Workshop to Align Voluntary Codes of Business Ethics for the Biopharmaceutical Sector

Chinese Taipei
July 10-11, 2012
General Session: Opening 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 Session: Opening Remarks

Mr. Shi-Jeng Yang
Deputy Director-General, Agency Against Corruption
Ministry of Justice, Chinese Taipei
General Session: Review of the Legal and Business Case for Biopharmaceutical Sector Code of Ethics

Mr. Shaharuddin Khalid
Deputy Commissioner
Malaysian Anti-Corruption Commission (MACC)
APEC “Business Ethics for APEC SMEs” Initiative

- Recognition that Small & Medium Enterprises (SMEs) can serve as an engine of economic growth as long as they are able to operate, trade, and innovate in ethical business environments

- APEC principles for voluntary codes of business ethics in sectors with a high concentration of SMEs
  - The Mexico City Principles for the Biopharmaceutical Sector
  - The KL Principles for the Medical Device Sector
  - The Hanoi Principles for the Construction & Engineering Sector
APEC “Business Ethics for APEC SMEs” Initiative

Principles endorsed by APEC Ministers (Foreign and Trade) at the APEC Ministerial in November 2011 in Honolulu

“APEC High Level Policy Dialogue on Open Governance and Economic Growth” Chaired by U.S. Secretary of State Hilary Clinton (November 2011)

“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.”
APEC “Business Ethics for APEC SMEs” Initiative

“Actions to Address Barriers facing SMEs in Trading in the Region”
Chaired by U.S. Trade Representative Ron Kirk (November 2011)

“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...”

Statement of 2012 Meeting of APEC Ministers Responsible for Trade
Kazan, Russia (June 2012)

“We endorse the importance of initiatives in anti-corruption activities within APEC economies to strengthen trade and investment in the APEC region, particularly by promoting public-private partnerships in this sphere...We welcome continued APEC capacity building efforts to implement voluntary codes of business ethics and facilitate industry regulators and anti-corruption enforcement authorities to advance ethical collaborations in line with the APEC principles.”
Why APEC Focused on Business Ethics

**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

Source: Presentation by Dr. Philip Nichols (Professor of Legal Studies and Business Ethics at the Wharton School of Business) at the APEC Business Ethics for APEC SMEs Workshop in Gifu, Japan – September 2010.
Key Examples

As the Government of Mexico explained at the May 2011 APEC SME Ministerial in Big Sky, Montana (USA), countries with higher perceived corruption tend to have lower real per capita GDP.


And more than US$1 trillion dollars are paid in bribes every year, meaning the cost of corruption is equal to a full THREE PERCENT of world GDP.

Key Examples

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.
Why APEC Developed Voluntary Codes of Ethics

- **Benefits APEC member economies**
  - Provides a platform for effective industry self-regulation
  - Supports government enforcement and anti-corruption efforts

- **Benefits businesses, especially resource-constrained SMEs**
  - Provides companies with clarity and harmonization in rules and practices
  - Allows companies to compete across the region at a reduced cost
  - In the case of the biopharmaceutical and medical device sectors, facilitates ongoing innovation

- **Benefits patients (in the case of the biopharmaceutical and medical device sectors)**
  - Ethical collaborations fuel advances and promote access to life-saving medicines
  - Ethical collaborations ensure that decisions are made in the best interest of patients
General Session: Review of the Legal and Business Case for Biopharmaceutical Sector Code of Ethics

QUESTIONS?
General Session: Review of The Mexico City Principles – A Voluntary Regional Approach Designed to Ensure Successful Code Adoption

Mr. Neil Pratt

Assistant General Counsel, Pharmaceutical Research and Manufacturers of America (PhRMA)
The Mexico City Principles
for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector

- Recognizes that appropriate and ethical interactions help ensure medical decisions are made in the best interests of patients

- Calls upon the entire biopharmaceutical sector and eco-system to embrace aligned standards for ethical interactions, including:
  - Companies and industry associations
  - Healthcare professionals and organizations
  - Government regulators and anti-corruption enforcement authorities
The Mexico City Principles
for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector

• Drafted by 36 Expert Working Group Members from industry, government, civil society and academia from 14 APEC Economies in September 2011.

• APEC multi-year funding awarded to implement The Mexico City Principles

• Implementation supported by:
  - APEC Life Sciences Innovation Forum
  - APEC Health Working Group
  - APEC Anti-Corruption & Transparency Working Group
  - APEC Business Advisory Council (ABAC)
The Mexico City Principles

*Biopharmaceutical Sector Codes of Ethics*

**Healthcare and Patient Focus** means everything we do is intended to benefit patients.

**Integrity** means dealing ethically, honestly, and respectfully in everything we do.

**Independence** means to respect the need of autonomous decision-making of all parties, free from improper influence.

**Legitimate intent** means everything we do is for the right reasons, is lawful, and aligns with the spirit and values of these Principles.

**Transparency** means a general willingness to be open about our actions while respecting legitimate commercial sensitivities and intellectual property rights.

**Accountability** means a willingness to be responsible for our actions and interactions.
## The Mexico City Principles

for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector

**The Principles cover:**

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<td>Safety of Medicines</td>
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<td>Patient Organizations</td>
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<td>17.</td>
<td>Adherence to Principles</td>
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Beyond companies and industry associations, the Principles also cover implementation by healthcare professional organizations and governments.

**The Mexico City Principles**

**for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector**

Implementation

In order to promote an ethical commercial environment, cooperation among multiple stakeholders is required. Therefore, it is recommended that Companies, healthcare professionals, and APEC economies engage in the following activities:

**Companies and industry associations should:**

- Develop and implement codes of ethics consistent with the Principles set out above. Industry associations should consider publishing those members who have signed onto the industry codes, among other steps to encourage adoption of industry codes.
- Make available training regarding industry codes of ethics to healthcare professionals and healthcare professional students in collaboration with recognized authorities.
- Contribute to and participate in capacity building, in particular for small and medium sized enterprises (SMEs).
- Work together to ensure that the above Principles and their industry codes of ethics remain relevant and effective to address new business arrangements that may emerge.

**Healthcare professional organizations should:**

- Respect these Principles and develop and implement codes of ethics consistent with the above principles.

**APEC Economies should:**

- Develop and make known clear, distinctive, accountable, and comprehensive policies on procurement processes and procedures.
- Encourage industry regulators and/or anti-corruption enforcement authorities to endorse and support the above Principles and national and local industry codes of ethics, where appropriate.
- Encourage Companies to adhere to the above Principles and national and local industry codes of ethics.
- Formulate and promote clear laws and regulations that are objectively applied.
- 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.

Appendix

- Work together to ensure that the above Principles remain relevant and effective to address new business arrangements that may emerge.

For the purpose of these Principles, the following definitions are provided:

"Congress" means an event sponsored and organized by a society, college, university or other non-Company entity for the purpose of providing medical and/or scientific information.

"Consultant" means an external, independent healthcare professional, scientist, patient association/patient representative, public or private referred individually or through an entity (e.g. university, hospital or research organization) to provide advice, information or other services.

"Healthcare Professional" means a provider of medical or health services and any other person or organization that furnishes, bills, or is paid for health care in the normal course of business, including but not limited to physicians, nurses, or pharmacists and their staff.

"Representative" means a person calling on healthcare professionals and/or their staff on behalf of a Company regarding the promotion or discussion of medicines.
General Session: Review of The Mexico City Principles – A Voluntary Regional Approach Designed to Ensure Successful Code Adoption

Mr. Ivan Ornelas Diaz

Co-Chair, APEC Expert Working Group to Develop an APEC Voluntary Code of Ethics for the Biopharmaceutical Sector & Director of International Relations, Mexican Ministry of Economy
WORKSHOP OBJECTIVE

To Support Biopharmaceutical Sector Associations Align Codes of Business Ethics with The Mexico City Principles
WHY WE NEED THIS REGIONAL INITIATIVE

• It’s a collective action, manifestation of APEC Ministers endorsement, and a pact by industry to encourage sustainability of the biopharmaceutical sector

• Standardize behavior among APEC economies in doing business in the biopharmaceutical sector

• Capacity building and strengthening accountability against unethical behavior, extending beyond industry to include healthcare professional organizations and governments
WHY ARE WE HERE

• To align voluntary codes of business ethics with The Mexico City Principles in a manner that is acceptable to all economies

• Make corruption and unethical behavior culturally and morally unacceptable in the biopharmaceutical sector throughout the APEC region
General Session: Review of The Mexico City Principles – A Voluntary Regional Approach Designed to Ensure Successful Code Adoption

QUESTIONS?
Coffee Break

10:15 – 10:30
Panel Discussion
Lessons Learned in the Biopharmaceutical Sector: Voluntary Code Implementation and SME Challenges

AUSTRALIA - Mr Michael Schwager
Head of Division
Industry and Small Business Policy Division (ISBP)
Department of Industry, Innovation, Science, Research & Tertiary Education
Australia: Lessons Learned in Prescription Medicines Industry Voluntary Code Implementation
Scope of Australian Codes

• Codes aligned with Therapeutic goods sectors:
  – Prescription medicines (innovator, biotech & generic)
  – Non-prescription medicines
  – Complementary Medicines
  – Medical Devices

• Efforts to develop consistency across sector
  – Ethical Principles
  – Operational areas and Governance
Scope of Australian Codes: Prescription medicines

• Address relationships between healthcare professionals and industry
• Focus is on ethical and transparent interactions – whether promotional or educational
• Concept of ‘healthcare professionals’ includes all who may prescribe, recommend, dispense
• Decision to prescribe, dispense or recommend a product must be in the best interests of a patient
Who does the Code apply to?

• Mandatory for members of industry association – Medicines Australia & GMiA
• Voluntary for non-members – raises issues of level playing field
• Codes include regular monitoring and enforcement of Code compliance
• Penalties and public reporting of breaches
Challenges for SMEs

- Ensuring that Code compliance has senior management commitment – driven from the top
- Ensuring that all staff are aware of Code – education & training
- Ensuring that all staff comply with Code – internal approval & monitoring processes
- Ensuring there is a confidential process to raise a breach of the Code with management
Panel Discussion:
Lessons Learned in Biopharmaceutical Sector
Voluntary Code Implementation
and SME Challenges

HONG KONG, CHINA - Ms. Sabrina Chan

Executive Director
The Hong Kong Association of the Pharmaceutical Industry (HKAPI)
Panel Discussion:
Lessons Learned in Biopharmaceutical Sector Voluntary Code Implementation and SME Challenges

THE PHILIPPINES - Mr. Reiner Gloor

Executive Director
The Pharmaceutical and Healthcare Association of the Philippines (PHAP)
Panel Discussion: Lessons Learned in Biopharmaceutical Sector Voluntary Code Implementation and SME Challenges

Interactive Q&A and Discussion

• What are the opportunities and challenges your association has faced during implementation of a code of business ethics?

• How has your association worked with other key stakeholders to improve the ethical business environment in your local economy?

• What are the challenges facing small and medium enterprises in this process as well as best practice solutions to address them?
Panel Discussion:
Unique Legal, Cultural, and Industry Factors Prevailing in Developing Local Voluntary Codes

INDONESIA - Mr. Johannes Setijono

Chairman
Indonesia Pharmaceutical Association (GP Farmasi)
APEC WORKSHOP PANEL DISCUSSION

Presentation by: Drs. Johannes Setijono, Apt.
Chairman of GP Farmasi Indonesia (Indonesian Pharmaceutical Association)
GP Farmasi is a non-profit organization that comprises of pharmaceutical companies in Indonesia. GP Farmasi was established in August 1969. GP Farmasi as a forum of communication and consultation with the government and other related parties on matters of drug production, distribution and services. The membership is divided into 4 sectors:

<table>
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<tr>
<th>Sector</th>
<th>TOTAL</th>
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<tbody>
<tr>
<td>Industry</td>
<td>239</td>
</tr>
<tr>
<td>Distribution/Wholesalers</td>
<td>2300</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>3193</td>
</tr>
<tr>
<td>Drug Store</td>
<td>2289</td>
</tr>
</tbody>
</table>

Source: GP Farmasi Data, 2011
Set a high standard for pharmaceutical industry in carrying out marketing activities of ethical products, include:

- Information and narratives of pharmaceutical product
- Medical Representative
- Symposium, congress and continuous medical education
- Donations to the health professions
- Printed goods for promotion/advertising
- Etc.

GP Farmasi Indonesia issued Code of Ethics and the Conduct of pharmaceutical business in 2003

The government initiated mutual agreement of ethical drug promotion between GP Farmasi and Indonesian Medical Association (Ikatan Dokter Indonesia - IDI) in 2007

Government approach in implementing Code of Conduct
Ethical drug promotion and mutual agreement between the GP Farmasi Indonesia and IDI (Indonesian Doctors Association):

In relation with drugs promotion, the doctor is prohibited to dictate their patients to buy particular medicine because they have received commissions from certain pharmaceutical companies.

In attending scientific meetings, any support given by pharmaceutical companies to the doctor should not be binding with the obligation to promote or prescribe any certain product.

Pharmaceutical companies may provide sponsorship to a doctor on an individual basis in continuing medical education, which is only covered for the cost of registration, accommodation and transportation.
Ethical drug promotion and mutual agreement between the GP Farmasi Indonesia and IDI (Indonesian Doctors Association):

Pharmaceutical companies are prohibited in giving honorarium and/or allowances to a physician to attend continuing medical education, unless the physician is acted as a speaker or a moderator.

In case of donations to the medical profession, pharmaceutical companies should not offer any gifts/rewards, incentives, donations, and other similar forms, which is associated with their professional capacity in prescribing of particular drug / product of specific company.

Donations or gifts from pharmaceutical companies are limited for medical and professional organizations and not given to individual physicians.

Indonesian Medical Association (Ikatan Dokter Indonesia - IDI) (including specialist organizations and other organizations within IDI) must arrange and verify the official activities of the organization, particularly related to sponsorship or funding of GP Farmasi Indonesia members and coordinate with GP Farmasi Indonesia to conduct the follow-up action.
**Unique Legal**

- GP Farmasi form code of ethics council in order to control and supervise code of conduct implementation of pharmaceutical business in Indonesia.
- It applies to all GP Farmasi members, especially for industry and distribution sector (e.g. marketing-related).
- Formation of a code of ethics committee to supervise code of conduct pharmaceutical business implementation in Indonesia.

**Opportunities & Constraints**

- Moral sanction imposed (e.g. Letter of warning or expelled from membership) will not reduce infringing code of conduct as very difficult to prove.

**Best Practice Solutions**

- Promote and socialize regulation No. 51/2009 (Section 24) regarding pharmacist practice in allowing changes from branded into generic drugs.
Thank You

We wish to share a better & beneficial relationship and grow together with all our strategic partners.
Panel Discussion: Unique Legal, Cultural, and Industry Factors Prevailing in Developing Local Voluntary Codes

PERU – Mr. Mario Mongilardi
President
COMSALUD – Lima Chamber of Commerce
WORKSHOP TO ALIGN VOLUNTARY CODES OF BUSINESS ETHICS FOR THE BIOPHARMACEUTICAL SECTOR

Grand Formosa Regent Taipei
Taipei, Chinese Taipei
July 10-11, 2012
MAIN INDICATORS - 2011

GDP: US$ 167,000 MILLIONS
POPULATION: 30.4 MILLIONS
INFLATION: 4.7%
EXPORTS: US$ 44.6 MILLIONS
IMPORTS: US$ 36.6 MILLIONS

SOURCE: IMF
Perú: PBI 2008-2012 (Var % anual)

- 2008: 9.8
- 2009: 0.9
- 2010: 8.8
- 2011*: 6.8
- 2012*: 4.7

SOURCE: IMF
INFLATION

SOURCE: IMF
FISCAL BALANCE

NOTE: % OF GDP
SOURCE: IMF
PUBLIC DEBT

<table>
<thead>
<tr>
<th>Year</th>
<th>Debt (%)</th>
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<tbody>
<tr>
<td>2008</td>
<td>24.1</td>
</tr>
<tr>
<td>2009</td>
<td>27.2</td>
</tr>
<tr>
<td>2010</td>
<td>23.5</td>
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<tr>
<td>2011*</td>
<td>21.2</td>
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<tr>
<td>2012*</td>
<td>20.1</td>
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NOTE: % OF GDP
SOURCE: IMF
Cámara de Comercio de Lima
Founded in 1888, more than 124 years

Membership: 10,500 companies

Not compulsory, voluntary membership

84.6 % of members have less than 50 employees

61.5 % of members have less than 10 employees

National coverage through PeruCamaras (61 Local Chambers of Commerce)

ISO 9001 Certification
THE LIMA CHAMBER OF COMMERCE IS ORGANIZED IN 14 COMMITTEES.

COMSALUD IS THE LARGEST OF THESE COMMITTEES.

IT IS ALSO THE LARGEST TRADE ASSOCIATION WITHIN THE HEALTH SECTOR.

COMSALUD MEMBERS ARE MANUFACTURERS AND IMPORTERS OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES.
WHAT COMSALUD AND LCC OFFERS

Support to take advantage of business growth

Business Contacts

Training

Updated information

Legal and labor advisory

Training Center for SEs

INFOSIE (IEDEP)

Master Conference Program (LCC-ESAN)

Legal Assistance Center for SEs Development

Family Business Program LCC - IDB

Business and Convention Center

4 decentralized facilities for services

SEs sell to the government Program
WHAT COMSALUD AND LCC OFFERS

- Commercial
- Showroom
- Promotion
- Guides
- Publications

- Strategic Alliance Program
- Specialized and Sectorial Guides for SEs
- Business Directory
- Local and International Fairs / Expos
- Marketplace (online)
WHAT COMSALUD AND LCC OFFERS

- Export to Europe Program for SE’s (CBI Holland)
- AI Invest IV Program for Internationalization (European Union)
- International Business Round Tables (ISO 9001)
- Foreign Trade International Summit
- Project of Labeling and Market Surveillance (EU)
- Guides to reach international markets
- Foreign Trade Certifications
- Programs for IT - SEs (IDB)

International Trade

- Technical assistance
- International Institutions (partners)
- Business opportunities
- Global network
WHAT COMSALUD AND LCC OFFERS

Improving the Business Environment

- Reduction of bureaucratic barriers
- Legislative initiatives
- Lobbying
- Publications

SE’s Representation and Defense (Consumer code, free competition, patents and trademarks)

Legislative Coordination Office

Institute of Economic and Business Development

Forums and events (Taxation, economics, labor, market access, SMEs)

Weekly business magazine and other publications

CCL TVi Online
- 2011: US$ 1,400 MILLIONS

- 34% IMPORTS / 66% LOCAL
PHARMACEUTICAL IMPORTS

- 2011: US$ 384.3 MILLIONS
THE PERU EXPERIENCE:

- IN A COMPETITIVE ENVIRONMENT, THE LACK OF CODES OF ETHICS MIGHT STIMULATE QUESTIONABLE COMMERCIAL PRACTICES.

- IF THE SECTOR IS NOT SELF REGULATED, THE POLITICIANS WITH COVER THAT SPACE.
- IF THIS HAPPENS, SUCH REGULATIONS ARE NOT ALWAYS BASED ON TECHNICAL ASPECTS.

- CONSUMERS NORMALLY SUPPORT SUCH KIND OF REGULATIONS.

- THIS IS NOT GOOD FOR THE BUSINESS, PATIENTS AND HEALTH PROFESSIONALS.
- COMSALUD BOARD DECIDED TO ADOPT A VOLUNTARY COMMERCIAL ETHIC CODE, BASED ON BRUNEI SUGGESTIONS FOR MEDICAL DEVICES.

- ITS MEMBERS WILL SIGN THE CODE THIS MONTH IN A PUBLIC CERENOMY. THEY WILL RECEIVE A CORRESPONDING CERTIFICATE.

- COMPANIES SIGNING THE CODE ARE ALLOWED TO SAY SO IN ITS PUBLICITY.
- COMSALUD also appointed an Ethic Commission to follow up compliances to the code and resolve related disputes.

- The Commission should have credibility and independence. It should be also accepted by the signing companies.

- COMSALUD appointed a Commission form by ex presidents.
Panel Discussion:
Unique Legal, Cultural, and Industry Factors Prevailing in Developing Local Voluntary Codes

THE PHILIPPINES – Mr. Tomas M. Agana III

President
The Philippine Chamber of the Pharmaceutical Industry (PCPI)
Panel Discussion: Unique Legal, Cultural, and Industry Factors Prevailing in Developing Local Voluntary Codes

Interactive Q&A and Discussion

• What are the unique legal, cultural, and industry factors – both opportunities and constraints – that impact code of ethics development and implementation in your local economy?

• How has your association responded to these unique factors and where do constraints still remain?

• What are best practice solutions to these constraints?
Lunch Break

12:30 – 13:30
Breakout Session: Aligning Voluntary Codes with The Mexico City Principles

13:30-17:00
Aligning Voluntary Codes with The Mexico City Principles

Key Breakout Session Discussion Points:

• Overview of local association’s operating environment, including existing codes of ethics (e.g. medical, hospital, and distributors), existing government guidelines and regulations, and voluntary industry action in other sectors.

• Maturity and independence of local association

• Biopharmaceutical industry presence and business arrangements in the economy

• Current local economy anti-bribery law and policy
General Session: Report Out from Breakout Sessions

17:00 - 17:30
Workshop to Align Voluntary Codes of Business Ethics for the Biopharmaceutical Sector

Chinese Taipei
July 10-11, 2012
General Session: Opening Remarks

Ms. Lynn Costa

Project Overseer
&
Senior Trade Development Advisor
U.S. Department of Commerce
Breakout Session:
Aligning Voluntary Codes with The Mexico City Principles

9:15-12:00
Aligning Voluntary Codes with The Mexico City Principles

Key Breakout Session Discussion Points:

• Detailed review of The Mexico City City Principles
• Identify governance and stakeholder process to develop, customize and adopt/update a code of business ethics
• Develop association plan of action, timeline, and resource needs
General Session:
Report Out from Breakout Sessions

12:00 - 12:30
Lunch Break

12:30 – 13:30
Breakout Session:
Aligning Voluntary Codes
with The Mexico City Principles

13:30-16:30
Aligning Voluntary Codes with The Mexico City Principles

Key Breakout Session Discussion Points:

- Detailed review of The Mexico City City Principles
- Identify governance and stakeholder process to develop, customize and adopt/update a code of business ethics
- Develop association plan of action, timeline, and resource needs
General Session:
Report Out from Breakout Sessions

16:30 - 17:00
General Session: Closing Remarks on Next Steps and Tracking Progress

Ms. Lynn Costa

Project Overseer
&
Senior Trade Development Advisor
U.S. Department of Commerce
What we have achieved in 18 months: From Gifu (Oct 2010) to Taipei (July 2012)

- **September 2010, Gifu, Japan**
  - APEC medical device workshop
  - Call by SME Ministers for APEC codes of business ethics

- **April 6-7, 2011, Kuala Lumpur, Malaysia**
  - Expert Working Group (EWG) formulates The KL Principles for the Medical Device Sector

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

- **November 2011, Honolulu, USA**
  - APEC Ministers (Foreign and Trade) endorse The KL, Mexico City, and Hanoi Principles

- **April 23-24, 2012, Brunei Darussalam**
  - APEC Workshop to Draft Voluntary Codes of Business Ethics for the Medical Device Sector

- **November 2010, Yokohama, Japan**
  - APEC Ministers welcomed development of codes to better align industry practices across APEC economies

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

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

- **June 5, 2011, Kazan, Russia**
  - APEC Ministers Responsible for Trade reaffirm support for the implementation of voluntary codes of business ethics

- **July 10-11, 2012, Taipei, Chinese Taipei**
  - APEC Workshop to Align Voluntary Codes of Business Ethics for the Biopharmaceutical Sector
What we will achieve in the NEXT 16 months: From Taipei (July 2012) to Indonesia (2013)

**October 2012**
First quarterly check-in to track progress in aligning codes

**January 2013**
Second quarterly check-in to track progress in aligning codes

**April 2013**
Third quarterly check-in to track progress in aligning codes

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

- **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

- **Fall 2013 (TBC)**
  Report progress to SME Ministers at 20th SME Ministerial Meeting in Indonesia
What we will need from YOU

October 2012
First quarterly check-in to track progress in aligning codes

January 2013
Second quarterly check-in to track progress in aligning codes

April 2013
Third quarterly check-in to track progress in 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

April/May 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-in process to prepare for the train-the-trainer

Using a quarterly questionnaire that asks:

Milestone 1: Code aligned with The Mexico City Principles

- Do you have a completed code? Indicate the elements of The Mexico City 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 Mexico City 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 APEC Workshop in Taipei
Our GOAL is that by Spring 2013....

Associations from all APEC member economies will:

- **Achieve Milestone 1:** Code aligned with The Mexico City Principles

- **Achieve Milestone 2:** Code endorsed/approved by association

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

**October 2012**  
First quarterly check-in to track progress in aligning codes

**January 2013**  
Second quarterly check-in to track progress in aligning codes

**April 2013**  
Third quarterly check-in to track progress in aligning codes

- 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

**April/May 2013 (TBC)**  
Report progress to SME Working Group

**Fall 2013 (TBC)**  
Report progress to SME Ministers at 20th SME Ministerial Meeting in Indonesia
Public-Private Implementation Group

The Public/Private Implementation 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
- Ivan Ornelas Diaz

Private:
- Sabrina Chan (TBC)
- Sabina Sudan (TBC)
MALAYSIA ANTI-CORRUPTION ACADEMY (MACA)
FACILITIES

Conference Hall

Lecture Hall

Syndicate Room

Meeting Room
FACILITIES

Library

Computer Lab
ROOMS:
20 suites
30 deluxe
20 twin sharing
8 dorms