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The Kuala Lumpur Principles for Codes of Ethics in the Medical Technology Sector

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The Kuala Lumpur Principles

For Codes of Ethics in the
Medical Technology Sector

Original Version 2011 | Updated 2021

The Kuala Lumpur Principles

Medical Technology Sector Codes of Ethics

Medical technology sector Codes of Business Ethics promote ethical interactions between medical device and diagnostics companies, as well as their Third-Party Intermediaries¹, (collectively referred to as “Companies”), Healthcare Professionals (“HCPs”)², patients and patient organizations, and governments. Ethical interactions improve patient access to appropriate medical technologies and their safe and effective use by ensuring necessary training and education of HCPs in such technologies by Companies. Ethical interactions also promote innovation, ongoing development, and commercialization of advanced medical technologies through legitimate, appropriate, and transparent collaboration between HCPs and Companies. Further, ethical interactions facilitate open and transparent business conduct free of corruption, enhancing the ability of all Companies, especially small and medium size Companies, to participate and compete in global markets. Ethical interactions ensure that medical decision-making is made in the best interests of the patient.

To ensure that relationships meet this standard, interactions between Companies and HCPs should be conducted in accordance with the following principles: Patients first, Integrity, Independence, Appropriateness, Transparency, Advancement and Responsibility.

Patients first means that Companies should prioritize the health and well-being of patients and other users of their products and technologies.

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

Independence means that HCP interactions with Companies should preserve the HCP’s medical decision-making being otherwise than in the best interests of the patient.

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

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

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

Responsibility means promoting a culture that supports social and ethical business practices including protecting patients’ safety, rights and privacy.

¹ Third-Party Intermediaries refers to third parties operating as distributors, wholesalers, distribution or sales agents, and/or independent sales representatives (Third Party SMIs³). The [APEC Guidance for Third Party Intermediary Relationships in the Medical Device Sector](#) further outlines these relationships.

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

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

1. All collaborative interactions between Companies and HCPs should preserve independent decision-making by HCPs and seek to enhance public confidence in the integrity of patient care, treatment, and product selection.
2. Consultancy arrangements between Companies and HCPs should be for legitimate purposes, such as for the support of research and development to advance medical science, development of new technologies, improvement of existing products and services or providing training and education in medical technology, with the objective of enhancing the quality and efficacy of care for patients. Consultancy agreements must never be used as an inducement³ to obtain, retain or direct business or any other inappropriate or unlawful inducement.
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 must never be used as a means of inducement to obtain, retain or direct business or any other inappropriate or unlawful inducement.
4. Companies may provide training to HCPs on their medical technologies including product specific device deployment, use and application to facilitate the safe and effective use of medical technologies by HCPs.
5. Companies may not provide gifts, including brand reminders, cultural courtesies, entertainment, or recreation to HCPs. Such benefits could be viewed as an inducement to obtain, retain, or direct business or some other inappropriate or unlawful inducement. In addition, the trust between Companies and HCPs, patients, and other stakeholders must be preserved; and the provision of benefits that could or could appear to compromise HCP independence must be avoided. Companies may provide modest, appropriate educational items or patient items to HCPs. Any attendance at events with entertainment, accepting 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. Charitable donations must not be a means to benefit an HCP directly or indirectly or otherwise be used as an inappropriate inducement to obtain, retain, or direct business or any other inappropriate or unlawful inducement.
7. Products at no charge should not be provided as an inducement to obtain, retain, or direct business or some other inappropriate or unlawful inducement. However, Companies may provide reasonable quantities of products to HCPs at no charge for evaluation, demonstration, and training and education purposes. Provision of products at no charge must be appropriately documented.

³Inducement means a remunerative or other arrangement intended to inappropriately influence an HCP’s medical decision making-and product selection.

To ensure Industry Codes are effective, they should encourage adherence to the following principles of practice and governance, applied through a Compliance Program⁴ or other polices, practices, and procedures, that are relevant to the Company's business:

1. Companies to appoint a senior executive responsible for oversight of and provide resources for the Company's training and education on and adherence to the Industry Code.
2. Companies to develop or adopt practical, useful, and meaningful policies, procedures, and tools on how to implement the Industry Code.
3. Companies to provide effective and ongoing training, education and communication to their employees and business partners 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.
5. Companies to institute appropriate internal monitoring, testing, and auditing mechanisms to assess ongoing compliance with the Industry Code.
6. Companies to create safe mechanisms for, and encourage, employees to raise concerns. Companies to communicate company policies consistent with the Industry Code to their third-party intermediaries with the requirement that they will comply with the Industry Code.
7. Patient data shall be collected only in accordance with applicable legislation. Such patient data shall not be used as a means of inducement.
8. Companies will implement guidance in accordance with the [APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector](#).
9. Books and records: Companies shall make and keep books and records that accurately and completely reflect transactions with HCPs and government officials.
10. Corrective Action: Companies shall respond promptly to detected problems and undertake corrective action.

The APEC region's health systems and stakeholders are extraordinarily diverse. Ethical collaboration among key stakeholders can strengthen ethical business conduct, build trust, promote accountability, and improve patient outcomes. Ethical collaboration among medical device enterprises, their industry associations and third-party intermediaries, healthcare professionals and providers, patients' organizations, health regulators, and other stakeholders is essential to the delivery of high-quality patient care, patient access to lifesaving and health-enhancing medical technologies, and the development of innovations that meet patient needs.

⁴ Compliance Program means a set of internal governance to comply with laws, rules and regulations or to uphold business reputation. Generally, an effective compliance program consists of following elements: designating a compliance officer and compliance committee, implementing written policies and procedures, conducting training and education, setting effective lines of communication, conducting internal monitoring and auditing, enforcing policies through disciplinary guidelines and detecting allegations and undertaking corrective action.

No one group can achieve an ethical environment in this sector alone. Ethical collaboration among these stakeholders strengthens the ability of small and medium enterprises (SMEs) to sustainably innovate, operate, and engage in cross-border trade.

Therefore, it is recommended that key stakeholders undertake the following activities to promote an ethical commercial environment:

MEDICAL TECHNOLOGY SECTOR

- Medical technology sector industry associations, their member companies and business partners 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;
- Work together to ensure that the above principles and Industry Codes remain relevant and effective to address new business arrangements that may emerge;

HEALTHCARE PROFESSIONALS

- HCPs, such as medical and academic institutions and physician groups, to develop and implement codes of ethical interactions 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/or appropriate codes of ethics;

GOVERNMENT

- Formulate and promote clear laws and regulations that are objectively applied;
- Medical technology sector regulators and/or anti-corruption enforcement authorities to promote, as appropriate, the adoption of Industry Codes, including through specific strategies that reward and incentivize code adoption;
- Promote government strategies to encourage ethical business conduct in six key areas:
 1. Convening Power: bring stakeholders together, including through Consensus Frameworks;
 2. Procurement: leverage the government's purchasing power;
 3. Regulatory Practices: promote ethical business conduct through the structure of government regulation;
 4. Enforcement Recognition and Incentives: recognize and incentivize strong ethics and compliance;
 5. Government Supported Business Ethics Training: offer government-sponsored training and SME capacity-building for local industry; and
 6. Trade Agreements: leverage international trade commitments; and
- Work to advance ethical collaborations regionally, including Consensus Frameworks, consistent with the above principles, through regular communication, joint policies, joint capacity building activities, and other forms of collaboration.

⁵ For more information, please refer to: [Government Strategies To Encourage Ethical Business Conduct: A Resource Guide for Economies from the Business Ethics for APEC SMEs Initiative](#)