Workshop to Draft Voluntary Codes of Business Ethics for the Medical Device Sector

Purpose: Information
Submitted by: United States
Workshop to Draft Voluntary Codes of Business Ethics for the Medical Device Sector

Brunei Darussalam
April 22-24, 2012

The “Business Ethics for APEC SMEs” Initiative

Key rationale
- SMEs (Small and Medium Enterprises) are the engine of economic growth and can serve as a key driver in global economic recovery as long as they are able to operate and innovate in open, ethical business environments.

16 co-sponsors
- Australia, Brunei Darussalam, Canada, Hong Kong China, Indonesia, Japan, Korea, Malaysia, Mexico, New Zealand, Peru, The Philippines, Singapore, Chinese Taipei, Thailand, Vietnam
The Legal and Business Case for Ethical Business Environments

Unethical behavior hurts economies
- Negative impacts on inflation
- Decreased GDP
- Currency depreciation
- Reduced foreign investment
- Undermined health systems

Unethical behavior hurts individual businesses
- Increases the costs of doing business (through bribes and penalties)
- Lowers sales growth and productivity
- Lowers the ability to enter new markets
- Constricts access to capital
- Over the long term undermines a company’s financial growth

Relationship between Corruption and Development (in 97 countries)

- Countries with higher perceived corruption tend to have lower real per capita GDP.
- Put differently, countries with low per capita income tend to have higher corruption.
The Legal and Business Case for Ethical Business Environments

- According to the World Bank Institute, more than $1 trillion dollars (US$ 1,000 billion) are paid in bribes every year. This means that each year the cost of corrupt activities is equal to a full 3% of the world’s GDP.

The Legal and Business Case for Ethical Business Environments

Corruption perceived as a major business obstacle by SMEs and large companies (in per cent)

- According to the Business Environment and Enterprise Performance Survey (BEEPS)
- More than 70 per cent of SMEs in transition economies perceive corruption as an impediment to their business
- Almost 35 per cent of small companies perceived corruption as a major business obstacle
The Legal and Business Case for Ethical Business Environments

World Map Index of perception of corruption 2010

Source: Transparency International

APEC: An Emphasis on Voluntary Codes of Business Ethics

Why?

- Benefits APEC Member Economies
- Benefits businesses
- Benefits patients
Voluntary Codes of Business Ethics: Benefits APEC Member Economies

- Provides a platform for effective industry self-regulation
- Supports enforcement efforts

Voluntary Codes of Business Ethics: Benefits Businesses, especially SMEs

- Provides companies with greater clarity and harmonization in rules and practices
- Allows companies to access new APEC markets through lower compliance costs
- Facilitates ongoing innovation in medical device sector
Voluntary Codes of Business Ethics: Benefits Patients

- Ethical collaborations fuel advances in medical technology, promoting access to life-saving technologies

- Ethical collaborations ensure that decisions are made in the best interest of patients

The Legal and Business Case for Ethical Business Environments

October 2010: 17th APEC SME Ministerial Meeting (Gifu, Japan)

- APEC SME Ministers issued a joint statement including a call for the development of APEC codes of ethics in sectors of export interest, beginning with the medical device sector

November 2010: APEC Ministerial Meeting (Yokohama, Japan)

- APEC Ministers welcomed development of APEC codes to improve and better align industry practices across the region
Expert Working Group Meeting:
Kuala Lumpur (April 6 – 7, 2011)

- 37 Expert Working Group members representing 18 of the 21 APEC Member Economies: 21 from Industry, 13 from Government; and 3 from Academia

Led by Co-Chairs:
- Dato’ Hafsah Hashim, SME Corp Malaysia
- Chris White, AdvaMed (USA)
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

**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.

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.

KL Principles: Endorsed by SME Ministers in Big Sky (USA), May 2011

“The Ministers endorsed the adoption and implementation of the Kuala Lumpur Principles Medical Device Sector Codes of Ethics (the “KL Principles”), which were developed by an Expert Working Group in Kuala Lumpur, Malaysia. 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: Pilot for the biopharmaceutical and construction sectors**

“Ministers fully support and look forward to the development of additional sets of voluntary ethical principles or codes of ethics in sectors where SMEs are important stakeholders, beginning with the construction and bio-pharmaceutical sectors.”

**KL Principles: Endorsed by APEC Ministers, November 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.”
KL Principles: Endorsed by APEC Ministers, November 2011

From "Actions to address barriers facing SMEs in trading in the region" in the trade track of the APEC Ministers Meeting, chaired by U.S. Trade Representative Ron Kirk:

“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...”

Workshop to Draft Voluntary Codes of Business Ethics for the Medical Device Sector

Brunei Darussalam
April 22-24, 2012
Welcome Reception

GUEST OF HONOR: YANG BERHORMAT PEHIN ORANG KAYA SERI UTAMA DATO SERI SETIA AWANG HAJI YAHYA BIN BEGAWAN MUDIM DATO PADUKA HAJI BAKAR
MINISTER OF INDUSTRY AND PRIMARY RESOURCES OF NEGARA BRUNEI DARUSSALAM

Welcome Remarks
Dr. Robert S.Q. Lai

Chairman, APEC SME Working Group &
Director-General, Small and Medium Enterprise Administration,
Ministry of Economic Affairs, Chinese Taipei
General Sessions & Panel Discussions

Drafting/Aligning Voluntary Codes with The KL Principles

<table>
<thead>
<tr>
<th>The Kuala Lumpur Principles</th>
<th>Sample Code Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>Section One: Purpose of Code &amp; General Provisions + ALL sample code sections</td>
</tr>
<tr>
<td>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.</td>
<td>Section Two: Consulting Arrangements</td>
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### Drafting/Aligning Voluntary Codes with The KL Principles

#### The Kuala Lumpur Principles vs Sample Code Section

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<td>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.</td>
<td>Section Three: Third Party Educational Programs</td>
</tr>
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<td>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.</td>
<td>Section Four: Company-Organized Education and Training</td>
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<td>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.</td>
<td>Section Five: Sales and Promotional Meetings</td>
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<td>6. Company donations for charitable or other philanthropic purposes should support <em>bona fide</em> charitable organizations and missions, and should not be a means to privately benefit an HCP.</td>
<td>Section Eight: Charitable Donations and Research and Education Grants</td>
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**APEC Asia-Pacific Economic Cooperation**
Drafting/Aligning Voluntary Codes with The KL Principles

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<td>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.</td>
<td>Section Nine: Demonstration and Evaluation Products</td>
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<tr>
<td>The Kuala Lumpur Principles’ measures to ensure code effectiveness.</td>
<td>Section Ten: Ensuring Effective Code Implementation</td>
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Key Breakout Session Discussion Points:
1. Overview of Local Industry Association’s Operating Environment
2. Maturity and Independence of Local Device Association
3. Device Industry Presence and Business Arrangements in Local Economy
4. Current Local Economy Anti-Bribery Law and Policy
5. Overview of Comparable Voluntary Codes in Local Economy
6. Review Sample Code
7. Identify Governance and Stakeholder Process to Develop, Customize and Adopt Code
8. Develop Local Economy Timeline and Resource Needs
### Drafting/Aligning Session Groups

<table>
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<tr>
<th>MENTORS</th>
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<tbody>
<tr>
<td>Ms. Anne Trimmer, CEO, Medical Technology Association of Australia</td>
<td>CHINA</td>
</tr>
<tr>
<td>Mr. Abdul Luheshi, Vice President, Asia-Pacific, Johnson &amp; Johnson, Healthcare Compliance &amp; Privacy</td>
<td></td>
</tr>
<tr>
<td>Ms. Jessie Yap, Chief Compliance Counsel, Asia-Pacific, Covidien</td>
<td>MALAYSIA, INDONESIA, SINGAPORE, BRUNEI DARUSSALAM</td>
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<tr>
<td>Ms. Sujata Dayal, Corporate Vice President and Chief Compliance Officer, Biomet</td>
<td>PERU, CHILE, MEXICO</td>
</tr>
<tr>
<td>Ms. Lynn Costa, Senior Trade Development Advisor, U.S. Department of Commerce</td>
<td></td>
</tr>
<tr>
<td>Ms. Lori Reber, Vice President, Office of Ethics and Compliance, Smith &amp; Nephew</td>
<td>VIETNAM, THE PHILIPPINES, THAILAND, PAPUA NEW GUINEA</td>
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<tr>
<td>Ms. Faye Sumner, CEO, Medical Technology Association of New Zealand (MTANZ)</td>
<td>RUSSIA</td>
</tr>
<tr>
<td>Ms. Diane Biagianti, Vice President, Chief Responsibility Officer, Edwards Lifesciences</td>
<td>KOREA JAPAN CHINESE TAIPEI</td>
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Next steps and tracking progress

Ms. Lynn Costa
Project Overseer &
Senior Trade Development Advisor
U.S. Department of Commerce

Dato' Hjh. Sutinah binti Sutan
Deputy Chief Commissioner
Malaysian Anti-Corruption Commission (MACC)

What we have achieved in 18 months:
From Gifu (Oct 2010) to Brunei (April 2012)

September 2010
Gifu, Japan
- APEC medical device workshop
- Call by SME Minister for APEC codes of business ethics beginning with the medical device sector

September 27-28, 2011
Mexico City, Mexico
Expert Working Group (EWG) formulates The Mexico City Principles for the Biopharmaceutical Sector

September 2010
Gifu, Japan
- APEC medical device workshop
- Call by SME Minister for APEC codes of business ethics beginning with the medical device sector

November 2011
Honolulu, USA
APEC Ministers endorse The KL, Mexico City, and Hanoi Principles

April 2011
Kuala Lumpur, Malaysia
Expert Working Group (EWG) formulates The KL Principles for the Medical Device Sector

May 21-23, 2011
Big Sky, Montana, USA
APEC SME Ministers endorse The KL Principles

November 2011
Honolulu, USA
APEC Ministers endorse The KL, Mexico City, and Hanoi Principles

April 2012
Brunei
APEC capacity building workshop to assist industry associations to draft voluntary code aligned with The KL Principles

October 5-7, 2011
Hanoi, Vietnam
Expert Working Group (EWG) formulates The Hanoi Principles for the Construction and Engineering Sector

What we have achieved in 18 months:
From Gifu (Oct 2010) to Brunei (April 2012)
What we will achieve in the NEXT 18 months:
From Brunei (April 2012) to Indonesia (2013)

July 2012
- First quarterly check-in to track progress in drafting/aligning codes

Oct 2012
- Second quarterly check-in to track progress in drafting/aligning codes

Jan 2013
- Third quarterly check-in to track progress in drafting/aligning codes

2013
- Train-the-trainer program on completed codes in Kuala Lumpur, Malaysia
- Awareness-building workshop on completed codes for anti-corruption officials, medical device regulators, and physician groups in Indonesia

May/June 2012
- Awareness-building workshop on completed codes for anti-corruption officials, medical device regulators, and physician groups in Indonesia
Aug 1 – 2, 2012
- Report progress to SME Ministers at 19th SME Ministerial Meeting in St. Petersburg, Russia

April 2013 (TBC)
- Report progress to SME Working Group

Fall 2013 (TBC)
- Report progress to SME Ministers at 20th SME Ministerial Meeting in Indonesia

What we will need from YOU

July 2012
- First quarterly check-in to track progress in drafting/aligning codes

Oct 2012
- Second quarterly check-in to track progress in drafting/aligning codes

Jan 2013
- Third quarterly check-in to track progress in drafting/aligning codes

2013
- Train-the-trainer program on completed codes in Kuala Lumpur, Malaysia
- Awareness-building workshop on completed codes for anti-corruption officials, medical device regulators, and physician groups in Indonesia

Aug 1 – 2, 2012
- Report progress to SME Ministers at 19th SME Ministerial Meeting in St. Petersburg, Russia

April 2013 (TBC)
- Report progress to SME Working Group

Fall 2013 (TBC)
- Report progress to SME Ministers at 20th SME Ministerial Meeting in Indonesia
How we propose conducting quarterly check-ins in preparation for the train-the-trainer

Using a quarterly questionnaire that asks:

Milestone 1: Code aligned with The KL Principles

- Do you have a completed code? Indicate the elements of The KL Principles that your completed code covers.

- If you do not have a completed code, then do you have a draft code? Indicate the elements of The KL Principles that your draft code covers. What is your plan and timeline to develop a completed code?

Milestone 2: Code approved/endorsed by association

- Where is your association in the process of approving/endorsing the code (or revisions to the code)?
  - Not in progress – Why not? What challenges are you facing?
  - In progress – Please describe (i.e., on upcoming agenda)
  - Completed
Milestone 3: Preparedness to implement the code

- How prepared does your association feel to move to implementing your code, for example to training your member companies on compliance programs and best practices?
  - Very prepared
  - Somewhat prepared
  - Not very prepared
  - Not prepared at all

Progress measured against survey results sent in prior to Brunei

Our GOAL is that by January 2013....

Associations from all 21 APEC member economies will:

✓ Achieve Milestone 1: Code aligned with The KL Principles

✓ Achieve Milestone 2: Code endorsed/approved by association

✓ Achieve Milestone 3: Very prepared to move to implementing its code, specifically the 2013 Kuala Lumpur train-the-trainer workshop
Economies that meet all milestones will be recognized at the SME Ministerials

July 2012 - First quarterly check-in to track progress in drafting/aligning codes
Oct 2012 - Second quarterly check-in to track progress in drafting/aligning codes
Jan 2013 - Third quarterly check-in to track progress in drafting/aligning codes

2013 - Train-the-trainer program on completed codes in Kuala Lumpur, Malaysia
- Awareness-building workshop on completed codes for anti-corruption officials, medical device regulators, and physician groups in Indonesia

Public-Private Monitoring Group

The Public/Private Monitoring Group will serve as the Secretariat and advisory body for the quarterly check-in process. The four members would:
1) review and approve the quarterly survey; 2) review survey results; 3) request mentors give extra support to those associations falling behind; and 4) help the Project Overseer (Lynn) report progress to the SME Ministers and Working Group. Members include:

Public:
- Lynn Costa
- Dato' Sutinah

Private:
- Chris White
- Jessie Yap
MALAYSIA ANTI-CORRUPTION ACADEMY (MACA)

FACILITIES

Conference Hall  Lecture Hall

Syndicate Room  Meeting Room
FACILITIES

Library

Computer Lab

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Brunei Darussalam | April 22-24, 2012