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Association of Medical Devices Manufacturers, Hungary

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ASSOCIATION OF MEDICAL DEVICES MANUFACTURERS, HUNGARY

CODE OF ETHICS

Preamble

In line with its Statutes and Procedures, the Association of Medical Devices Manufacturers (the 'Association') is an association established by enterprises registered in Hungary and engaged in the manufacture, distribution, development, research, and provision of services related to medical devices, devices used for diagnostics, in telemedicine, and health information technology devices.

The Association, as the Hungarian member association of MedTech Europe, is committed to comply with the rules relevant to and governing its activities, to fair business conduct and competition; to this end, the members of the Association have passed the following Code of Ethics which they accept as fully binding.

1. Scope of the Code of Ethics

The scope of the present Code of Ethics shall extend to the members of the Association. Any new member wishing to join the Association shall accept the provisions in this Code of Ethics.

2. Compliance with law

2.1. In the course of business, members of the Association shall make every effort to comply with the relevant legal rules of the Hungary, in particular with respect to the followings:

- manufacture, trading, distribution;
- product liability;
- competition law;
- public procurement;
- trading practices, advertisements, promotion.

2.2. The members of the Association shall monitor and keep up with the changes in the legal rules relevant to their activities and, if and when required, shall adjust their business practices accordingly.

2.3. The members of the Association shall be responsible for getting their employees aware and observe the legal rules relevant to their work and business environment of their enterprise.

3. General business conduct

3.1. In the course of business, members of the Association shall not take any measure that restricts free competition or trade.

3.2. With regard to the products manufactured or distributed by or to services rendered by member companies, only information that can be verified and correspond to the facts shall be disclosed.

3.3. The information disclosed on products manufactured or distributed by or on services rendered by member companies shall be stated clearly and precisely.

3.4. In the course of business, members of the Association shall not decry competitors and other players in business environment, nor they shall disparage products of another company or the company itself.

3.5. In the course of public comparison, the member companies shall not disclose names of other companies their products or services; no data that may question the quality of other verified product may be disclosed, unless they have any study or examination report published by an independent institution.
When disclosing results of comparative studies, the criteria, the method applied, and the source of data shall be stated clearly.

4. Relationship with health care professionals

4.1. Health care professionals includes all private individuals (for example, hospital, health institute, health training, research institute managers and professional staff members, including doctors, nurses, technical and administration staff, specialists who co-ordinate research activities), who directly or indirectly purchase, lease, resale, use, or arrange for or order the purchase or lease of medical equipment, devices, instruments and services of member companies by acting on behalf of themselves or any organization.

4.2. The relation between member companies and health care professionals shall be established upon ethical business conduct and comply with the provisions set forth in legal rules.

4.3. In the course of keeping a relationship with health care professionals, the member companies shall not force purchase decision by offering illegal benefits and supports sponsored by member companies shall not be dependant on the purchase or use of products or services manufactured or rendered by such member company.

4.4. Member companies shall no longer provide financial or in kind support directly to individual Healthcare Professionals (HCPs) to cover costs of their attendance at third party organised educational events; they may not pay for or reimburse HCPs travelling, lodging expenses and/or registration fee for such events.

The exceptions to this are third party organised procedure training events.

Third Party Organised Educational Events mean activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of a person or entity other than a Member Company to fulfil Healthcare Professional medical educational needs.

5. Specific provisions for support

5.1. A member company shall not organise Events which include social, sporting and/or leisure activities or other forms of entertainment, nor support such elements where part of third party organised educational events.

5.2. For third party organised educational events, entertainment must be outside of the educational programme schedule and paid for separately by the healthcare professionals.

Entertainment should not dominate or interfere with the overall scientific content of the programme and must be held during times that do not overlap with a scientific session. The entertainment should not be the main attraction of the third party organised educational event.

5.3. The events location and venue, organized or sponsored by member companies, should not become the main attraction of the event.

5.4. For third party organised procedure training events member companies must apply the requirements laid under points 5.1-5.3.

In case of procedure training events member company may only pay for or reimburse for reasonable and actual travel. Travel provided to healthcare professionals should not cover a period of stay beyond the official duration of the event.

Member companies are not permitted to facilitate or pay for meals, travel, accommodation or other expenses for guests of healthcare professionals, or for any other person who does not have a bona fide professional interest in the information being shared at the event.

5.5. Member companies may provide reasonable hospitality to healthcare professionals in the context of company educational events but any hospitality offered must comply with the national laws, regulations and professional codes of conduct.

5.6. Member Companies may provide restricted Educational Grants for HCPs for the advancement of genuine medical education.

Member Companies shall specify the intended purpose of the Educational Grant in the Grant agreement.

A Member Company shall ensure that the Educational Grant agreement with the recipient organisation includes rights to enable it to verify that the Grant is in fact used for the agreed intended purpose.

Member Companies shall document and publicly disclose all Educational Grants provided by them. The disclosure may be done either on the Member Companies' homepage and/or the Association's homepage and/or on the Medtech Europe Transparency platform.

5.7. Member Companies may provide examples of their products to healthcare professionals and/or healthcare organisations that are used for healthcare professionals and patient awareness, education and training.

5.8. Member Companies, comply with the national laws and regulations, may provide a reasonable number of samples at no charge to allow healthcare professionals and/or healthcare organisations to familiarise themselves with the products and/or related services, to acquire experience in dealing with them safely and effectively in clinical use.

6. The Rules of Procedure of the Ethics Committee of Medical Devices Manufacturers' Association

In order to observe the Code of Ethics and investigate ethics-related claims, the Association has founded an Ethics Committee (EC). The Statutes and Procedures of the Association govern the election and resign of members and chair of the Ethics Committee.

6.1. General provisions

6.1.1 The Members of Board (Board) of the Association shall provide for the conditions of operation the EC require.

6.1.2 Any member employed by either part concerned or interested in a particular case being brought to the EC for evaluation or evaluation shall not participate in evaluation and judgement process. Evaluation of a case shall include participation in the procedure, taking resolution, and appeal procedure as well. In the event the Chair of EC is employed by a party concerned in a particular case under review, then EC members shall, among themselves, elect a deputy chair to proceed the case. In place of members not participating in a procedure on account of conflict of interest the EC may ask alternate member or members from the Board.

6.2. Competence

6.2.1. EC shall be entitled to proceed exclusively in ethical matters of the members of the Association.

6.2.2. The members of the Association shall have the option to submit a written claim against non-Association actors to the EC.

6.2.3. In possession of approval by the Board of the Association, the EC shall be entitled to communicate the general business conduct norms and the Code of Conduct of the Association to state decision-makers, health administration, other interest-representing organs, and the public.

6.2.4. In possession of approval by the Board of the Association, the EC shall be entitled to appeal to healthcare decision-makers and the public, in particular if market players outside the Association conduct business in a way that conflicts legal rules or general norms.

In the course of their activities, EC and its members represent the Association's position and shall be entitled to make statements and consult representatives of other organizations.

6.2.5. In the event of a cross-border dispute the matter shall be referred to the MedTech Europe Compliance Panel for a determination under the rules of Medtech Code of Ethical Business Practice.

6.3. Scope

The followings shall fall within the scope of EC:

- protection of those who observe the provisions set forth in the Code of Ethics and, in general, the written and unwritten rules of the relevant law, the trade, and conduct;
- to protect members from ungrounded and unjustified accusations;
- to try preliminary proceedings to settle disputes and ethical matters and condemn the party in default if offence has been established;
- in cases beyond its competence take measures it shall make proposition for the Board to take measures as appropriate.

6.4. Rules of procedure

6.4.1. Ethical investigation may be instituted on the basis of written claim lodged directly to the EC or the Board.

The Board shall forward the claims received within three working days to the EC. The EC shall inform the Board on the claim submitted within three working days.

6.4.2. The claim shall clearly specify the ethical offence and provide reference to legal rules or provisions in the Code of Ethics, which the Claimant believes the party in default has offended.

6.4.3. The EC shall give response to every complaint submitted. Term of limitation shall be one year from occurrence of ethical offence.

6.4.4. Since the EC advocates the ethical matters raised by the parties be resolved amicably, it takes preliminary proceedings to address claims prior to ethical proceedings is instituted. The EC shall inform the Board on initiating claim procedure.

In the course of preliminary claim procedure, the EC or the chairman of EC consults the representatives of parties (claimant and the party in default) involved in the claim and makes an attempt to resolve the dispute amicably.

In the event the preliminary claim procedure fails, the EC shall institute ethical procedure.

6.4.5. The EC shall initiate consultations addressing claims submitted by a member of the Association against non-Association actors with participation of the claimant and the party in default.

6.4.6. The EC or the Board shall institute ethical proceedings within 8 days from failure to settle claim procedure, but at the latest on the 30th day after the receipt. The EC notifies the claimant, the party in default, and the Board on the commencement of ethical proceedings in writing.

6.4.7. In the course of ethical proceedings EC shall proceed under the Hungarian law and in consideration with the Association's Code of Ethics and Medtech Europe Code of Ethical Business Practice.

6.4.8. Information and documents available in the course of investigation shall be examined comprehensively with utmost care.

6.4.9. After all available information and documents are investigated, EC members, the secretary general, the claimant and the party in default shall be called for and heard.

6.4.10. The minutes of hearing shall be recorded in writing or by recording.

The minutes of hearing shall specify the

- Venue,
- Time of hearing,
- Name of members present,
- Data of claimant and the party accused,
- Subject matter of procedure,
- Brief description of the course of proceedings.

6.4.11. The resolutions passed by the EC shall be put into writing and specify the subject matter of the proceedings, the decision of EC, and reasoning of decision. Within 8 days after passing a resolution, the EC shall send the resolution in writing via registered mail with return slip or deliver it in person to the parties it may concern. In its written resolution, the EC may establish that

- no ethical offence has been made, or
- an ethical offence has been made.

6.4.12. In the event the EC has established an ethical offence, then it shall pass a resolution to advice the party in default to stop or refrain from repeating such conduct, and to make the party in default to send a written report on the observance and execution of provisions stipulated in the resolution.

6.4.13. The EC may impose the following sanctions on the party offending ethical rules:

- a written notice of default,
- may propose the General Assembly to exclude the party in default from the Association.

6.4.14. In its resolution, the EC shall establish to what extent the ethical offence and the corresponding resolution shall be made public; accordingly, the resolution may be:

- limited in publication, that is addressed exclusively to the members of the Association,
- unlimited for publication.

6.4.15. An appeal lies against the resolution of the EC and shall be lodged to the Board in writing within 15 days from the receipt of the resolution. The Members of the Board shall adjudge the appeal within 30 days from the receipt of appeal. Within 8 days after passing a resolution, the Board shall send the resolution in writing via registered mail with return slip or deliver it in person to the EC and parties it may concern.

The Board may opt to confirm or annul the resolution made by and sanctions imposed by the Ethics Committee.

7. Miscellaneous and closing provisions

7.1.1. The EC shall provide the General Assembly with a written report on ethical cases of the preceding period every year.

7.1.2. Both the EC and the Board shall monitor the changes in business environment, legal regulations, and in codes of ethics of international organizations, and together shall take measures to amend the Code of Ethics when necessary.

8. Entry into force

8.1. Present Code of Ethics – which contains the changed and consolidated text of the Code of Ethics currently in force – was approved by the General Assembly of AMDM Hungary on 14 October 2020.

Budapest, 14 October 2020

Andrea Ollári
Chair
Ethics Committee