



INTERNATIONAL MEDICAL DEVICE MANUFACTURERS ASSOCIATION

**Ethical Code for medical device  
manufacturers International Medical  
Device Manufacturers Association  
IMEDA**

**Russia, Moscow 2008**

## Contents

1. The aim and the principal idea of the Code. _____	3
2. Interactions between Members of Association and healthcare professionals. _____	4
2.1 Training and educational programs on medical devices for healthcare professionals of different descriptions organized by Association Members. _____	4
2.2 Sponsoring, organizing and holding of scientific and practical events (conferences, congresses, symposia etc.) initiated by the third parties. _____	5
2.3 Provision of educational grants to medical institutions. _____	6
2.4 Business meetings and activities with the commercial partners _	7
2.5 Involvement of healthcare professionals in the provision of an expert opinion and consultations to Association members. _____	7
2.6 Donations. _____	8
2.7 Gifts. _____	9
3. Enforcement procedures for violations of the code by Association Members _____	9
4. Conclusion. _____	9
5. The list of companies that approved current Ethical Code. _____	9
6. Glossary. _____	10

## 1. The aim and the principal idea of the Code.

The current Ethical Code is accepted on a voluntary basis and presents the essential standards and requirements, which should be followed by the Members of the International Medical Device Manufacturers Association (IMEDA) when performing their activities on the territory of the Russian Federation. The Code was developed on the basis of international ethical codes. The mission of the International Medical Device Manufacturers Association consists in introducing new medical technologies aimed at increasing the efficiency of the Russian Healthcare system and providing the population of Russia with access to the modern, high-quality medical devices and equipment.

The main priorities and activities of the Association are to support the development and maintenance of a favorable legal and economic climate in the area of healthcare services; to strengthen the position of the medical devices manufacturers in the development and regulation of this sector, and the creation and introduction of civilized standards in conducting business activities among the Association Members and in the whole medical device market on the territory of Russian Federation.

In accordance with the declared mission, the Members of the Association accept that adherence to the ethical standards and local legislation in the sphere of interaction with the healthcare professionals and other parties involved is an integral requirement for the creation of equal conditions for all participants engaged in the provision of medical devices

The Members of the Association have voluntarily approved this Ethical Code and confirm their readiness to follow the principles of ethical and civilized business practices and collaborate with the representatives of government, business and society as a whole. This Ethical Code will be effective as of January 1, 2008.

This current Ethical Code must not and cannot replace the existing legislation of the Russian Federation. The laws and regulations of the Russian Federation will always have precedence while this Code constitutes supplementary principles for IMEDA Members to follow.

All companies that confirmed their readiness to follow the principles of the given Ethical Code undertake the responsibility to perform their

activities and interact with other parties of the industry in accordance with the principles stated in the Code.

In accordance with the mission of the Association to increase the access to high quality medical care the Association recognizes the existence of various ethical interactions between Association Members and medical professionals. The modernization of medical technologies and higher quality of medical devices are the joint responsibility of the Association Members and healthcare professionals.

## **2. Interactions between Members of Association and healthcare professionals.**

### **2.1 Training and educational programs on medical devices for healthcare professionals of different descriptions organized by Association Members.**

To ensure safe and effective application of medical devices the Association Members may conduct special training and education programs on various trends in medicine and healthcare for a wide range of healthcare professionals.

Training and educational sessions can be organized at large scientific sites as well as at regional and local patient care institutions.

In case of necessity the educational programs for specialists are allowed to be conducted at a “working place” - in a real clinical or laboratory environment in hospitals, laboratories, institutes and other places if it does not contradict with the existing regulations. The educators should be appropriately trained and qualified for conducting such programs.

In cases where educational programs require a license, permission, and/or other approvals under the existing regulation, the Association Members can only conduct such educational programs after having received the required license, permission or approval.

Educational programs may take place in various regions of Russia as well as abroad and in this case the expenses for accommodation, food and transportation of participants may be paid for by Members of the Association.

The reimbursement of costs listed above should meet the aims and tasks of the educational and training programs organized.

The Association Members should not pay expenses for accommodation, food, transportation or any other expenses of family members or guests of the program participants or any other person who does not have a *bona fide* professional interest in the information being presented at the events.

The participation of medical professionals in educational programs and payment of any expenses related to such participation is allowed if it is not prohibited by existing regulations.

## **2.2 Sponsoring, organizing and holding of scientific and practical events (conferences, congresses, symposia etc.) initiated by the third parties.**

Scientific, educational and practical events (conferences, congresses, symposia etc.) represent a necessary instrument for the development and promotion of scientific knowledge and medical technologies with the purpose of raising the effectiveness of and access to the medical services. The primary goal of such events should be the advancement of scientific knowledge. Entertainment and other forms of hospitality should be subordinate with such goals.

Association Members can carry out methodical or financial support of such events organized by the third parties as follows:

### **Sponsorship of scientific and practical events implemented by the third parties**

If the Association Member provides financial support to a scientific and practical activity related to medicine/healthcare or educational programs the terms of sponsorship by the Association Member should be expressed by signing an agreement beforehand.

Any of the informational material (brochures, advertising pamphlets or computer data) obtained from the meetings should precisely reflect the topics investigated, contents of speeches and their discussion. Association Members may acquire from the event organizers an advertising package for their advertising materials being presented or rent areas for the displays/expositions in the form allowed by the existing regulations.

### **Payment of expenses for healthcare professionals participating in educational and practical events**

The Association Members may provide the financial support to healthcare professionals for conducting educational programs and lecturing. All expenses imposed for the participation of medical professionals in such programs (transportation, accommodation and food expenses) may be payable by Association Members. Companies should not pay any costs for people accompanying the participating medical professionals.

Any kind of support to a practicing healthcare professional to participate in such an activity should not imply any obligations for promoting the medical devices of the company.

If the Association Member is the organizer of the activity, it should also sign an agreement with the lecturer describing obligations of the parties involved.

Any kind of support to the healthcare professionals to participate at educational and practical events organized by the third parties and Association Members, including payment of their expenses related to the participation, may be provided in accordance with the principles of the current Code and the existing regulation of the Russian Federation.

### **2.3 Provision of educational grants to medical institutions.**

The Association Members, if this is not prohibited by existing regulations, may provide educational medical institutions (non-profit

organizations) with grants or sponsor the education of individual medical professionals in the area of healthcare.

The provision of grants is formally registered by signing an agreement between the non-profit organization and Association Member describing the donations made. The agreement also reflects the exact aims and purposes for the grant application. Depending on the requirements of the Association Member the agreement may also indicate that the donation recipient should provide detailed reports on the use of donations in accordance with the aims stated.

The provision of a grant cannot oblige a non-profit organization or its staff members to promote the medical devices of the sponsor.

## **2.4 Business meetings and activities with the commercial partners**

Association Members may conduct meetings with their partners and medical professionals to discuss the advancement of medical technologies and the matters of selling of medical devices. The Association Members may sponsor these meetings in the form of paying for food expenses and reception within the limits of the current Code and existing regulations. The Association Members may pay transportation costs of their partners on condition that visits of specialists are caused by the necessity of installing some equipment, or its adjustment etc. Association Members should not pay any expenses for food, receptions, transportation and accommodation for the guests of their partners or other persons bearing no professional relation to the information provided at such meetings.

## **2.5 Involvement of healthcare professionals in the provision of an expert opinion and consultations to Association members.**

Medical institutes and healthcare professionals may work as experts providing the Association Members with necessary consulting services including research, scientific work, participation at expert council and committees, presentations at conferences, training, sponsored by the Association Members, performing clinical trials and other joint scientific projects. In such cases the Association Members should pay for the services of this kind according to a signed agreement.

Consultation services of the medical institutions and professionals provided to Association Members should be performed in accordance with the following principles:

- The consulting services should be stated in a signed agreement. The agreement should clearly define the kind of services to be provided and the rights and obligations of both parties;
- The consulting services should be in conformity with the existing regulations;
- All payments for services provided should be confirmed and be in line with the agreement signed, and reflect the market price;
- The meetings of the Association Members with the persons providing these services should be conducted at clinics, hospitals, institutes, at conferences and other places including hotels and other commercial facilities appropriate for the business meetings;
- The Association Members may agree in the contract to reimburse documented expenses incurred in fulfilling the requested consulting services.

## **2.6 Donations.**

Association Members may provide donations for carrying out independent medical research, for the development of medical technologies, doctor and patient education, and increasing the quality of medical care.

The donations should only be given to the medical, educational, social and other non-profit organizations and philanthropic funds in the form that does not contradict with existing regulations. In rare cases donations might be given to individuals, having their principal task in the development and maintenance of a health protection system.

The Association Members are not allowed to make any donations aimed at paying for the use of or acquiring in the past or rewarding for the future purchase of donator's goods, or for the reason of having a donation receiver recommending utilizing the goods of the donator to the patients.



All the donations should be strictly documented in accordance with the existing regulations.

## **2.7 Gifts.**

The Association Members can make small gifts to healthcare professionals in the form that is in accordance with the existing regulation of the Russian Federation. <sup>[1]</sup>; the presents having an educational and/or scientific value or related to their every-day practice and/or to the improved quality of patient treatment. The value of the present should not exceed 4000 roubles per year.

## **3. Enforcement procedures for violations of the code by Association Members**

In case of violations or deviations from the regulations of the Code, companies that have confirmed their readiness to follow the principles of this Code are invited to a meeting of the Ethical Committee of the Association to evaluate if the code was violated by activities of the member. If so, the unethical conduct of company will be announced in press and on the IMEDA official web-site; and depending upon the severity of the violation the question of continued membership in the Association can be considered.

## **4. Conclusion.**

Association Members should follow the practice of conducting business in an ethical way and check for the implementation of the principles of the code by fellow Association Members and promote these principles to all other parties in the field of healthcare.

## **5. The list of companies that approved current Ethical Code.**

- 1. Abbott Laboratories**
- 2. Alcon**

3. **Baxter**
4. **Beckman Coulter**
5. **BD**
6. **Bio-rad Laboratories**
7. **Biotronik**
8. **Fresenius**
9. **Gambro AB**
10. **General Electric**
11. **Johnson & Johnson**
12. **Medtronic**
13. **Olympus**
14. **Philips**
15. **Roche**
16. **SCA Health**
17. **Smith & Nephew**
18. **Stryker**
19. **Unomedical**
20. **Ursapharm**
21. **Zimmer**

## **6. Glossary.**

**Medical devices** – any instrument, apparatus, appliance, device, material or any other substances, objects or pieces of equipment used separately or in combination, including the necessary software, for the purposes defined by its manufacturer and used in treatment for a human being for:

- diagnostics, prophylaxis, monitoring, treatment of a disease or alleviation of its symptoms;
- diagnostics, monitoring, treatment, relief or improvement of an injury or disability;
- research, replacement or modification of parts of anatomy or physiological process;
- with the principal condition that the main influence is not based on pharmacological immunological, nor metabolic activity, but can contribute to the organism or delivery to the body.

**Healthcare professional**– a person who has a medical education (i. e. a member of patient care institution staff, a clinician with his/her own private practice, paramedical personnel, a student of a medical educational institution, etc.), bearing a professional relation to the healthcare system.

**Grant** – voluntary material support provided to organizations or individuals in money or other equivalents for the purpose of conducting scientific research, education or training, with a follow-up report on how the support was used

**Donations** – voluntary material support provided with “no strings” attached – disinterested

**Scientific and practical activities (conference, congress, symposium etc.)** – a meeting or conference of the representatives of healthcare organizations or medical professionals, scientists for discussing various healthcare related issues.

**Training** – obtaining new knowledge and skills necessary for effective professional medical activities based on intensive methods of education combining theoretical lectures and/or practical activities.

**Gifts** – property or any other material benefit provided voluntary with the agreement of the receiver.