

# CODE OF ETHICS

## Medical Device Suppliers Association of Slovakia SK- MED

### 1. Purpose and main principles

Medical Device Suppliers Association of Slovakia SK-MED (the “SK-MED association”) is an association representing the interests of medical device suppliers within Slovak Republic. The members of SK-MED (the members) are confident that high-quality and cost-efficient medical devices represent significant contribution to the safety and good health status of patients and to improvement of the health care system.

The objective of the Code of Ethics (the CE) is to provide guidelines for morally sound and ethical behavior of members which will be applied to their respective business practices. At the same time the members are aware that one of the requirements in order to achieve this objective is the commitment to follow not only laws, guidelines and notices applicable exclusively to the area of medical devices but also generally applicable legal norms and requirements applicable to the entire resort of health care as well as other resorts. The Code of Ethics therefore does not replace and is not superior to the laws of Slovak Republic, instructions or other professional or other codes of business behavior (including intra-corporate codes) which may be applicable to the members.

The present Code of Ethics regulates the relations of individual members with the following entities:

- a) health care providers established by the state, region, city or municipality
- b) private health care providers
- c) state authorities
- d) physicians and health care staff
- e) patients – users of medical devices
- f) suppliers of goods and services

### 2. Scope of application

#### 2.1. Cooperation with medical staff

In order for the entities involved in distribution of medical devices to be able to successfully cooperate with medical staff, it is necessary to observe standards of ethics and valid laws. This cooperation may be in several forms: a) development of medical technology, b) organization of practical workshops, education, training services in order to enable safe and efficient use of medical technology, c) support of medical research, education and professional skill development. These activities are essential for progress of medical science and improved patient care.

To ensure ethical cooperation with individuals and institutions who purchase, lease, recommend or use products supplied by members, it is essential for all members to observe the Guideline on application of the principles of the Code of Ethics and on cooperation with medical staff (see attached SK-MED Code of Ethics)

#### 2.2. Advertisement and promotion

The members will ensure that all business presentations and product information are accurate, balanced, unbiased and unambiguous. The data should be supported by suitable evidence and should not mislead the target audience.

### **2.3. Unlawful payments and practices**

The members shall not directly or indirectly offer, provide or approve the use of funds or other articles of material nature in order to unlawfully : a) influence the judgment or actions of any individual, customer or company b) acquire or maintain business, c) influence any negotiations, decisions by government officials, d) obtain any advantage. This requirement applies not only to direct payments of such nature but also to indirect payments, made by any member through agents, consultants or third parties. The members should devote special attention to laws and notices prohibiting bribes to physicians or other persons who make decisions on the use of medical devices.

### **2.4. Conformance with the law**

The members should carry on business in accordance with the requirements of the valid laws, applicable to competition and public procuring. Among the prohibited activities are: a) arrangements with competitors on prices, division of customers or regions, or limitations of business, b) exchange of pricing information, or other confidential information with competitors, c) price discrimination or rejection of sale.

### **2.5. Export control and sanctions**

The members must provide for observation of laws on export and import control and other regulations limiting business transactions with some countries.

### **2.6. Environmental issues**

The members are required to transact business in all valid environmental laws and regulations including waste management.

### **2.7. Confidentiality of information**

The members must provide for all data on patients and other confidential and personal information to kept and used in accordance with valid legislation.

## **3. Observation and enforcement of the Code of Ethics**

The members must provide for observations of the principles of the present Code of Ethics by their employees, agents or representatives. In case of doubt in relation to observation of the present Code of Ethics, a complaint may be filed with SK-MED Ethics Committee, either by member, individual or any government or private entity. Activities of the Ethics Committee, composition of the committee and method of submission and resolution of complaints are governed by the Guideline on application of the principles of the Code of Ethics and on cooperation with medical staff (attached Code of Ethics of SK-MED association).

### **3.1. Validity of the Code of Ethics**

The CE enters into validity upon its approval by the General Assembly Meeting (regular, extraordinary) of SK-MED association and any changes are subject to approval by the General Assembly of SK-MED.

**GUIDELINE**  
**ON APPLICATION OF THE PRINCIPLES OF THE CODE OF ETHICS**  
**AND ON COOPERATION WITH MEDICAL STAFF**  
(Attachment to SK-MED Code of Ethics)

**I. Introduction**

The purpose of the present guideline is to provide recommendations related to the cooperation of the member of SK-MED association with institutions or individuals who purchase, lease, recommend, use, provide for procurement or lease or prescribe medical devices supplied by members of SK-MED association (the medical staff).

There are several forms of cooperation among the members of SK-MED association (the Members), which increases the level of medical science and improves patient care, including:

- **Support of therapeutic technology.** Development of new medical accessories and improvement of the existing products is often a result of cooperation between the Members and medical staff. Innovation and creativity are essential components in the development of medical devices and accessories and often occur outside of headquarters of manufacturers of these medical devices.
- **Safe and efficient use of medical technology.** Safe and efficient use of medical technology often requires that members provide medical staff with suitable instructions, training, practical training, services and technical support. Regulators may even request re-training of medical staff as one of the pre-conditions for official approval of a product.
- **Research and education.** Support of medical research, education and broadening of professional knowledge of association members contribute also to safety of patients and improve patient access to new technology.

The members are aware that in order for the field involved in medical technology/devices to be capable to continue cooperation with medical staff, it is essential to observe valid laws and standards of ethics. The members must also respect the duty of medical staff to decide on therapy independently and must act and behave in their relations with them in accordance with standards of ethics and with awareness of public responsibility.

**II. Member supported training and education**

If convenient, the members should provide "product training" as well as "hands-on" training to medical staff, to enable safe and efficient use, recommendation or prescription of individual medical devices. These educational and training programs (the Programs) should respect the following rules:

\* The programs should be organized in clinical, laboratory, educational, conference or other suitable settings/premises – including member's premises or commercially rented conference rooms – which enable efficient transfer of knowledge and skills, including product presentation. The training staff should have adequate level of qualification and experience in organization of similar training sessions..

\* The members may offer to participants of such training sessions a reasonable scope of refreshments in case of programs requiring more than one day in duration this provision may include

further food and beverages. However the cost of such catering should not be overestimated, exceeding the scope and purpose of the program.

\* The members may compensate the program participants for any travel costs, or accommodation in reasonable amount, and in accordance with valid legal regulations.

\* Nevertheless, the members should not refund any travel expenses or costs to partners or guests of the medical staff or to any other personnel without direct professional interest in information presented in the course of the program.

### **III. Support of third-party educational congress activities**

Independent, educational or professional congress activities support development of professional knowledge, progress in medicine and provision of efficient health care. These include congresses organized by national, regional or specialized medical associations or accredited providers of graduate education. The members may support such congress activities in the following ways:

- **Congress support.** Members may offer financial grants or refund congress fees, reasonable travel expenses, accommodation expenses to medical staff (and medical students, teachers and other staff – medical staff with unfinished education), provided that the congress is primarily focused on the support of the related professional and educational activities. Such support must be in conformance with Slovak legal regulations and clearly specified before the congress.
- **Reasonable refreshments.** The members may offer financial support to congress organizers in form of refreshments for program participants. Any refreshments should be of reasonable value and corresponding with the educational purpose of the congress.
- **Lecturer's expenses.** The members may offer financial contribution for reasonable lecturer's fees, travel expenses and room and board for medical staff with active participation on the congress (lecturers, presenters)
- **Advertisement and promotion activities.** The members may purchase advertisement space or time for commercial promotion activities within such congress venues.

### **IV. Sale and promotion meetings**

If the members meet with medical staff in a discussion on the properties of medical devices, in contractual negotiations and sales promotion activities, these meetings should generally be organized close to the workplace of the medical staff. For the purposes of such meetings the members may provide the medical staff with reasonable refreshments and accommodations. If appropriate the members may also refund travel expenses (such as field trips in manufacturing process or presentation of immobile equipment etc.). It is considered inappropriate to refund meals, travel expenses and refreshments to the guests of medical staff or to other personnel without direct professional involvement and interest in information presented during such meeting.

### **V. Contracts with consultants**

Medical staff may become consultants for the members in the field of research, personal consulting, for the purpose of presentations at the meetings sponsored by the members and cooperate on development of medical devices. Reasonable fees can be paid to medical staff for such services.

- Consultancy contract with medical staff must specifically and accurately specify which services are to be provided and must conform to valid legal regulations.

- Consultancy contract should be signed only with pre-determined legitimate purpose of the services.
- Consultants should be selected based on their qualification and experience which enables fulfillment of the defined purpose of the contract by the selected consultant.
- Place and circumstances of meetings between members and consultants should correspond to the topic of consultations. Any refreshments sponsored by the members in relation to such consultation meetings should be of reasonable value and should be adequate to the primary purpose of the meeting.
- Financial compensations (fees) for the consultation services provided by the medicals staff should be based on the nature of the service and adequate to the extent of such service. Such compensation may not be linked to sales of medical accessories where the consultant is in position to influence the quantities sold/purchased. The compensation must be adequate to the extent of actually provided services and must conform to valid tax and other legal regulations. Members may provide adequate compensation of expenses related to provision of consultation services.
- If the member enters into contract with medical staff with respect to research consulting services, a written protocol must be completed and all required approvals and permits must be provided.

## **VI. Gifts**

From time to time the members may offer to medical staff small gifts of modest value and in accordance with valid legal regulations of Slovak Republic. Generally the gifts should bring benefit to patient care, improve working condition of medical staff or be exclusively of educational nature.

In addition the members may from time to time offer to the medical staff promotional articles related to the type of work performed by the medical staff or those which bring benefit to the patient. Members may not offer financial gifts to medical staff.

This provision does not apply to practices in providing samples and opportunities for testing of medical devices by medical staff.

## **VII. Charity and humanitarian gifts**

The members may provide gifts (including grants) for charity or other humanitarian purposes, such as support of non-commercial research to promote the progress of medical science and education, sponsoring of activities, earnings from which are to be used for charity. All gifts must be duly documented. Examples of suitable gifts with corresponding explanation.

- Support of medical education. The members may establish grant programs to support exclusively medical education of medical students and their teachers, participating on professional programs which are of charitable nature or which are related to academic activities or to other medical staff – subject to initial provisions of article VII. (for further details on educational grants – see article III. Support of third party educational congress activities.)

- Support of scientific research. The members may establish grant programs for support of non-commercial research. The purpose of such grant must be clearly documented (Instructions related to limitations applicable to signing of contracts between members and medical staff in relation to research in the name of the member – see article V. Contracts with consultants).

- Public education. The members may establish grant programs to support patient or public education on important health topics.

## VIII. Ethics committee

1. If a complaint is filed following the approval by Ethics Committee (upon approval by all members of SK-MED association at regular, extraordinary General Assembly Meeting) with respect to actions by any of the members, such complaint will be discussed by SK-MED Ethics Committee. Only written complaints meeting the following requirements for contents will be discussed:
  - a) name and registered office of the claimant, including ID No. (in case of legal entities) and contact information (telephone, fax, e-mail)
  - b) defenders identification and contact information
  - c) specification of the subject matter of the complaint
  - d) specific reference to the provision within the Code of Ethics, which was supposedly violated
  - e) the complaint must be filed to the address of SK-MED association
2. The Ethics Committee consist of 5 members, proposed and elected by SK-MED chairmanship for a period of 2 years. First election is held at the time of filing of first complaint. The Ethics Committee meets only for the purposes of deliberation on specific complaints. Composition of the Ethics Committee:
  - 2.1. Permanent members:
    - a) lawyers
    - b) chairman or vice-chairman of the chairmanship(if not involved in the complaint)
    - c) executive director of SK-MED
  - 2.2. Transient members:
    - d) 2 independent members (not involved parties – claimant, defendant) proposed by the executive director
3. Before starting the complaint process the claimant shall be required to post a bond deposit of SKK 10,000 (ten thousand Slovak crowns ) by wire transfer to the account of the SK-MED. If the Ethics Committee admits the complaint as justified the bond deposit shall be returned at the end of the proceeding, failing which the bond will be forfeited in favor of SK-MED association.
4. Procedural issues and organization of the proceedings/deliberations of the Ethics Committee will be provided for by the executive director of SK-MED.
5. The Ethics Committee decides by qualified majority, whereas the lawyer has no voting rights and the purpose of his/her presence is only for legal counseling and consultations for the committee members.
6. Upon discovery of violation of the Code of Ethics the Ethics Committee is authorized to fine members up to SKK 500,000,- (five hundred thousand Slovak crowns). The amount of fine is determined by the annual turnover and size of the member (involved) in the market. The Ethics Committee shall also decide on the method of fine collection (payment).
7. If repeated complaints are filed in relation to a single member and the Ethics Committee accepts such claims as justified three times in a row, the members of the Ethics Committee shall propose to the General Assembly the expulsion of such member from SK-MED association due to repetitive violation of the Code of Ethics.
8. The involved party may appeal against decisions taken by the Ethics Committee with the General Assembly Meeting (regular, extraordinary – organized for this purposes) of SK-MED association. Attending members -through majority of their vote - can confirm or reject the resolution of the Ethics Committee.