

**Sample Medical Device Association Code of Ethical Conduct for
Interactions with Healthcare Professionals¹
(Based on the APEC Kuala Lumpur Principles)²
February 15, 2012**

This Code of Ethical Conduct (“Code”) is effective as of [date]. Company certifications should be submitted no later than the first of [month] of each year, beginning in [year]. [Association name] will publish the certification form that Companies should use on its website at [association web site].

1. Purpose of Code & General Provisions

[Association name] recognizes that ethical interactions between the medical device and diagnostics industry and healthcare professionals advance Medical Technologies 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, produce, manufacture, market or distribute medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities (“Medical Technologies”) in [APEC Member Economy] (“Companies”) and those individuals and entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ Medical Technologies in [APEC Member Economy] (“Health Care Professionals”).

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 “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. Note that there may be laws and other codes applicable to relationships with Healthcare Professionals, including relationships with government employees.

² The APEC Kuala Lumpur Principles, endorsed by APEC Ministers in 2011, can be accessed here: http://aimp.apec.org/Documents/2011/MM/SMEMM/11_smemm_009.pdf

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 significant 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, requires collaborative interactions between Companies and Healthcare Professionals. However, when interactions are not conducted in accordance with appropriate ethical standards, 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 inducement.³ 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. Consulting Arrangements.

Companies may engage Health Care Professionals to provide services that support research and development to advance medical science, develop new technologies, improve existing products and services, or enhance the quality of patient care. Companies may pay consultants fair market value compensation for performing these types of services, provided that they are intended to fulfill a legitimate business need. Companies may not engage Healthcare Professionals as a means of inappropriate inducement.

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

Companies should comply with the following standards in connection with consulting arrangements with Health Care Professionals:

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. Consultants should be selected based on their qualifications to perform the required services. Consulting services should be engaged pursuant to written agreements describing the services to be performed and the compensation to be provided. Consulting arrangements should be disclosed in advance and in writing to the Healthcare Provider's institution or employer, unless applicable laws, regulations or institutional rules specifically require disclosure to a different body, in which 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 consultant'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 consulting services that meet the standards set forth above, which may include expenses for travel, meals and accommodation. However, excessive travel arrangements (side trips, extended stays) or reimbursement may be perceived as an inappropriate inducement and should be avoided. 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 an inappropriate inducement. Companies should not pay any expenses of spouses or other guests accompanying Healthcare Professional consultants.

Companies may organize meals for consultants, but these should be reasonable and subordinate in time and focus to the scientific or business purpose for which services have been engaged.

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 sponsors 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 may inappropriately benefit individual Healthcare Professionals or provide 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. A Company may not provide such grants as an unlawful inducement.

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 reasonable, and are subordinate in time and focus to the scientific or educational purpose of the conference. 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. Companies may also provide education to Healthcare Professionals 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 Professional's 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.

When it is impractical or inefficient to provide training at or close to a Healthcare Professional's place of business, Companies may pay the reasonable travel and lodging costs of the attending Healthcare Professional incurred solely for the purpose of attending the program.

Companies may provide reasonably-priced meals in connection with training and education programs. 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, conduct contract negotiations, or discuss sales terms. Such meetings should generally occur at or near the Healthcare Professional's place of business, although occasionally such discussions may take place at another mutually convenient location. It is appropriate to pay for reasonable travel and lodging costs of attendees when travel is necessary, for example for plant tours or demonstrations of non-portable equipment. Companies may provide reasonable meals in connection with such meetings in a venue that is conducive to the exchange of information. Companies should not pay for or invite spouses or guests of Healthcare Professionals to participate in business meetings or meals

6. Educational Items

Companies may occasionally provide items to Healthcare Professions that benefit patients or serve a genuine educational function for Healthcare Professionals. With the exception of textbooks and anatomical models, any such item should have a fair market value of less than [appropriate value] 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.

This section is not intended to address the practice of providing products for evaluation and demonstration purposes, which is addressed in Section 8.

7. No Gifts or Entertainment

Companies should not provide Healthcare Professionals with gifts, including gifts of cash, food, wine or spirits, gift baskets, gift cards/certificates, or flowers. Companies may not provide Healthcare Professionals any type of non-educational branded 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. Demonstration and Evaluation Products

Companies can improve patient care by providing Medical Technologies to Healthcare Providers free of charge for demonstration and evaluation purposes. Companies may provide reasonable quantities of Medical Technology products and equipment to Healthcare Professionals at no charge for evaluation and demonstration purposes, provided that such products are not given or intended as an inappropriate inducement.

Demonstration products are typically unsterilized products that are used for training of healthcare professionals or patient educations. These should be marked “not for human use” or otherwise to indicate that they are solely for demonstration purposes.

Evaluation products are typically provided for human use, either as free samples of single-use products, or loans of reusable products or capital equipment. Because evaluation products are intended for human use, they may constitute a financial benefit to Healthcare Professionals. Therefore, Companies should only provide evaluation products in quantities (or for a duration) that is reasonably calculated to permit adequate evaluation by the Healthcare Professional. Evaluation products should be appropriately disclosed and documented to minimize the risk that they will provide a financial benefit to any individual Healthcare Professional, and Companies should ensure that loaned products are retrieved or returned if not purchased at the end of the evaluation period.

9. Charitable Donations and Research and Education Grants.

Companies may provide support to organizations engaged in disaster relief, indigent care, public education, patient education, and other charitable missions. Companies may also advance Medical Technology by supporting education of Healthcare Professionals and the public, 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. A Company may not provide such grants or donations as an unlawful inducement. Donations should be motivated by bona fide charitable purposes and should be made only to bona fide charitable organizations.

- A. **Charitable Donations.** Companies may make monetary and in-kind donations 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 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.

- B. **Educational Grants.** Companies may provide grants for legitimate educational 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. Companies may also make educational grants to sponsors of third-party educational conferences (described in Section 3 of this Code). Educational grants should not be paid to individual Healthcare Professionals and care should be taken to avoid making grants that may provide an inappropriate benefit to individual Healthcare Professionals.
- C. **Research Grants.** Companies may provide research 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. Sponsored research should have well-defined objectives and milestones and may not be linked directly or indirectly to the purchase of Medical Technologies. Company-initiated or directed research involving a Company's Medical Technologies is not covered by this section and should be evaluated under the provisions of Section 2.

10. Ensuring Effective Code Implementation

In order to ensure effective implementation of Code principles, each [Association name] Member Company should take the following concrete steps

- A. Appoint a senior executive responsible for oversight of the Company's compliance with this Code;
- B. Adopt practical, useful, and meaningful policies, guidance and tools intended to ensure compliance with the Code;
- C. Provide effective and ongoing training and education on the Code and on company policies implemented to ensure Code compliance;
- D. Ensure that senior management and the company's board of directors or other governing body have expressly committed to support the Code;
- E. Institute appropriate internal monitoring and auditing mechanisms;
- F. Create safe mechanisms for, and encourage, employees who raise concerns;
- G. Require that third party intermediaries (including consultants, distributors, sales agents, and brokers) that may interact with Healthcare Providers in connection with Company Medical Technologies agree to comply with this Code; and

H. Provide a certification to [Association name] that the Company has signed onto the [Association name] Code of Ethical Conduct, so those Member Companies can be publicized.

ANNEX A

INTERIM COMPROMISE POINTS ON CERTAIN ISSUES

Added August 19, 2015

As medical technology associations have been drafting and revising codes of ethics in line with the Kuala Lumpur principles, some have felt the need to take interim steps on the path to full compliance for certain areas with a history of business cultural norms that resist rapid change. This annex contains suggested interim language for two such areas, *direct sponsorship of health care professionals to attend third-party educational conferences*, and the *ban on gifts*. Inclusion of this text in a code of ethics should be subject to a requirement for reevaluation within one year.

Direct Sponsorship

Add to the end of section 3 (“Third Party Educational Programs”) a fourth category:

Direct Sponsorship of Health Care Professionals. Companies may sponsor individual HCPs to attend third-party educational conferences under the following conditions:

- A. Companies cannot reimburse HCPs’ travel expenses directly to the HCP;
- B. Companies may recommend the list of HCPs to attend educational meetings, from an educational and scientific perspective, and should develop internal procedures to ensure that company-sponsored attendees are properly qualified;
- C. Companies should establish internal controls to evaluate and qualify 3rd party service providers (e.g. logistics/travel agencies), if they want to reimburse 3rd party service providers (e.g. logistics/travel agencies) for meeting related expenses.

Ban on Gifts

Replace sections 6 (“Educational Items”) and 7 (“No Gifts or Entertainment”) with the following new sections:

6. Prohibition on Entertainment and Recreation.

Company interactions with Health Care Professionals should be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, a Company should not provide or pay for any entertainment or recreational event or activity for any Health Care Professional. Such activities include, for example, theater, sporting events, skiing, golf, lavish meals and leisure or vacation trips. These activities also include recreational activities such as city tours organized in conjunction with bona fide travel. Such entertainment or recreational events or activities should not be provided, regardless of: (1)

their value; (2) whether the Company engages the Health Care Professional as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.

7. Educational Items and Branded Promotional Items

As permitted by applicable laws and regulations, a Company occasionally may provide items to Health Care Professionals that benefit patients or serve a genuine educational function for Health Care Professionals. Other than medical textbooks or anatomical models used for educational purposes, any such item should have a fair market value of less than [appropriate value]. A Company may not provide items that are capable of use for non-educational or non-patient related purposes, for example, a smartphone, tablet computer, laptop, etc. Such items shall not be provided to Health Care Professionals as an inappropriate inducement.

Companies may provide branded promotional items of minimal value to Health Care Professionals related to the Health Care Professional's practice. Such items could include stationery items, USB drives, mouse pads, and other items bearing a company's logo. Such items should have a value of [appropriate value].

This section is not intended to address the legitimate practice of providing products for evaluation and demonstration purposes, which is addressed in Section 8.

Under no circumstances should companies provide the following items to Health Care Professionals: alcohol, tobacco, cash, gift cards, or other cash equivalents.