 19.14. 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.

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

20.1. 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).

20.2. 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;
 - ab)* 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;
 - ac)* information on the issues of regulatory changes with impact for the Company and its products, and information for prospective employees;
- b)* if the information is related to health education:
 - ba)* the website may also include health education information of non-advertisement nature, on the characteristics, prevention, screening and treatment methods of diseases;
 - 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 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;
- d)* on prescription-only medicinal products only the following information may be posted:
 - da)* labelling, package leaflet, and summary of product characteristics as approved by the authority;
 - db)* factual; informative announcements or informative materials relating to packaging changes of the medicinal product or to adverse reactions associated with the medicinal product;

- dc)* commercial price lists provided they include no product claims with regard to the effect of the 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.

20.3. 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.

20.4. References (links)

20.4.1. Websites maintained by third parties may refer to the website directly or indirectly maintained by the Company, but Companies shall not place links on platforms accessible by patients and lay consumers that refer to websites intended for Healthcare Professionals and maintained by the Company. Similarly, links referring to other websites may also be placed on the website, including websites maintained 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.

20.4.2. The title of a website might be included on the label in compliance with relevant legislation.

20.5. Professional control

20.5.1. 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 falls does not comply with the provisions of this Code, the sponsorship or maintenance shall be discontinued.

20.5.2. 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

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 to the CEC, 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. The members delegated to CEC are elected by the Associations in accordance with their statutes. The chairpersons of the Associations shall notify each other and the CEC in email 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 thirds of the CEC members are required to propose the recall of a CEC chairman.

2.1.6. The independent chairman of the CEC and the assistant helping the work of the CEC may not be employed by or be in any other legal relationship based on work or financial compensation with any market player engaged in promotional activities under the Medicinal Products Act within or outside the scope of the Code, from which the chairman of the CEC may not directly or indirectly accept financial or other benefits. Any other legal relationships based on work or other financial compensation for working with other non-pharmaceutical company outside the scope of the Code that are compatible with the spirit of the Code, the interests of the Associations, and the values they declare and represent, and operating ethically, is not a disqualifying reason. The chairman of the CEC shall be appointed for two (2) years and can be reappointed every two years but no more than twice. This provision is first applicable upon the first appointment following the effective date of the Code. The Associations shall unanimously decide on the appointment of the chairman of the CEC, the procedure for their appointment and assignment, the expectations related to their office, the performance of duties, and the provision of other necessary conditions.

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 affected parties;
- d) monitoring the implementation of the decision(s);
- e) overseeing observance of the provisions of this Code;
- f) ad hoc representation of the CEC in regulatory and professional relations as defined in advance by the Associations;
 - i. The neutral/independent presentation of industry ethical standards and related values primarily to professional audiences based on content unanimously approved by the CEC (general communication plan, individual appearances, etc.) in order to improve the perception of the industry;
 - ii. Promoting cooperation between Associations related to ethical pharmaceutical communication;
- g) Provision of information and training to industry associations, patient organisations and healthcare professionals regarding the rules of the domestic and international Codes of Ethics;
- h) Preparation of the wording of position statements referred to in subsection 2.5 of Chapter 5 of this Code for approval by the CEC and transparent communication of the approved statements to the Associations and industry actors.

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/notification submitted in email (hereinafter: notification) or open any ex officio proceedings at its own initiative for issues it has become aware of. The notification can be submitted in an electronic mail to the info@etikusgyogyszer.hu e-mail address. A procedure is started ex officio if it has been initiated by a member of the CEC. Notifications 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 email 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 via email of the conduct it has identified as presumably 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 email 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 AEC. 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, the Secretariats 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. CEC meetings may also be held by electronic means of communication in justified cases. The chairman shall convene the meetings of the CEC by an invitation sent by email 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 meeting of the CEC has a quorum if at least nine (9) members are present, either in person or simultaneously by electronic means of communication. 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. CEC passes its decisions in person or by electronic means by a simple majority of the CEC 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 of CEC members, 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 affected parties or independent experts or may hear a party if any of the affected parties 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

2.2.17. CEC is not authorised to disclose Benefits provided to Healthcare Professionals, Healthcare Organisations and Patient Organisations.

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 affected parties by email within fifteen (15) days from the date of the adoption of the decision.

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 launched against a business entity classified as an Association member company and the party specified in the notification 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 in the event that it is presumable based on the complaint that 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 affected parties had ceased without legal successor;

be) the circumstance justifying the proceeding no longer exists;

bf) if the affected parties 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 affected parties 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. If an ethical violation is established, in respect of the offender, in particular in view of the gravity of the ethical violation, the duration of the situation in breach of the Code, the advantage gained by the ethical violation, the reprehensibility of the ethically objectionable conduct, the conduct of the offender during the investigation of the matter and of the frequency of the ethical violation the CEC may:

a) warn the offender in writing;

b) call upon the offender to immediately cease the violation;

c) by setting a deadline, require the offender to withdraw the promotional/advertisement material or to collect those that have been issued and to submit a written report on compliance with the obligations set out in the resolution;

d) in the case of an ethical violation of a communicational nature where the deceptive communication may lead to the inappropriate use of a medicinal

product or pose any other risk to patients/consumers, order the offender to distribute within a certain deadline a circular letter for rectification to the Healthcare Professionals involved in commercial communication;

e) obligate the offender to present the circular letter for rectification specified in Section d).

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 by email 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 affected parties 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 by email 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 by email, 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 herein 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 affected parties, the CEC, and the Boards in writing, by email 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 on competence and adoption of its full text requires a majority vote of two third of the members present at the CEC meeting in person or via an electronic communication device.

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 day 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.

4. Entry into force of the Code

4.1. The Code enters into force on 1 June 2022.

Budapest, 31 May 2022

Dr. Dávid Greskovits
Chairman
MAGYOSZ

Oliver Rozboril
Chairman
Association of
Innovative
Pharmaceutical
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Dr. Péter Gaszner
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