

General Session: Review of the KL Principles – A Voluntary Regional Approach Designed to Ensure Successful Code Adoption


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The KL Principles

- Medical Device Industry Specific
- Region Wide Adoption
- Voluntary; Self Regulatory
- Guidelines to assist in the creation and alignment of codes



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The Kuala Lumpur Principles Medical Device Sector Codes of Ethics

Purpose: Consideration
Submitted by: SMEMM Chair

bring and auditing mechanisms.

and encourage, employees who raise policies consistent with the Industry expectation that the intermediaries will

ment, cooperation among multiple at APEC economies encourage:

member companies to develop and principles set out above and to consider Industry Codes, among other steps to

in enforcement authorities to endorse

and physician groups, to develop and principles;

ve, accountable and comprehensive in line with respective government 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.

The Kuala Lumpur Principles

Medical Device Sector Codes of Ethics

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

Independence means that Health Care Professional (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.

The KL Principles

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.
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 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 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.

The KL Principles

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.

The KL Principles

Measures to Ensure Effectiveness:

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.
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.