“THE KUALA LUMPUR PRINCIPLES
For Medical Device Sector
Codes of Business Ethics”

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www.sprm.gov.my
ACCOUNTABILITY & CHECK AND BALANCE MECHANISM OF THE MACC

SPECIAL COMMITTEE ON CORRUPTION (Sec. 14)

ANTI-CORRUPTION ADVISORY BOARD (Sec 13)

COMPLAINTS COMMITTEE (Sec. 15)

CONSULTATION AND CORRUPTION PREVENTION PANEL

OPERATIONS REVIEW PANEL
3-PRONGED STRATEGIES

OPERATION (ENFORCEMENT)
- Detection of any suspected offence
- Investigation of corruption cases
- Prosecution of offenders

PREVENTION
- Detection of corruption loopholes
- Corruption prevention advice

COMMUNITY RELATIONS
- Public education against corruption
- Fostering public support in combating corruption
EFFECTS OF CORRUPTION ON TRADE AND BUSINESS

GENERAL EFFECTS

1. Increases transaction costs
2. Eliminates a level playing field
3. Expose to legal risks
4. Affects business sustainability
5. Kills healthy business transactions

EFFECTS ON THE HEALTHCARE INDUSTRY

1. LIFE THREATENING !!!
2. SUB-STANDARD EQUIPMENTS & MEDICATION
3. INACCURATE DIAGNOSIS
4. INEFFECTIVE TREATMENT
5. IMPEDES INNOVATION
WHY ENGAGE IN CORRUPT WAYS?

• SUPPLY > DEMAND
• FULFILLING PRODUCT LIFESPAN
• HIGH RESEARCH & DEVELOPMENT COST (R&D)
• FULFILLING THE OBJECTIVES IN OBTAINING PROFITS
CORPORATE LIABILITY FOR CORRUPTION

- Current laws only punish individuals
- Instructions from top management, CEO or Board of Directors
- Provision to punish corporations
  - Fine
  - Blacklisting
  - Termination of tender/contract
Companies get punished for corrupt acts..... eg:

- **SIEMENS**
  - Siemens has faced accusations of bribery and other corporate malfeasance in roughly 20 countries. Bribes were given to win many contracts.
  - Siemens agreed to pay a record **$1.34 billion** in fines in December 2008 after being investigated for serious bribery.

- **ALCATEL-LUCENT**
  - Alcatel was charged with two counts of violating the US Foreign Corrupt Practices Act. Three of its subsidiaries agreed to plead guilty to one count each of conspiracy to violate the anti-bribery law.
  - Agreed to pay more than **US$137 million** (RM430.4 million) to settle US charges that it paid millions of dollars in bribes to foreign officials to win business in Latin America and Asia, US authorities.

- **ALSTOM**
  - Alstom has been the subject of several international corruption probes. A Swiss subsidiary of Alstom settled corruption-related charges with Swiss authorities in 2011 and paid a **$42.7 million** fine.
WHY THE NEED FOR THIS INITIATIVE?

• INDUSTRY PACT TO ENCOURAGE INDUSTRY SUSTAINABILITY

• CAPACITY BUILDING IN FORMING A STRONG VOICE AGAINST UNETHICAL PRACTICES

• IMPROVE THE QUALITY OF PATIENT CARE, ENCOURAGE INNOVATION AND SME GROWTH.

• STANDARD CONDUCT OF BUSINESS AMONG APEC ECONOMIES
PREVENTING BRIBERY AND CORRUPTION IN THE PRIVATE SECTOR

the advantages ……

- REDUCE COST OF BUSINESS
- INCREASE MARKET COMPETITION
- ENHANCE GROWTH OF SALES & PRODUCTIVITY
- ALLOW NEW ENTRY
- GREATER SUSTAINABILITY CAPABILITY
- ESTABLISH A LEVEL PLAYING FIELD
- GREATER ACCESS TO CAPITAL
- ATTRACT FOREIGN INVESTMENT
The Kuala Lumpur Principles

Medical Device Sector Codes of Ethics

Code of ethics for the region’s medical devices industry

Promote ethical interactions between medical device and diagnostics companies (“Companies”) and Healthcare Professionals (“HCPs”)

Towards ethical delivery and practice of medical services and its business community
APEC Medical device workshop
- Call by SME Ministers for APEC codes of business ethics beginning with the medical device sector

Sept/Oct 2010

Nov/Dec 2010

Mac/Apr 2011

May/Jun 2011

Nov/Dec 2011

Mac/Apr 2012

May '12 /Feb '13

26-30 Aug 2013

Mac/Apr 2012

Nov/Dec 2011

APEC SME Ministers endorses the KL Principles

APEC Ministers welcomed development of the codes to better align industry practices across APEC economies

Expert Working Group formulates the Kuala Lumpur Principles for the Medical Device Sector

Train-the-Trainer Workshop for anti-corruption officials, medical device regulators and physicians groups

APEC SME Ministers endorses the KL Principles

Healthcare Stakeholder Awareness Workshop

- Drafting of Code
- 3 quarterly tracking progress

3rd Sep 2013

- APEC Ministers endorses the Kuala Lumpur Principles

Workshop to assist industry associations to draft voluntary code aligned with the KL Principles
“Ministers called on the medical device sector industry associations and their member companies to adopt and implement codes of business ethics consistent with the KL Principles and encouraged capacity building initiatives so that these measures are fully implemented.”
KL PRINCIPLES: ENDORSED BY APEC MINISTERS
Honolulu, Hawaii, United States, 11 Nov 2011

“APEC High Level Policy Dialogue on Open Governance and Economic Growth” chaired by U.S. Secretary of State Hilary Clinton:

“We applaud the decision of the APEC SME Ministers at Big Sky, Montana in May 2011 to endorse the Kuala Lumpur Principles for Medical Device Sector Codes of Business Ethics. This set of principles for the region’s medical devices industry is the first of its kind, and will improve the quality of patient care, encourage innovation, and promote the growth of SMEs that produce medical devices. We also congratulate the work of the APEC SME Working Group in establishing voluntary sets of ethics principles for the biopharmaceutical sector (the Mexico City Principles) and the construction and engineering sector (the Hanoi Principles). We endorse these three sets of principles and look forward to further APEC efforts to ensure that these principles have a practical impact for small and medium-sized companies.”
“Therefore, economies have committed to undertaking the following actions.... Endorse principles for voluntary codes of business ethics in the construction and engineering, medical devices, and biopharmaceutical sectors to ensure open and transparent business environments....”
Promoting ethical and healthy interactions

- Integrity
- Independence
- Appropriateness
- Transparency
- Advancement

Medical Device and Diagnostics Companies

Health Care Professionals (HCP)
ENTERPRISE ANTI-CORRUPTION POLICIES AND GUIDELINES

- GIFTS, HOSPITALITY/ENTERTAINMENT EXPENSES
- POLITICAL CONTRIBUTIONS
- CHARITABLE CONTRIBUTIONS/SPONSORSHIP
- FACILITATION PAYMENTS
- CONFLICT OF INTEREST
- POLICY ON WHISTLE BLOWING
- CORPORATE SOCIAL RESPONSIBILITY (CSR)
“INDUSTRY CODES” SHOULD INCORPORATE, BUT NOT NECESSARILY BE CONFINED TO THE FOLLOWING:

1. Independent decision-making by HCPs.
2. Consultancy Agreements as inappropriate inducement.
3. Use of Educational Grants.
4. Training Provision.
5. Control on entertainment and recreation to HCPs.
7. Purpose of Free Products.
Effective Elements in the Industry Code

1. Appoint a senior compliance executive.
2. Develop or adopt practical, useful and meaningful policies and tools.
3. Provide effective and ongoing training and education.
4. Commitment and support of senior management and governing body.
5. Institute appropriate internal monitoring and auditing mechanisms.
6. Create safe mechanisms for employees to raise concerns.
7. Communicate company policies.
• Encourage Medical device sector industry associations to develop and implement Industry Codes;

• Endorsement of Industry Codes
• Develop and implement codes of ethics consistent with the KL Principles;

• Develop and make known clear, distinctive, accountable and comprehensive policies on procurement processes and procedures;
“The world will not be destroyed by those who do evil, but by those who watch them without doing anything”

- Albert Einstein