Code of Ethics of the Association of Legal Entities

Slovak Association of Medical Devices Suppliers

Valid from 1st February 2018

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1. Introduction

The Slovak Association of Medical Devices Suppliers SK+MED (hereinafter referred to as "SK+MED") is an interest association of legal entities established in 1999. SK+MED represents the interests of suppliers of medical devices and special medical material operating in the Slovak Republic. Its mission is to provide safe, innovative, and reliable medical technologies, devices and associated services.

As a member of MedTech Europe, SK+MED has issued the new Code of Ethics that is based on MedTech Europe's Code of Ethical Business Practice. In accordance with the Statutes of SK+MED, each member is required to observe the Code of Ethics of SK+MED (hereinafter referred to as the "Code").

The Code:

- does not supplant national laws or professional codes (including company codes)
- does not have precedence over legislative standards of the Slovak Republic, the laws of the Slovak Republic, regulations, or other professional or business codes (including company codes) that may be binding for the members
- expresses the attitudes and standards of conduct required from Member Companies, which they must follow in their business practice
- sets out the minimum standards for Member Companies appropriate to the various types of activities and applying to various types of relationships with Healthcare Professionals.

The Code governs the attitude of Member Companies towards the following entities:

- healthcare organizations established by the state, regions, cities, or municipalities
- private healthcare organizations
- state administration bodies
- healthcare providers
- patients – users of medical devices
- suppliers of goods and services.

The Member Companies must observe the ethical standards and conduct business in line with the requirements of applicable laws governing the competition and public procurement. Forbidden activities include:

- conclusion of price cartels, division of territories or customers, placing limits on sales
- sharing information with competitors on prices or possibly other confidential information
- price discrimination or refusal to sell.

All Member Companies are required to make sure that their cooperation with Healthcare Professionals and healthcare organizations is in accordance with the applicable legislation and this Code.

The Member Companies may not, directly or indirectly, offer, provide or approve the use of funds or other in-kind items to unlawfully:

- influence the judgment or action of any individual, customer, or company
- win or maintain any business,
- influence any negotiation, decision of a government official,
- gain any advantage.

This requirement applies both to direct payments of such nature and any indirect payments made by a Member Company by way of its agents, consultants or third parties. The Member Companies must pay special attention to the laws and regulations prohibiting bribing physicians or other persons who may be deciding on the use of medical devices.

2. Aims and Principles of the Code

The purpose of this Code is to set out the minimum ethical standard applying to cooperation between SK+MED members (hereinafter referred to as the "Member Companies") and healthcare organizations or healthcare professionals (hereinafter referred to as the "Healthcare Professionals") who purchase, lease, recommend, use, or prescribe the medical devices of Member Companies. There exist various forms of collaboration between Member Companies, Healthcare Professionals and healthcare organizations that improve the medical science and enhance patient care. These include:

■ Advancement of Medical Technologies
The development of innovative medical devices, technologies and in vitro diagnostics and the improvement of existing products require collaboration between Member Companies and Healthcare Professionals and healthcare organizations. Innovation and creativity are essential to the development and evolution of medical technologies and/or related services.

■ Safe and Effective Use of Medical Technology
The safe and effective use of medical technology and related services requires Member Companies to offer Healthcare Professionals and healthcare organizations appropriate instruction, education, training, service and technical support. The regulatory authorities may even require retraining as a condition for product approval.

■ Research and Education
Member Companies' support of *bona fide* medical research and education serves to enhance Healthcare Professionals' clinical skills and thereby contributes to patient safety and improves access to new technologies and/or related services. In each such interaction Member Companies must respect the obligation of Healthcare Professionals to make independent decisions regarding treatment and safeguard the environment in which the interaction takes place to ensure the integrity of the industry. To achieve this aim, the Code provides guidance on the interactions of Member Companies with both Healthcare Professionals and healthcare organizations, based upon the following underlying principles:

■ The Principle of Image and Perception
Member Companies should, at all times, consider the image and perception of the medical technology industry that will be projected to the public when interacting with Healthcare Professionals and healthcare organizations.

■ The Principle of Separation
Interaction between industry and Healthcare Professionals/healthcare organizations must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of Member Companies' products.

■ The Principle of Transparency
Interaction between the industry and Healthcare Professionals/healthcare organizations must be transparent and comply with national and local laws, regulations or professional codes of conduct. Member Companies shall make sure that all business presentations and product information is accurate, clear, balanced, objective, and unambiguous. Such information should be likewise supported by appropriate arguments and should not be misleading for target audience.

■ The Principle of Equivalence
Where Healthcare Professionals are engaged by a Member Company to perform a service for or on behalf of a Member Company, the remuneration paid by the Member Company must represent a fair market value for the services performed by a Healthcare Professional or speaker.

■ **The Principle of Documentation**

For interactions between a Member Company and a Healthcare Professional, such as where services are performed by a Healthcare Professional for or on behalf of a Member Company, there must be a written agreement setting out, inter alia, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses, as well as the remuneration to be paid by the Member Company. The activities envisaged by the agreement must be substantiated and evidenced by activity reports and the like. Adequate documentation such as the agreement, related reports, invoices etc. must be retained by the Member Company for a reasonable period of time to support the need for, and materiality of, the services as well as the reasonableness of the remuneration paid.

3. Product Training and Educational Events Supported by Member Companies

In order to facilitate the safe and effective use of medical technologies, therapies and/or services, Member Companies should provide product and procedure training, practical training and education to relevant Healthcare Professionals. Member Companies shall ensure that personnel conducting the product and procedure training and educational events have the appropriate expertise to conduct such training.

Product training, procedure training may be designed as satellite symposiums that are held at the same location and at the same time as a third party organised educational conference.

They should be designed so that their content is professional and does not include any inappropriate social, entertainment and/or leisure activities.

The programmes should always be held in suitable locations and premises that allow efficient knowledge sharing by their equipment.

The Member Companies may:

- provide participants with reasonable meals during training
- reimburse participants for reasonable travel and accommodation costs in accordance with the applicable legal regulations, reasonable meaning air tickets in economy or standard class (for flight time shorter than 5 hours, including connection flights), or possibly business class (for flight time over 5 hours); *(First class is never appropriate.)*

The Member Companies may not:

- reimburse participants for costs of personal activities not associated with the educational programme;
- reimburse Healthcare Professionals' partners or guests for travel or other costs.

Member Companies may support a Healthcare Professional who is an active participant in the event – **speaker** in the form of reasonable honorarium (remuneration representing fair market value of the services provided).

4. Support for Educational Conferences Organised by Third Party

The independent, educational or scientific events, so-called conferences, promote development of scientific knowledge, medical advancement and delivery of effective healthcare. These typically include conferences organised by national, regional, or specialty medical societies or accredited providers of continuing medical education.

Conferences complying with the Code:

- should only include educational content and should not involve any inappropriate social, entertainment and/or leisure activities;
- location and venue should be suitable for holding such event and centrally located when regard is given to the place of residence of the majority of invited participants;

- selected time of year must not be associated with a touristic season for the selected geographic location;
- perceived image of the location and venue must not be luxury, or tourist/holiday-oriented, or that of an entertainment venue;
- participants should be offered meals and accommodation in the same hotel;
- accommodation and/or other services provided to Healthcare Professionals however may not exceed the official event duration.

Member Companies may provide financial grants to Healthcare Professionals' employers or reimburse the costs indirectly, and this via an account set up by the employer of the Healthcare Professional and/or other state official, or possibly via an institution educating the students, in particular to reimburse:

- conference fees;
- reasonable travel costs, reasonable meaning air tickets in economy or standard class (for flight time shorter than 5 hours, including connection flights), or possibly business class (for flight time over 5 hours); *(First class is never appropriate. Travel costs should not cover a period beyond the official event duration.)*
- adequate meals during the event;
- adequate accommodation, adequate meaning maximum 4-star hotels

If a conference is held in an attractive foreign destination, particular emphasis is laid on justifiability of supporting the attendance of the Healthcare Professionals. If a conference is held in a luxury 5-star hotel, it shall be possible to reimburse only the registration fee and travel costs, in no case accommodation in such hotel.

The reimbursement of travel costs must correspond with conference duration and ±1 day tolerance. This support must be in accordance with the Slovak legal regulations and must be clearly specified before the conference.

Member Company is required to ask the beneficiary (employer, educational institution) for a **written document** on the actual use of the funds paid and to archive this document in a same manner as other payment documents.

Member Companies shall not:

- reimburse the participants for costs of personal activities not associated with the educational event programme;
- reimburse the participants for travel or other costs of Healthcare Professionals' partners or guests.

Members Companies may also indirectly contribute to cover the speaker's costs in the form of sponsorship arrangement with conference organiser. Member Companies may reimburse **speaker fees** at a third party organised conference only if it represents a block/symposium/lecture sponsored by a Member Company and provided that this fact is explicitly mentioned in the official programme of such third party organised conference.

Members Company may purchase **advertisement time** at conferences or rent a **booth space for company displays**. It is forbidden to serve alcohol in the booths.

5. Sales, Promotional and Other Business Meetings

Member Companies may organise sales, promotional or other business meetings to discuss the properties and benefits of products and associated services, hold contractual negotiations or discuss the sales terms and conditions. These meetings should normally take place near the workplaces of Healthcare Professionals.

It is not appropriate for Healthcare Professionals to receive reimbursement for travel or accommodation costs from Member Companies, except when demonstrations of non-portable equipment are necessary.

6. Arrangements with Consultants

Healthcare Professionals may become consultants in research, expert advice, presentations at the meetings sponsored by a Member Company and in development of healthcare technologies. In all cases, consulting arrangements must be permitted under the laws and regulations of the country where the Healthcare Professional is licensed to practise and be consistent with applicable professional codes of conduct in that country.

Healthcare Professionals may be paid reasonable **remuneration** for performing these services. This remuneration shall not be contingent in any way on the consultant's past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the Member Company's products or services, the volume/implementation of which the consultant is able to influence in her/his practice. The remuneration shall be paid for services actually provided and must comply with all applicable tax and other legal requirements. The remuneration paid to Healthcare Professionals engaged as consultants by Member Companies shall reflect fair market value for the services provided.

Member Companies may pay for expenses reasonably expended by consultants in providing services which are the subject of consulting arrangement, including reasonable travel, meals and accommodation expenses incurred by consultants when attending meetings with, or on behalf of Member Companies. The **written agreement** signed by both parties (in advance of the commencement of the services) must specify in detail the nature of expenses the consultant may ask for reimbursement in relation to the provision of services and the basis for remuneration by Member Company.

The **number** of consultants retained must not be greater than the number reasonably necessary to achieve the identified need. Member Companies shall always inform the consultant's employer in writing by the so-called notification which shall disclose the purpose and scope of services or shall contractually transfer this responsibility to the consultant.

The **selection** criterion for consultants must be the consultant's qualification and his/her experience which must allow the consultant to fulfil the stated purpose of the agreement.

The venue and other arrangements for Member Companies meetings with consultants shall be in line with the subject of consultation. The meals sponsored by Member Company in connection with consultation meeting shall be of reasonable value, incidental in terms of duration and shall correspond to the primary purpose of the meeting.

Member Companies shall keep **records** of services and associated work products provided by the consultant Healthcare Professionals and of the use made of those services by the Member Company.

Member Companies undertake to always inform the consultant's employer in wiring by the so-called notification which shall disclose the purpose and scope of services or shall contractually transfer this responsibility to the consultant.

7. Charitable Donations and Grants

Charitable donations may be made only to charitable organizations or other non-profit entities which have charitable and/or philanthropic purposes as their main goals and which are objectively engaged in genuine charitable or philanthropic activities.

Restricted charitable donations to non-profit hospitals may be permissible in case of demonstrated financial hardship, when charitable donations serve exclusively the benefit of the patient, are limited in value, or explicitly permitted by applicable national laws.

Member Companies may provide restricted **educational grants** for the advancement of genuine medical education. Member Companies shall specify the intended purpose of the educational grant in the grant agreement. The Member Company shall also ensure that the educational grant agreement includes the right to enable verification that the grant is in fact used for the agreed purpose.

Member Companies shall implement an independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with the provision of a grant or a charitable donation to specific prospective recipients. This process shall include a documented, prior evaluation of any such associated risks and of the relevant information concerning the intended recipient organization or entity.

Moreover, grants and charitable donations shall only be provided in response to a written request submitted by the requesting organization or documented initiative from a Member Company containing sufficient information to permit an objective evaluation of the request to be carried out by the Member Company. No grant or charitable donation shall be provided until a written agreement documenting the terms and conditions thereof is signed by both parties.

Member Companies shall document and publicly disclose all educational grants and charitable donations (where applicable, they shall have approval via the conference vetting system).

Member Companies providing a grant or charitable donation shall be required to report to SK+MED the list of recipients and the amount of such grant/charitable donation using a form published on SK+MED's website.

Member Companies may provide educational grants for the following purposes:

Support for Healthcare Professionals' participation at third party organised educational events:
Where the educational grant is provided for the purposes of supporting Healthcare Professionals' attendance at third party organized educational events, the healthcare organization receiving the grant shall be solely responsible for the selection of participants and this shall be expressly reflected in the written grant agreement.

Support for third party organised educational events:
Where the prospective beneficiary of an educational grant is the organizer of a third party organized educational event, and is also a healthcare organization, the recipient healthcare organization shall be solely responsible for:

- programme content
- speaker selection
- payment of speaker's honoraria, if any.

Member Companies shall not have any detailed involvement in determining the content of the educational programme or in speaker selection, which shall be reflected in the written grant agreement. If expressly requested to do so, Member Companies may recommend speakers or comment on the programme.

Scholarships at Various Levels
Member Companies may provide educational grants on a restricted basis in the form of grants for scholarships and fellowships to support advancement of genuine medical education of Healthcare Professionals. Only healthcare organizations where Healthcare Professionals are in professional training shall be eligible to request and/or receive such educational grants.

The Member Company shall not provide educational grants to support scholarships and fellowships at the request of individual Healthcare Professionals. Likewise, the Member Company shall not have any involvement in the selection of Healthcare Professionals who will benefit from educational grants and this shall be reflected in the written grant agreement between the Member Company and the recipient healthcare organization.

Grants for Public Awareness Campaigns
Member Companies may also provide educational grants on a restricted basis to healthcare organizations for the legitimate purpose of providing information, promoting awareness and/or educating patients, careers or the general public about relevant healthcare topics or medical conditions or diseases in therapeutic areas in which Member Companies are interested and/or involved.

8. Educational Items and Gifts

Under the Advertisement Act, the Member Companies may occasionally provide educational items, gifts or promotional items to Healthcare Professionals, which however shall be inexpensive and in accordance with the applicable legal regulations of the Slovak Republic. The general rule is that gifts should relate to the given Healthcare Professional's type of practice and should be beneficial to patient care, improve the Healthcare Professional's working conditions or possess a genuine educational function. It is explicitly prohibited to provide gifts in any financial form.

Member Companies may occasionally provide educational items of greater value to a healthcare organization, always provided that the items serve the Healthcare Professionals at that given healthcare organization and improve patient care. For higher value educational items, Member Companies must maintain appropriate records of their provision to healthcare organizations.

The items should only relate to the therapeutic area in which the Member Company is involved. No gifts should be associated with sales, and this neither as an acknowledgement, compensation or incentive, and they must not encourage prescription.

Such items shall not be provided to Healthcare Professionals for their personal need. Member Companies must maintain appropriate records of all such items/gifts.

9. Research

Member Company-Initiated Research
Member Companies may initiate, conduct, manage and finance scientifically valid research to generate data, whether pre- or post-market. Legitimate needs include, in particular, patient safety, support for future scientific development, measurement of product performance and quality indicators, regulatory issues, or possibly assessment of economic impacts, usually in connection with the determination of reimbursement.

All research activities must be documented in written form with corresponding clinical follow-up protocol. Prior to initiating their research activities, Member Companies must arrange all required approvals from local authorities and implement their research activities in compliance with applicable laws, as well as ethical requirements. Member Companies shall also ensure transparency in relation to data generation and evaluation process. Member Companies may also initiate user evaluation of products/services by third parties, and this provided that a written agreement is concluded for evaluation purposes.

Member Company Post-Market Product Evaluation
Member Companies may initiate user evaluation of their products, therapies and/or related services by a third party following the market introduction and may therefore provide evaluation products under a written contract for services in order to obtain defined user evaluation by

healthcare organizations in relation to the products. Evaluation products may be provided on a no charge basis in return for the user feedback from Healthcare Professionals at the healthcare organization, which shall be formally described in a written protocol or questionnaire forming part of the contract.

Where the evaluation products are multiple-use products the defined period of time necessary for the evaluation and feedback to occur will depend on the frequency of anticipated use, the nature of the user evaluation feedback requested, the duration of any required training and similar considerations.

Member Companies shall in all cases ensure that they retain title to multiple-use Evaluation Products and that they have a process in place for promptly removing such multiple use evaluation products and/or any unused single-use products from the healthcare organization's location at the conclusion of the evaluation period, unless these are purchased by the Healthcare Organization.

Provision of evaluation products and/or related services must not improperly reward and/or encourage Healthcare Professionals and/or healthcare organizations to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services. Any offer and/or supply of such evaluation products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct.

Third Party-Initiated Research

Where permitted by national laws, regulations, national guidelines and professional codes of conduct, Member Companies may provide restricted research grants to support clearly defined third party-initiated research studies for clinical or non-clinical research programmes in therapeutic areas in which the Member Company is interested and/or involved.

Research grants may include in kind or financial support for legitimate, research-related, documented expenses or services, and/or reasonable quantities of single-use and/or multiple-use free of charge products for the limited duration of the research.

Member Companies providing research grants shall ensure that they do not influence the research. However, in order to ensure that research grants are provided on a "restricted" basis, Member Companies shall clarify the intended research scope and purposes for which the grant is requested and shall ensure that the written grant agreement with the recipient organization includes rights for the Member Company to verify that the grant is applied solely for the agreed intended research use. Such verification may include a request for study-related documentation, such as a copy of the research protocol, a copy of the ethics committee and/or regulatory approvals or a copy of the study report upon completion or earlier termination of the research.

All requests for research grants from prospective grant beneficiaries must be in writing and must detail, as a minimum, the type, nature and objectives of the research activity, the milestones and budget, the approximate duration of the research, and where applicable, the requirements for ethics committee, regulatory and/or other authorization's or approvals.

Research grant agreements shall include provisions relating to adverse event reporting where appropriate, and shall require full disclosure of the Member Companies and of the grant by the grant recipient organizations and the lead-investigator in all oral or written presentations of the results.

10. Samples and Demonstration Products (Demos)

Member Companies may provide their own products as demonstration products (demos) and/or samples at no charge in order to enable Healthcare Professionals and/or healthcare organizations to familiarise themselves with the safe, effective and appropriate use and functionality of the product and/or related services. Demonstration products and/or samples

may be either single- or multiple-use products. Member Companies may also provide products from another company in conjunction with the Member Company's own demonstration products and/or samples on an exceptional basis if those other company's products are required in order to properly and effectively demonstrate, evaluate or use the Member Company's products, e.g. computer hardware and software produced by a company other than the Member Company.

Demonstration Products (Demos)
Member Companies may provide examples of their products to Healthcare Professionals and/or healthcare organizations in the form of mock-ups (such as unsterilised single use products) that are used for Healthcare Professionals and patient awareness, education and training.

Demonstration products are not intended for clinical use in any patient care nor are they intended for on-sale or other transfer. Member Companies shall clearly record in the Member Company's records, as well as clearly disclose to Healthcare Professionals and/or healthcare organizations, the no-charge basis and other conditions applicable for the supply of demonstration products no later than at the time of supply. We recommend the disclosure to Healthcare Professionals and healthcare organizations to be in writing.

Samples
Member Companies may provide a reasonable number of samples at no charge to allow Healthcare Professionals and/or healthcare organizations to familiarise themselves with the products and/or related services, to acquire experience in dealing with them safely and effectively in clinical use and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

For samples, which are single-use products, the quantity provided for purposes of familiarisation must not exceed the amount reasonably necessary for the Healthcare Professionals/healthcare organization to acquire adequate experience in dealing with the products.

For samples that are multi-use products, the specific time required for a Health Professional to learn about the product will depend on the frequency of intended use, the duration of the required preparation, the number of Healthcare Professionals who will need to experience product handling and similar factors.

Member Companies shall in all cases ensure that they retain title to multiple-use samples and that they have a process in place for promptly removing such multiple use products from the Healthcare Professional's location at the conclusion of the familiarisation period.

Provision of demonstration products and/or related services must not improperly reward and/or encourage Healthcare Professionals and/or healthcare organizations to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services. Any offer and/or supply of such these products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct.

Member Companies shall in all cases maintain appropriate records in relation to the provision of demonstration products and/or samples to Healthcare Professionals and/or healthcare organizations, for example recording proof of delivery for any demonstration products or samples provided and receipt of return for multiple-use demonstration products or samples.

11. Transparency

Member Companies shall ensure transparency and shall duly document all activities and expenses associated with cooperation with healthcare organizations, in compliance with the applicable law, as well as in accordance with the Code of Ethics of SK+MED.

Member Companies shall publish information relating to grants provided to support third party organised educational conferences via the European platform (MedTech Transparency), and this in aggregate form (donor name, name of organization and total amount for the past calendar year) at the latest by the end of February of the following year.

12. Validity and Certification

The Code shall enter into force on the day it is approved by the General Meeting (ordinary, extraordinary) of SK+MED and all changes hereto must be approved by the General Meeting of SK+MED. This Code, which enters into force on 1 February 2018, shall be binding for all Member Companies.

Member Companies who shall declare the adoption of the Code in writing (by signature) shall be certified by SK+MED as the Ethical Members of SK+MED. The Certificate shall be issued for indefinite period.
The certified Member Companies shall be listed on the SK+MED's website, or possibly they shall be mentioned in other SK+MED's lists or documents. They may use the certificate for their own communication purposes.

13. Ethics Committee Statutes

Introduction

The Ethics Committee of SK+MED Association (hereinafter referred to as the "Ethics Committee") is a body whose key role is to enforce this Code's principles and to oversee their observance. The Code, its application and any eventual sanctions are accepted by Member Companies on a voluntary basis as a prerequisite of their membership in SK+MED.

The activity of the Ethics Committee is perceived as activity that facilitates resolution of complaints and clarification of disputes to prevent similar problems occurring in the future.

No action or decision adopted by the Ethics Committee shall limit any Member Company in acting independently. No verdict adopted by the Ethics Committee shall be of legal force or prevent any Member Company in using applicable legitimate legal means in connection with the activity complained of to the Ethics Committee.

Member Companies shall confirm in writing not to take any legal action against SK+MED or its individual Member Companies based on a decision adopted by the Ethics Committee in any matter.

Member Companies shall ensure that the principles of this Code are observed by their employees, agents or representatives. Should there arise any doubts regarding the compliance with the principles of this Code, it shall be possible to file a complaint with the Ethics Committee of the association, and this by any Member Company, individual person, or state or private entity.

Composition

The Ethics Committee consists of 5 members and is proposed and elected by the SK+MED Board for the period of 2 years. The first election shall take place at the occasion of hearing the first complaint. The execution of the office of an Ethics Committee member is non-substitutable. The Ethics Committee only meets to hear a specific complaint.

Composition of the Ethics Committee:

Permanent members:

- Lawyer

- Chairman or Vice-Chairman of the Board (unless the Board is a party to the complaint)
- Executive Director of SK+MED

Non-permanent members:

- 2 independent members (not parties to the complaint – i.e. claimant or defendant) proposed by the Executive Director

Organizational Arrangements
The procedural issues and organization of the meeting of the Ethics Committee are arranged by the Executive Director of SK+MED.

Method of Filing and Resolution of Complaints
Should, after the Code is adopted (following its approval by all members of the SK+MED at a regular or extraordinary General Meeting), any complaint be filed against any action of a Member Company, the Ethics Committee of SK+MED shall hear such complaint. Only a complaint filed in writing and containing the following particulars shall be heard:

a) name and registered office of the claimant, including company identification number (legal entities) and contact details (telephone, fax, e-mail)
b) identification and contact details of the defendant
c) specification of the subject matter of the complaint
d) specific reference to EC provision that has been allegedly violated
e) complaint must be filed to the address of SK+MED

Should a complaint be filed repeatedly against a certain Member Company and should the Ethics Committee recognise such complaints as justified three times in a row, its members shall propose to the General Meeting to exclude the concerned Member Company from SK+MED on grounds of repeated Code violation.

A concerned Member Company shall be entitled to appeal against the decision of the Ethics Committee at a General Meeting (ordinary, extraordinary – convened for this purpose) of SK+MED. The Member Companies present at the general meeting shall vote on the decision adopted by the Ethics Committee and either confirm or reject it by the simple majority of votes.

In the event of discrepancies in the interpretation of the Code, the Ethics Committee shall take full account of MedTech Europe's Code of Ethical Business Practice. Should it be impossible to resolve a given dispute at the level of SK+MED, or for a relevant reason (such as the international nature of the dispute), such dispute shall be referred to MedTech Europe's Compliance Panel for resolution.

Conflict of Interest
If a complaint is filed by a member of the Ethics Committee, or a Member Company s/he represents, such member of the Ethics Committee shall be excluded from hearing and deciding on the complaint. Similarly excluded shall be any member of the Ethics Committee against whom a complaint is filed, as well as when a complaint is filed against a Member Company s/he represents.

In the event of conflict of interest, the Ethics Committee may invite ad hoc some other member of the "Business Ethics and Code of Ethics" working group operating within SK+MED.

Voting
The Ethics Committee decides by qualified majority, while the lawyer does not have the right to vote and his/her participation serves solely to provide legal counsel and consultations for the committee members.

Confidential Information
The members of the Ethics Committee shall be required to maintain strict confidentiality of the negotiated cases. The Ethics Committee may ask members of SK+MED's working groups to

provide support in the event that more fields of expertise are required to resolve any specific complaints.

MedTech Europe Code of Ethical Business Practice and the Code of Ethics of SK+MED
The Ethics Committee shall follow the Code of Ethics of SK+MED. The Code of Ethical Business Practice of MedTech Europe (an international association based in Brussels representing national associations of suppliers and manufacturers of medical devices and technology from all over Europe, of which SK+MED is a regular member) has served as a template for drawing up this Code.