

CODE OF CONDUCT



**REGULATIONS OF THE ETHICAL BUSINESS BEHAVIOR
OF THE MEMBER COMPANIES OF
THE ASSOCIATION OF HEALTH TECHNOLOGY SUPPLIERS
AND MEDICAL DEVICE MANUFACTURERS
(CODE OF CONDUCT)**

Members of the Association of Health Technology Suppliers and Medical Device Manufacturers (ETOSZ), as responsible participants of the Hungarian health technology and medical device sector, are committed to create and maintain a transparent and ethical business environment.

In full awareness of their responsibility and for the sake of the enforcement of the highest level business-ethical expectations, they created the following self-restrictive business ethical regulations and pronounce them to be obligatory followable.

1. GENERAL REGULATIONS, PRINCIPLES

1.1. The purpose of the Code of Conduct is to strengthen and exclusively enforce lawful and fair business practice. For the sake of that, these regulations cover:

- a) all activities related to the promotion of the order, procurement, sale and consumption of a tool, device or service of an ETOSZ member company, including all its appearance, communication and all related commercial practice;
- b) the practice of ETOSZ member companies with healthcare organisations, healthcare employees, financial-technical employees of healthcare service providers and state office holders, and general business relations;
- c) activities of all participants who accept this conduct as obligatory.

1.2. Although ETOSZ has a regular contact with the participants of the health sector and the political organisation system, this status is not used to gain unlawful advantage for its members.

1.3. All ETOSZ member companies introduce this code of conduct to their employees, trustees, agents and all participants whose activities they are responsible for.

1.4. ETOSZ and its members steer clear of any unlawful activity that may disfigure or result in disfiguring competition at official and informal discussions. For which, the member companies steer clear of even the tangential discussion of the below issues:

- a) customized prices, concessions and offer packages or contractual terms related to these, except for the regulatory issues related to price subsidy (reception) and the general terms and conditions of tenders regarding the issues requiring a common position of interest representation of the participants of the sector;
- b) customized customer relations and mutual evaluation of customer risks;
- c) individual issues of customized tender invitations – in progress or planned;

- d) business plans, commercial strategies, market prognosis, specific production, transport and stockpiling issues or any data related to customized market share;
- e) not public issues related to research and development and other business secret;
- f) personal data, especially health data.

The above a)-f) points do not regard data that is not classified as confidential business information, cumulative sector data, or data not classified as personal data.

1.5. Independent of membership – ETOSZ members offer vital respect to all competitors in business and other relations, and steer clear from malicious comments related to the products or services of the competitors and emphasizes only the ethical introduction of their own products and services.

1.6. The commercial practice of the ETOSZ member company related the distributed tools and devices must promote the sensible use and supported evaluation by objectively describing their qualities.

1.7. The ETOSZ member in business and other relations provides only lawful and ethical support to healthcare organisations, healthcare professionals and the financial-technical employees of healthcare providers and state office holders. This support or its offer cannot be a condition to ordering or purchasing any product or service and cannot promote ordering or purchasing any product or service, or any other unethical condition. The ETOSZ member has an adequate register of the support it provides, that facilitates the satisfactory settlement of any related argument.

1.8. Agreements concluded by ETOSZ member companies with healthcare professionals, financial-technical employees of healthcare providers indirectly or directly (especially medical research, clinical study, market research, study writing or professional ministrations) and its other contracts are concluded watchfully and ethically, as defined in this Code of Conduct.

1.9. In case of the breach of any regulation of the Code of Conduct, anyone can initiate the ethical procedure according to the Code of Conduct. In case of a case reported, the Ethics Committee is obliged to conduct the ethical procedure. In case of anonym reports, the Ethics Committee has the discretionary right to decide of releasing the ethical procedure.

1.10. Publicity is the most important tool of creating an ethical environment; therefore the Ethics Committee annually publishes its summary report. Those member companies that make a summary report of the support and benefaction they make this information available for the public at their website.

1.11. ETOSZ considers the supervising and monitoring authorities as strategic partners, and regularly updates the responsible healthcare and competition authorities about the issues concerned by the Code of Conduct.

1.12. ETOSZ publishes the list of companies that volunteer to be bound by the Code of Conduct. The companies wishing to join officially verify their will by their written Declaration (appendix of the Code of Conduct), that they sign at the director of ETOSZ.

1.13. The member company that accepts the obligatory, self-restrictive business behavior regulations included in the Code of Conduct, and enforce these regulations during daily business practice in its commercial and other relations, professional and general communication, is entitled to use the title ETHICAL HEALTHCARE SUPPLIER and its symbol, granted by the Ethics Committee.

1.14. Definitions used in this Code of Conduct:

- (i) ETOSZ: Association of Health Technology Suppliers and Medical Device Manufacturers, a trade association of Hungarian health technology suppliers and medical device manufacturers, that aims to enforce the sustainability of Hungarian healthcare supply system, supports promotion of new and innovative technologies and therapies in Hungary, creation of transparent and ethical business environment, and promotion of a general change of approach.
- (ii) Code of Conduct: The document summarising the regulations of ethical business behavior of member companies of the Association of Health Technology Suppliers and Medical Device Manufacturers;
- (iii) Healthcare organisation: a healthcare service provider and – irrespective of its legal or organisational form – except for patient organisations – all kinds of healthcare, medical or scientific organisation, body or foundation which may directly or indirectly influence the order, purchase, sale or consumption of medical devices and related services.
- (iv) Healthcare professional: physician, pharmacist or any person with healthcare activities of healthcare providers, and the salesperson – with the relevant license – participating in the commerce of pharma products and medical devices;
- (v) Financial-technical employees of healthcare providers: those employees of the healthcare providers that are not classified as healthcare professionals;
- (vi) State office holder: employees of the civil service, especially those of the healthcare institute system, government representatives and other civil servants that are not classified as healthcare professionals or financial-technical employees of healthcare providers, including state leaders, members of Parliament, and other employees and office holders of the Parliament;
- (vii) Financial advantage: money or equal assignment, or any other thing with a property value or a related claim;
- (viii) Self-restrictive, reasonable rate: a rate not surpassing and generally accepted among the local relations, that is not suitable to trigger a well-based disapproval;
- (ix) Commercial practice: any kind of information, activity, display method, marketing or other commercial communication related to promotion of the order, purchase, sale or use of a health technology or medical device or equipment;
- (x) Repeated and significant ethical infringement: if the Ethical Committee finds

that the concerned company violates the Code of Conduct within two years, and the unethical behavior concerns state office holders, or numerous healthcare professionals, or financial-technical employees of healthcare providers.

2. SPONSORSHIP

2.1. ETOSZ member companies are committed to the development of the Hungarian healthcare supply system: besides providing high quality, innovative tools for the promotion of the cure of Hungarian patients, they also support the information, further training of healthcare professionals so that they learn about new technologies and therapies. This sponsorship or the offer of the sponsorship cannot be partly or fully conditional to the order or purchase of any product or service and cannot level at the promotion of the order or purchase of any product or service, or cannot be related to any unethical condition.

2.2. ETOSZ member companies act as follows in point of sponsorship:

2.2.1. Sponsorship of professional events

ETOSZ members sponsor only professional, scientific or tuitional events or programs. In case of sponsoring an event like that, the direct or indirect sponsorship must be of a self-restrictive, reasonable rate; the sponsorship must remain secondary compared to the professional, scientific or tuitional aims of the event, and the scope of invitees is limited to healthcare professionals, financial-technical employees of healthcare providers and state office holders.

ETOSZ members may provide sponsorship for healthcare organisations, healthcare professionals and the financial-technical employees of healthcare providers, and state office holders to attend conferences and methodological, practical trainings (hands-on trainings) organised by third parties, however, this sponsorship must be granted in accordance with the prohibition under 2.2.2.

Within the professional, scientific and tuitional programs, the tools and devices distributed by ETOSZ members, and their services are separated; the related presentations, exhibitor booth, etc., the fact of sponsorship is transparently portrayed.

The rate and method of representation of the sponsored event must be of a self-restrictive, reasonable rate, and must be secondary compared to the main objective of the event.

ETOSZ members only sponsor an event that is held at an adequate location, where the necessary resources and expertise is available solely at that location, or another location nearer the workplace of the participants would result in disproportional cost. Regarding the selection of the sponsored event's location, ETOSZ members act in a reasonable and self-restrictive way.

2.2.2. Prohibition of direct sponsorship

ETOSZ members may not provide direct sponsorship to healthcare professionals, financial-technical employees of healthcare providers, or state office holders to attend conferences organised by third parties either in cash or in kind. However, the prohibition of

direct sponsorship does not cover the sponsorship of participation in methodological, practical (hands-on) trainings organised by third parties, and the support for a person holding a presentation at a satellite symposium (member company event within the framework of a conference organised by third parties) based on a consultancy or advisory contract in accordance with this Code of Conduct.

2.3. ETOSZ member companies document their sponsorship activities in a prudent and legitimate manner, helping to settle any related disputes as soon as possible.

2.4. ETOSZ member companies respect the independence of healthcare professionals in the choice of patient care methods and the provision of safe patient care, furthermore, in order to improve the transparency of their relations with healthcare professionals and healthcare organisations, they seek to eliminate conflicts of interest. Accordingly, ETOSZ member companies shall:

- a) Inform the employer and / or supervisor of the healthcare professionals concerned of the purpose and subject of the service contracts concluded with them,
- b) Inform the employer and / or supervisor of the healthcare professionals, financial-technical employees of healthcare providers, and state office holders of both the direct sponsorship provided to them in accordance with the provisions of this Code of Conduct and the indirect support provided to them within the exceptional scope of the prohibition under 2.2.2.
- c) Annually publish the amount of their previous year's contribution to healthcare professionals, financial-technical employees of healthcare providers, state office holders and healthcare organisations as regulated by the member company, in particular but not exclusively on their own website or the public domain of ETOSZ or other European trade organisations, dedicated to this purpose.

3. SALES AND PROMOTION

3.1. ETOSZ member companies have an ethical commercial practice regarding the sales and related promotion of the tools and devices they distribute and the services they provide.

3.2. During the sales and promotion, ETOSZ member companies act transparently, and indicate the person providing the commercial practice obviously.

3.3. Gifts, financial advantage or any other contribution in-kind can only be provided, offered or promised at a reasonably self-restrictive rate, and it cannot be fully or partly pre-conditional to the order or purchase of a product or service, or cannot tend towards the promotion of order or purchase of a product or service, or must not be related to any unethical condition. ETOSZ member companies strive to offer gifts that relate to the healthcare activities of the healthcare professionals and the financial-technical employees of healthcare providers, furthermore subserve the interest of the patients or serve other legitimate teaching purposes.

3.4. ETOSZ member companies do not provide, offer or promise financial or equaling contribution or advantage within the framework of commercial practice related to sales and promotion.

3.5. The code of conduct related to the gifts provided during sales and promotion do not

regard the scope of lawfully providable product samples or evaluative use of devices, and the commercially usual contractual use concessions based on price and other general term and conditions is not concerned as forbidden advantage.

3.6. Within the framework of sales and promotion, the given tool, device or service must be described in such detail, that healthcare professionals, financial-technical employees of healthcare providers and state office holders can offer a well-based opinion about the tool, device or service.

3.7. All the information and written documentation provided during the sales and promotion must be detailed, verifiable and up-to-date. Quotes, charts and other visual materials from medical journals or other scientific sources must be introduced in a form near the original and the exact source must be indicated.

3.8. During the sales and promotion, the salesperson cannot disturb the healthcare service providing activity of the healthcare professionals, especially the curative-preventive activity according to the treatment order of the healthcare service provider.

3.9. In cases when visiting an exact location is necessary for the transmission of information during the commercial practice, e.g. the introduction of the operation of a tool or device, the necessary travel and accommodation fees can be provided at a reasonable, self-restrictive rate. In cases like that, the rate of related representation cannot exceed the reasonable, self-restrictive rate and must be secondary compared to the main objective of the event.

3.10. ETOSZ member companies do not provide, offer or promise financial or equaling contribution or advantage to state office holders. A gift of a self-restrictive rate can be given if – in the given circumstances – especially at or related to some public event – it is socially acceptable and cannot be related to a misuse-like and political, investment or procurement decision that excludes competition.

4. CHARITABLE DONATIONS AND SOCIAL RESPONSIBILITY

4.1. ETOSZ member companies may provide charitable donations to healthcare organisations for the sake of corporate social responsibility. These charitable donations shall always be fully transparent, considering patient interests.

4.2. The grant of or an offer for a charitable donation cannot be partly or fully pre-conditional to the order or purchase of a product or service, and cannot tend to promote the order or purchase of a product or service or cannot be related to any unethical condition.

4.3. ETOSZ member companies shall not unilaterally define the use of their charitable donations, and if possible, offers for a charitable donation shall be made to independent donation organisations, or they shall do their best so that the recipient can decide about the actual use of the donation without being influenced.

4.4. ETOSZ member companies handle and document their charitable donations separated from business activities and if preparing an annual report, the donations and the recipients are published on their websites or official publications.

5. FURTHER PLEDGES OF ETOSZ MEMBER COMPANIES RELATED TO BUSINESS ACTIVITIES

5.1. In case of contracts concluded with healthcare professionals and technical-financial employees of healthcare service providers (especially medical scientific research, clinical research, market research, study writing, expert contribution, etc.) ETOSZ member companies enforce the following:

- a) the service-consideration is always based on legal title;
- b) the selection of the contractual partner is based on the objective of the contract or the order;
- c) the understanding is always written watchfully, with reasonable details;
- d) the consideration in terms is reasonably self restrictive, fair, at the same rate of the service, and of a real market value;
- e) the certificate of completion is documented with proper details.

5.2. ETOSZ member companies do not conclude contracts of financial or equaling contribution with state office holders.

5.3. ETOSZ member companies appoint the person in charge for observing the rules of ethical business behavior (ethics officer), who is independent and separated from the sales and marketing organisational unit and employees. In this framework, all member companies ensure that any employee or external partner can inform the ethics officer or the managing director of the company about the concerns rose in relation to the ethical behavior. The ethics officer regularly informs the managing director of the ETOSZ member company, and is directly entitled and obliged to inform them about the reported ethical concerns for the sake of efficient provisions.

6. THE ETHICAL PROCEDURE

6.1. Violation of the Code of Conduct results in the ethical procedure of the ETOSZ Ethics Committee. Any violation can be reported by anyone, and the procedure can be also initiated by anyone. In case of a violation report, the Ethics Committee is obliged to conduct the ethical procedure regardless of the form of report. In case of anonymous reports, the Ethics Committee has the discretional right to decide upon the initiation of the procedure.

6.2. Any violation can be reported to the Ethics Committee within 30 days after finding out about the activity violating the Code of Conduct. If the violation happened more than a year before the report, the Ethics Committee can examine it only in cases of special appreciation.

6.3. The chair of the Ethics Committee immediately informs the Ethics Officer of the concerned member company of the report, requesting their opinion about the report. Moreover, the chair of the Ethics Committee sees about the soonest settlement of the given concern with all the affected (henceforward: Mediation), and collects the information necessary for the established judgment of the report.

6.4. In case of an unsuccessful Mediation, the Ethics Committee makes a decision based on the available information, except when the concerned member company demands a trial. In this case, the Ethics Committee has a trial with the representative of the concerned member company, and – if possible and necessary – the reporter of the violation.

6.5. Mediation or the ethical procedure must be conducted within a reasonable period concerning the given case.

6.6. The Ethics Committee observes the available information watchfully and sagely and decides the issue. As a result:

6.6.1. states that the given activity is not violating the Code of Conduct;

6.6.2. states the unethical behavior and

- a) calls the concerned member company to immediately seize the activity violating the Code of Conduct and enforce ethical practice;
- b) withdraws the use of “ETHICAL HEALTHCARE SUPPLIER” title;
- c) in case of repeated and significant ethical violation, initiates the exclusion of the concerned member company;
- d) in case of suspicion of a higher volume violation, reports the case to the authority with the tether and cognizance.

6.7. The decision of the Ethics Committee and its preamble is published at ETOSZ website.

6.8. The Ethics Committee has a meeting at least annually, or if necessary, and the chair of the Ethics Committee reports to the General Assembly annually, or if necessary.

6.9. The Ethics Committee gives an overview of its activity to the relevant healthcare and competition authorities overseeing the activities of the member companies.

6.10. The Ethics Committee decides upon granting the “ETHICAL HEALTHCARE SUPPLIER” title upon request – if the requestor accepts the regulations of the Code of Conduct and declares so in the Declaration attache

DECLARATION

Undersigned [NAME OF COMPANY] (seat: [.....], Company registry number: [.....], represented by: [name and position of representative]) hereby declare that I accept the obligatory

CODE OF CONDUCT, THE ETHICAL BUSINESS BEHAVIOR REGULATIONS FOR THE MEMBER COMPANIES OF THE ASSOCIATION OF HEALTH TECHNOLOGY SUPPLIERS AND MEDICAL DEVICE MANUFACTURERS.

With my signature I also declare that I am familiar with the regulations of the Code of Conduct, I agree with its purposes and I enforce its provisions during my business activities.

place:

date:

yyyy.

mm.

dd.

[Name]
[Position]

[Name]
[Position]

In our presence as witnesses

1.

Name:

Address:

Signature:

2.

Name:

Address:

Signature: