



**Asia-Pacific
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Agenda Item: 3

The Kuala Lumpur Principles Medical Device Sector Codes of Ethics

Purpose: Consideration
Submitted by: SMEEM Chair



**18th Small and Medium Enterprises
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Big Sky, United States
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The Kuala Lumpur Principles

Medical Device Sector Codes of Ethics

Medical technology sector Codes of Business Ethics promote ethical interactions between medical device and diagnostics companies (“Companies”) and Healthcare Professionals¹ (“HCPs”). Ethical interactions enhance patient access to the safe and effective use of medical technologies by ensuring appropriate training of HCPs by Companies. Ethical interactions also promote innovation and the ongoing development of advanced medical technologies through legitimate and transparent collaboration between HCPs and Companies to identify, and bring to market new products. Further, ethical interactions facilitate open and transparent business environments free from the high costs of corruption, enhancing the ability of Companies, especially small and medium size 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 HCPs should be conducted in accordance with the following principles: **Integrity, Independence, Appropriateness, Transparency and Advancement:**

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

Independence means that HCP interactions with Companies should not skew the HCP’s medical decision making from the best interests of the patient.

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

Transparency means that Companies and HCPs are open regarding significant financial relationships between the parties.

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

Accordingly, medical technology industry codes of ethics (“Industry Codes”) should incorporate, but not necessarily be confined to, the following:

1. Collaborative interactions between Companies and HCPs should preserve independent decision-making by HCPs and public confidence in the integrity of patient care, treatment and product selection.

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. Consultancy agreements between Companies and HCPs should support research and development to advance medical science, develop new technologies, improve existing products and services, and enhance the quality and efficacy of care for patients. Consultancy agreements should not be used as a means of inappropriate inducement².
3. Company support of HCPs' education, for example through support to third-party educational programs and educational grants, should preserve the independence of medical education and should not be used as a means of inappropriate inducement.
4. Companies may provide training of HCPs on product specific device deployment, use and application to facilitate the safe and effective use of medical technologies by HCPs.
5. Companies should not provide entertainment and recreation to HCPs as an inappropriate inducement. Any attendance at entertainment events, consenting or agreeing to receive any gift, commission, or gratuity shall not be regarded as appropriate for nurturing appropriate business relationships.
6. Company donations for charitable or other philanthropic purposes should support *bona fide* charitable organizations and missions, and should not be a means to privately benefit an HCP.
7. Free products should not be used as a means of inappropriate inducement. However, Companies may provide reasonable quantities of products to HCPs at no charge for evaluation and demonstration purposes.

To ensure Industry Codes are effective, they should encourage adherence to the following elements that are relevant to a Company's business:

1. Companies to appoint a senior executive responsible for oversight of the Company's compliance with the Industry Code.
2. Companies to develop or adopt practical, useful, and meaningful policies, guidance, and tools on how to implement policies consistent with the Industry Code.
3. Companies to provide effective and ongoing training and education on the Industry Code and the Company's policies consistent with the Industry Code.
4. Companies' senior management and governing body, if applicable, commit to support the Industry Code.

² Inappropriate inducement means a remunerative arrangement intended to inappropriately influence an HCP's medical decision-and product selection.

5. Companies to institute appropriate internal monitoring and auditing mechanisms.
6. Companies to create safe mechanisms for, and encourage, employees who raise concerns. Companies to communicate company policies consistent with the Industry Code to their third party intermediaries with the expectation that the intermediaries will comply with the Industry Code.

In order to promote an ethical commercial environment, cooperation among multiple stakeholders is required. Therefore, it is recommended that APEC economies encourage:

Medical Device Sector

- Medical device sector industry associations and their member companies to develop and implement Industry Codes consistent with the principles set out above and to consider publicizing those members who have signed onto the Industry Codes, among other steps to encourage adoption of Industry Codes;
- Medical device sector regulators and/or anti-corruption enforcement authorities to endorse and support Industry Codes;

Healthcare Professionals

- HCPs, such as medical and academic institutions and physician groups, to develop and implement codes of ethics consistent with the above principles;

HCPs to develop and make known clear, distinctive, accountable and comprehensive policies on procurement processes and procedures in line with respective government policies on procurement and Industry Codes, if appropriate;

APEC Economies

Each APEC economy to formulate and promote clear laws and regulations that are objectively applied;

APEC economies to work to advance ethical collaborations consistent with the above principles regionally, through regular communication, joint policies, joint capacity building activities, and other forms of collaboration; and

APEC economies to work together to ensure that the above principles and Industry Codes remain relevant and effective to address new and relevant business arrangements that may emerge.

BACKGROUND

At the 14th Economic Leaders' meeting held in Hanoi in 2006, APEC Leaders reaffirmed their high commitment to fight corruption. In 2006 APEC Ministers stressed the importance of preventive measures and integrity systems in the fight against corruption and urged member economies to adopt and implement codes or norms of conduct. In 2007 APEC Leaders endorsed anti-corruption principles for the public and private sectors, including an APEC Code of Conduct for Business.

In 2010 SME Ministers issued a joint statement which called for "facilitating open and transparent business environments free from the high costs of corruption by the development of APEC codes of business ethics in sectors of export interest to APEC economies, beginning with the medical device sector." And APEC Ministers "...welcomed steps taken to improve...understanding of the ethical business practices needed to sustain participation in international trade, and look forward to the development of codes to improve and better align industry practices across APEC economies."

Following this, an Expert Working Group convened in Kuala Lumpur, Malaysia, on April 6-7, 2011, to develop a set of APEC Principles for Codes of Business Ethics to Ensure Ethical Interactions Between Medical Technology Companies, drawing upon existing best practices and voluntary codes of business ethics in APEC economies.