



**Asia-Pacific
Economic Cooperation**

Working With a Code of Ethics Key Areas for Third Parties

Training Slides

Why Do Codes of Ethics Matter?

- MedTech manufacturers expect third parties to adhere to same ethical rules as they do
- Enforcement actions involving a few unethical medical device distributors has all distributors in the government's scope
- The effectiveness of compliance programs of manufacturers is evaluated by enforcement officials in part by their management of third parties

Key Area for Third Parties

1. Consulting Agreements
2. Entertainment, Recreation and Gifts for HCPs
3. HCP Education, Training and Sales Promotion (including provision of meals)
4. Entertainment, Recreation and Gifts for HCPs
5. Grants and Charitable Donations



The Medical Device Industry Difference:

Close and ongoing collaboration between health care professionals and medical technology companies is necessary for patient safety and medical innovation.

- Medical technologies require hands-on training and practice to assure safe and effective use and retraining as medical technologies undergo repeated changes (short life cycle).
- Physicians bring practical field and other experience vital to continued development and improvement of medical technology.

APEC Kuala Lumpur Principles

- ***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.

Scope

“includes any individuals or entities that develop, produce, manufacture, sell, market or distribute Medical Technologies and Health Care Professionals (HCPs)”

Defining Medical Technologies

“includes medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities.”

Defining Healthcare Professionals

“those individuals and entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ Medical Technologies.”

Consulting Agreements

- Companies and their representatives may engage Healthcare Professionals to provide services that support R&D to advance medical science, develop new technologies, improve existing products and services, or enhance patient care
- Companies **may not** engage Healthcare Professionals as a means of inappropriate inducement.
- Payments for services should be at fair market value, and companies should engage only the number of Healthcare Professionals reasonably needed to perform the services
- Consulting arrangements should be disclosed in advance and in writing to the Healthcare Provider's institution or employer or other authority as provide by local laws
- Companies may reimburse appropriate and reasonable expenses, including travel and accommodations

General Education Programs

- Grants to Conference Organizers
 - Provisions to provide funds for bona fide educational expenses that do not inappropriately benefit individual HCPs
- Conference Meals and Refreshments
 - Reasonable expenses may be compensated for the HCPs only, not spouses or guests.
- Advertisements and Demonstrations; Satellite Symposia
 - Companies and their representatives may purchase advertisements and lease booth space for Company displays at conferences

Product-Specific Education & Training

- Companies and their representatives may provide training of HCPs.
- 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 program.
- Companies may pay the reasonable travel, meals and lodging costs of the attending HCP but may not provide recreation, entertainment.
- Companies **may not** pay expenses for a guest or spouse.

Product-Specific Education & Training

Do's

- Appropriate location
- Signed simple agreement with the healthcare professional (for large event)
- Agenda / program (for smaller events)

Don't's

- Resort locations
- Hospitality shouldn't be the main focus
- Not for partners or guests of the healthcare professional
- Gifts and inducements

Sales & Promotional Meetings

- It may be appropriate for Company representatives to meet from time to time with HCPs.
 - E.g., to discuss medical technology features, sales terms, or contracts.
- Such meetings should generally occur at or near the HCP's place of business, although occasionally such discussions may take place at another mutually convenient location.
- It is appropriate to pay for reasonable meals and travel costs of attendees but Companies *may not* pay for or invite spouses or guests of HCPs to participate in business meetings.

Educational Items

- A company or its representative occasionally may provide items to HCPs that benefit patients or serve a genuine educational function for HCPs
- 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 HCPs (or their family members, office staff or friends) for non-educational or non-patient related items

No Gifts or Entertainment

- It is inappropriate to provide gifts or entertainment in the context of any type of interactions with HCPs
- Companies **may not** provide gifts
 - Prohibited items include, for example: cash/gift cards, food, wine/spirits, gift baskets, or flowers
- Companies **may not** provide or pay for any entertainment or recreational event or activity for any HCP.
 - Prohibited activities include, for example: sporting events, cultural or artistic activities, or leisure activities

Charitable Donations and Research & Education Grants

- Companies and their representatives may provide support to organizations engaged in disaster relief, indigent care, public education, patient education, and other charitable missions and support scientific and medical research.
- A company may not provide such grants or donations as an unlawful inducement, and donations should be motivated by bona fide charitable purposes and should be made only to bona fide charitable organizations.

Charitable Donations and Research & Education Grants (cont.)

- Charitable Donations

- Companies and their representatives 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 HCP.

- Educational Grants

- Companies and their representatives may provide grants for legitimate educational purposes including grants to support medical education 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

Charitable Donations and Research & Education Grants (cont.)

- Research Grants
 - Companies and their representatives 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.



Any Questions?