

International Medical Device Manufacturers Association

Code of Ethical Conduct

for Interactions with Healthcare Professionals

This Code of Ethical Conduct (“Code”) is effective as of September 1, 2013 and fully replaces the previous version of the IMEDA Code approved in 2008. Company certifications should be submitted no later than the first of January of each year, beginning in 2013 (for 2013 no later than 1st of January 2014). IMEDA (International Medical Device Manufacturers Association) will publish the certification form that Companies should use on its website at www.imeda.ru. Each certified member company may use the IMEDA Ethical Certification Logo in its materials to show compliance to the highest ethical industry standards.

1. Purpose of Code & General Provisions

IMEDA recognizes that ethical interactions between the medical device and diagnostics industry and healthcare professionals advance medical technologies¹ and ensure public confidence in the Medical Device and Diagnostics industry. The purpose of this Code is to facilitate ethical interactions between companies that develop, manufacture, sell, market or distribute Medical Technologies in the Russian Federation (“Companies”) and Healthcare Professionals².

Interactions with Health Care Professionals. Ethical interactions between Companies and Healthcare Professionals enhance patient access to the safe and effective use of Medical Technologies by ensuring appropriate training of Healthcare Professionals by Companies. Ethical interactions also promote innovation and the ongoing development of advanced Medical Technologies through legitimate and transparent collaboration between Healthcare Professionals and Companies. Further, ethical interactions facilitate open and transparent business environments free from the high costs of corruption, enhancing the ability of Companies to participate in global markets.

Ethical interactions ensure that medical decision-making is made in the best interest of the patient. To ensure that relationships meet this standard, interactions between Companies and Healthcare Professionals should be conducted in accordance with the following principles:

Integrity, Independence, Appropriateness, Transparency and Advancement:

¹ The term “Medical Technologies” means products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities.

² The term “Healthcare Professionals” includes those individuals and entities that purchase, lease, recommend, use or arrange for the purchase or lease of, or prescribe Companies’ medical technology products. This includes both clinical and non-clinical individuals who make product-related decisions of the type described above. This is a broad definition, intended to encompass anyone with material influence over purchasing decisions. For avoidance on doubt this definition includes medical and pharmaceutical professionals as defined in the legislation of the Russian Federation. Note that there may be laws and other codes applicable to relationships with Healthcare Professionals, including relationships with government employees.

Integrity means dealing honestly, truthfully, and fairly with all parties.

Independence means that Healthcare Professionals' interactions with Companies should not skew the Healthcare Professional's medical decision making from the best interests of the patients.

Appropriateness means that arrangements conform to proper commercial standards, and are accurate and free from corrupt purposes.

Transparency means that Companies and Healthcare Professionals are open regarding financial relationships between the parties.

Advancement means that relationships are intended to advance medical technology, innovation and patient care.

The safe and effective use of Medical Technologies, and the continuing advancement of Medical Technologies, require collaborative interactions between Companies and Healthcare Professionals. However, when interactions are not conducted in accordance with appropriate ethical standards and applicable legislation, they pose a risk of inappropriately influencing the decision-making of Healthcare Professionals. Even appropriate interactions may undermine the public's confidence if they appear to be intended as an inappropriate inducement³. Collaborative interactions between Companies and Healthcare Professionals should preserve independent decision-making by Healthcare Professionals and public confidence in the integrity of patient care, treatment and product selection. Companies and Healthcare Professionals should avoid interactions that could improperly influence a Healthcare Professional's purchasing or medical decision-making or appear to do so.

The above guidelines and principles apply to all interactions between Companies and Healthcare Professionals. They supplement, and are subject to, the laws of each country, province or region in which a Company conducts business and Companies are responsible for knowing and complying with those laws. The additional principles set forth below are intended to supplement, not to limit, the general provisions above.

2. Contractual Arrangements

Companies may engage Healthcare Professionals to provide services that support research and development to advance medical science, develop new technologies, improve existing products and

³ Inappropriate inducement means a remunerative arrangement intended to inappropriately influence an HCP's medical decision and product selection.

services, or enhance the quality and efficacy of patient care and constitute scientific or pedagogic activity for Healthcare Professionals. Companies may not engage Healthcare Professionals as a means of inappropriate inducement.

Companies should engage only the number of Healthcare Professionals reasonably needed to perform services for which a preexisting need has been identified by the Company. Services should be engaged pursuant to written agreements between the Company and Healthcare Professionals describing the services to be performed and the compensation to be provided. Contractual arrangements with Healthcare Professionals should include guarantees and assurances of Healthcare Professional that provided to the Company services are not in direct or indirect conflict of interest between his employment / job duties at the main place of work and such services provided by a Healthcare Professional to the Company, as well as provisions on responsibilities of Healthcare Professional to disclose the information about arrangements with the Company to the Healthcare Professional's institution or his another employer in the manner prescribed by the rules of his institution and / or by applicable law. If applicable laws, regulations or institutional rules specifically require disclosure to a different body, in this case disclosure should be made in accordance with the applicable laws, regulations or rules.

Payments for services should be at fair market value, and payments in advance of services rendered should be avoided whenever possible. Fees should not be based on or influenced by the volume of or value of the service provider's business. Payments should be appropriately documented.

Companies may pay for or reimburse the reasonable, documented actual expenses incurred by Healthcare Professionals in connection with the provision of services that meet the standards set forth above, which may include expenses for travel, meals and accommodation. However, excessive travel arrangements (e.g., side trips) or reimbursements are prohibited. Companies should provide or reimburse only appropriate travel and accommodations, which should not include luxury/resort hotels, lavish meals or extravagant travel arrangements. Companies should not provide entertainment and recreation to Healthcare Professionals as it constitutes an inappropriate inducement. Companies should not pay any expenses of spouses or other guests, who are not Healthcare Professionals, accompanying Healthcare Professional service providers.

3. Third Party Educational Programs

Bona fide independent, educational, scientific or policy-making conferences promote scientific knowledge, medical advancement and assist in the delivery of effective health care. Companies may support such conferences, provided that the support is consistent with relevant guidelines established by the conference organizer and any accrediting body. Company support of third-party educational conferences should preserve the independence of medical education and should not be used as a means of inappropriate inducement.

Grants to Conference Organizers. Companies may make grants to conference organizers to support the reasonable costs of third-party educational conferences. Such grants should be made only following a written request from the conference organizer including sufficient information to allow the Company to evaluate the scientific and educational merit of the conference as well as the appropriateness of the venue and agenda. Funds may be granted for *bona fide* educational expenses (including reasonable faculty expenses), but care should be taken to avoid grants that organizers may use to inappropriately benefit individual Healthcare Professionals, such as providing for side trips, recreation, entertainment or lavish meals or accommodation. All grant arrangements should be appropriately documented. Grants should be consistent with the applicable standards established by the conference organizer and any entity accrediting the educational activity. The conference organizer should independently control and be responsible for the section of program content, faculty, educational methods and materials. Companies cannot directly or through third parties provide any contrary to current legislation support to specific Healthcare Professionals for participation in such conferences, as well as cannot cover their travel, accommodation and other expenses.

Conference Meals and Refreshments. Where consistent with the conference organizer's guidelines, companies may sponsor or organize appropriate meals and hospitality in connection with conferences, provided that such meals are offered to all conference attendees, are subordinate in time and focus to the scientific or educational purpose of the conference, the cost of the meals is reasonable, and provision of the meals matches applicable law and common business practice. Companies may not provide or arrange for entertainment or recreation in connection with such meals and may not invite or permit attendance by spouses or other guests of Healthcare Professionals who are not *bona fide* conference attendees.

Advertisements and Demonstrations; Satellite Symposia. Companies may purchase advertisements and lease booth space for Company displays at conferences. Companies may also sponsor satellite symposia at conferences and provide content and faculty for these symposia, provided that the arrangements are disclosed in writing in all materials relating to the satellite event.

4. Company-Organized Education and Training

Companies may provide training of Healthcare Professionals on product specific device deployment, use and application to facilitate the safe and effective use of medical technologies by Healthcare Professionals, including training on topics concerning or associated with the use of their Medical Technologies. Training and Education programs include "hands-on" training sessions, cadaver workshops, lectures and presentations. Training and Education should be conducted by qualified personnel, which may include sales personnel with appropriate technical expertise.

Training and Education programs should be conducted in venues that are conducive to the transmission of learning and are selected based on their suitability for the proposed program and their convenience for attending trainees. Appropriate venues may include the Healthcare institutions premises, the Company's premises, or other clinical, laboratory, educational or conference facilities

(including hotel conference rooms) depending on the nature of the program. Training and education programs should not be conducted in resort locations or facilities.

Companies cannot provide contrary to current legislation financial support to individual Healthcare Professionals for participation in such Training and Education programs, including cover their travel, accommodation and other expenses. When it is impractical or inefficient to provide training at or close to a Healthcare Professional's place of business, Companies may contract with medical institutions to provide necessary training to its unidentified personnel, in which case all payments related to reimbursement of reasonable costs with respect medical institutions personnel's participation in such trainings are to be done to the medical institution only.

Companies may provide reasonably-priced meals in connection with training and education programs provided that provision of the meals is justified by the length of the program and matches applicable law and common business practice. Companies should not provide recreation, entertainment or lavish meals or accommodation, and should not pay or arrange for meals, accommodation or travel of spouses or other guests of participating Healthcare Professionals.

5. Sales and Promotional Meetings

It may be appropriate for Company representatives to meet from time to time with Healthcare Professionals to discuss product features and provide other information that raises the professional level of the Healthcare Professional. Such meetings should generally occur, if permitted by the internal regulations of the medical institution, at or near the Healthcare Professional's place of business, although occasionally such discussions may take place at another mutually convenient location. Such Meetings can take place in compliance with Russian legislation.

6. Educational Items

Companies may occasionally provide printed promotional materials to Healthcare Professionals that serve a genuine educational function for Healthcare Professionals. Companies should not provide items that are capable of use by Healthcare Professionals (or their family members, office staff or friends) for non-educational or non-patient related items.

7. No Gifts or Entertainment

Companies should not provide Healthcare Professionals with gifts of cash. Companies should not provide Healthcare Professionals with any other gifts, like food, wine or spirits, gift baskets, gift cards/certificates, or flowers, unless otherwise provided by Russian law. In the same manner Companies

may not provide Healthcare Professionals any type of non-educational promotional items, even if the item is of minimal value and related to the Healthcare Professional's work or for the benefit of patients.

Companies should not provide, organize or pay for any recreational or entertainment activities for Healthcare Professionals, including (without limitation) sporting events, cultural or artistic activities, or leisure activities.

It is inappropriate to provide gifts or entertainment in the context of any type of interactions with Healthcare Professionals, including in connection with sales and promotional meetings, consulting services, third-party educational conferences or product training and education.

8. Charitable Donations and Research and Education Grants

Companies may provide support to non-commercial organizations engaged in disaster relief, indigent care, public education, patient education, and other generally beneficial or charitable missions. Companies may also advance Medical Technology by supporting education of Healthcare Professionals and the public in compliance with this Code and Russian law, and by supporting scientific and medical research. Prior to making grants or donations, Companies should adopt objective grant making criteria that do not take into account the volume or value of purchase made by, or anticipated from, the grant recipient or affiliated Healthcare Professionals, and should evaluate grant requests against those objective criteria. Companies' sales personnel may provide input to help evaluate the suitability of a proposed program or recipient, but should not control or unduly influence grant making decisions. Companies should consider implementing procedures to ensure an objective grant making process.

Charitable Donations. Companies may make monetary and in-kind donations for generally beneficial purposes to support *bona fide* charitable organizations and missions, provided that the donation is not intended as an inappropriate inducement and does not privately benefit a Healthcare Professional. Donations should be made only in response to written requests and should be evaluated against objective criteria adopted by the Company. Donations should be made only to nonprofit healthcare institutions and nonprofit organizations and should not be paid or provided to individual Healthcare Professionals. Donations should be documented appropriately and care should be taken to ensure that local laws and transparency requirements are respected.

Educational Grants. Companies may provide grants to nonprofit organizations for legitimate generally beneficial educational and research purposes. These include grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs that are charitable or have an academic affiliation, and grants to support the education of patients and the public about important healthcare topics. This also includes grants to support independent medical research with scientific merit for the purpose of advancing scientific and clinical information, improving clinical care, promoting improved delivery of

healthcare, or to otherwise benefit patients. Any such research should have well-defined objectives and milestones and may not be linked directly or indirectly to the purchase of Medical Technologies. Companies may also make educational grants to organizers of third-party educational conferences (described in Section 3 of this Code). Educational and research grants should not be paid to individual Healthcare Professionals or provided for the use by a specific Healthcare Professional and care should be taken to avoid making grants that may provide an inappropriate benefit to individual Healthcare Professionals.

9. Demonstration and Evaluation Products

Companies can provide Medical Technologies to nonprofit medical institutions free of charge for demonstration and evaluation purposes, solely for the purposes of improving patient care in Russia. Companies may only provide reasonable quantities of Medical Technology products and equipment to nonprofit medical institutions at no charge for evaluation and demonstration purposes, provided that such products are not given or intended as an inappropriate inducement.

The use of demonstration and evaluation products has to comply with Russian legislation requirements.

10. Disease Awareness

Companies may occasionally provide disease awareness and other general recommendations materials to Healthcare Professions that can benefit patient and be used to educate patients about their disease, life style changes and requirements as well as contain other specific information without promotional or advertising messages about brands, devices and company specific technologies.

11. Ensuring Effective Code Implementation

In order to ensure effective implementation of Code principles, each IMEDA Member Company should take the following particular steps.

- appoint a senior executive responsible for oversight of the Company's compliance with this Code;
- adopt practical, useful, and meaningful policies, guidance and tools intended to ensure compliance with this Code;
- provide effective and ongoing training and education on the Code and on company policies implemented to ensure Code compliance;
- ensure that senior management and the company's board of directors or other governing body have expressly committed to support the Code;

- institute appropriate internal monitoring and auditing mechanisms;
- create safe mechanisms for, and encourage employees who raise concerns;
- require that third party intermediaries (including consultants, distributors, sales agents, and brokers) that may interact with Healthcare Professionals in connection with Company Medical Technologies agree to comply with this Code; and
- provide a certification to IMEDA that the Company has signed onto the IMEDA Code of Ethical Conduct, so those Member Companies can be publicized.

IMEDA commits to ensure that Companies representatives which are nominated responsible for the proper implementation of the Code are trained and updated on the training and other IMEDA activities in promoting this Code to the members, members' partners and other industry stakeholders. Support and enforcement activities shall be discussed and proposed for approval to the Board of Directors by the IMEDA Compliance committee on an annual basis.

Signed by the Chairman of IMEDA Board of Directors

Name Armen Voskanyan

Signature 

Date 01.09. 2013