BIOPHARMACEUTICAL SECTOR

OPENING SESSION

Mr. Patrick Kirwan
U.S. Delegate, APEC SME Working Group
Director, Trade Promotion Coordinating Committee
U.S. Department of Commerce
APEC’S JOURNEY IN ETHICAL BUSINESS CONDUCT CAPACITY-BUILDING

Mr. Thomas Cueni, Industry Co-Chair, APEC Biopharmaceutical Working Group on Ethics

Director General, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
More than 70 percent of SMEs in transition economies perceive corruption as an impediment to their business.

1/3 of SMEs view corruption as a major business obstacle.

Source: World Bank and EBRD
The Journey from 2010 to 2017
The Journey from 2018 to 2019 and Beyond

APEC SME Leaders in Ethics and Integrity Program (LEIP)

SME Guide to the APEC Mexico City Principles

Tailoring Resources to Your Enterprise:

Need/Motivation:
- What is your need/motivation for using the site?
- Does your company have a code of ethics?
- Are you aware of the Mexico City Principles?
- Does your industry association have a code of ethics?

Enterprise Segmentation:
- What is the size of your enterprise?
- What type of business is your enterprise?

Governance:
- What is your role in the company?

Resource Toolkit

<table>
<thead>
<tr>
<th>Resource Name</th>
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<tbody>
<tr>
<td>Communicating the Value of High Standard Business Ethics Within a Small and Medium-Sized Enterprise (SME)</td>
<td>Microsoft PowerPoint</td>
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<tr>
<td>Compliance Program Outcomes: A toolkit to build upon the 6 elements of a compliance program including: examples, outcomes, measurements, and materials</td>
<td>Microsoft Word</td>
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<tr>
<td>The Value from and Responsibility for Ensuring Ethical Codes of Conduct: Industry and Association Responsibilities</td>
<td>Microsoft PowerPoint</td>
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<tr>
<td>Data on Ethical Performance</td>
<td>Microsoft PowerPoint</td>
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ESTABLISHING TONE AT THE TOP:
INSIGHT FROM SME CHIEF EXECUTIVES AND ASSOCIATIONS

Facilitator:

Discussants:

Ms. Sabrina Chan
HONG KONG, CHINA

Mr. Le Quoc Khanh
VIET NAM

Mr. Vicente Astorga
CHILE

Mr. Ma Ensheng
CHINA

Mr. Rafael Andres
Diaz Granados
REGIONAL (LATIN AMERICA)
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MORNING TEA/COFFEE BREAK
10:45 – 11:00
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APEC SME LEADERS IN ETHICS AND INTEGRITY PROGRAM ("LEIP")

Ms. Kate Hamann
Partner, Pierce Atwood
SME Compliance Program Trainer

Ms. Karen Eryou
Head, Global Ethics & Compliance Programs, UCB

Ms. Chrisoula Nikidis
Head of Ethics and Compliance, Takeda (Canada)
The Journey since 2010

INDUSTRY ASSOCIATIONS WITH A CODE OR CODE COMMITMENT

- ASSOCIATIONS WITH A CODE OR CODE COMMITMENT
- ASSOCIATIONS WITHOUT A CODE OR CODE COMMITMENT
The Journey from 2018 to 2019 and Beyond

APEC SME Leaders in Ethics and Integrity Program (LEIP)
APEC SME LEADERS IN ETHICS AND INTEGRITY PROGRAM ("LEIP")

Goals:
• Incentivize Chief Executive Officers/heads of country operations to prioritize ethics and integrity within their organizations – ensuring commitment from the top
• Provide not just the downsides to unethical conduct, but to make the business case for ethics and integrity
• Create a network of leaders to continually enhance ethics and integrity across the sector
• Establish metrics that can be used to measure genuine implementation of the Codes of Conduct over time

Stakeholders:
• Business Ethics for APEC SMEs Initiative
• Industry Associations
• Enterprises (Large, Medium, and Small)
• Governments
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APEC SME LEADERS IN ETHICS AND INTEGRITY PROGRAM (“LEIP”)

- **Phase One**, Invitation Selection

- **Phase Two**, Ethics and Integrity Assessment: online assessment to verify their level of efforts to implement ethical business practices in their organization

- **Phase Three**, LEIP Seminar: SME leaders to participate in an in-person seminar that includes 1) the business case for ethics and integrity and 2) low-cost methods of creating a culture of integrity.

- **Phase Four**, Networking Meeting and Certification: Incentives for participation in the program, including interacting with peers and potential collaborators or customers; certification or other external opportunity to demonstrate commitment to the program
Ongoing Network

Phase Five

• In period following the seminar, SME leaders will participate in a brief survey;

• Those who have completed LEIP will be invited periodically to return to refresh and catch up on new developments, as well as to share their experiences;

• Continued engagement online and in-person, including feedback on ways to improve the LEIP over time; and

• Gather metrics on participation and continuing commitment.
APEC SME LEADERS IN ETHICS AND INTEGRITY PROGRAM (“LEIP”) DELEGATE EXERCISE (15 MINUTES)

• What does success look like for APEC SME LEIP? What incentives could encourage SME leaders to participate (i.e., networking or international recognition)?

• What could be the benefits and consequences of offering SME leaders certification or membership as a component of APEC SME LEIP?

• Should APEC SME LEIP differ between APEC member economies and, if so, how?

• How should industry associations recruit APEC SME LEIP participants?
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LUNCH (SAN CRISTOBAL A)
11:45 – 12:45
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INAUGURAL CHINA INDUSTRY ASSOCIATION SURVEY AND REPORT

Ms. Patricia Wu
Managing Director
Crowell & Moring International
Overview

• First survey on code of ethics implementation by China’s biopharmaceutical industry association

• Circulated to the 25 industry association signatories of the *Consensus Framework for the Ethical Collaboration in the Pharmaceutical and Medical Device Sectors*

• Responses from 13 of the 25 signatories
Key finding 1:
General awareness of “business ethics” but lack of in-depth understanding

• While 85% of respondents recognize the importance of business ethics for the industry’s future only 46% understand the concepts of business ethics guidelines related to the biopharmaceutical industry “very well”
Key finding 2:
Interest to adopt ethical guidelines

• 55% of respondents already officially adopted ethical guidelines.

• Of those who have not 71% are now actively considering officially adopting ethical guidelines.
Key finding 3:
Strong interest to improve capacity, building on existing training

- Nearly all respondents expressed interest in training activities to develop business ethics guidelines.
- 83% already provide some form of training.
Key finding 4:
Opportunity to find consensus on how to achieve alignment among associations

• When asked to choose a preferred approach to ensure alignment among associations...
  • 47% chose “common principles among associations”
  • 40% chose “establish partnerships with the government”
  • 17% chose “establishment of a recognized ethics committee between associations”
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PATIENT ORGANIZATIONS AND IMPLEMENTING THE APEC PRINCIPLES

Mr. Russell Williams
Patient Co-Chair, APEC Biopharmaceutical Working Group on Ethics
Senior Vice President, Diabetes Canada
THE APEC MEXICO CITY PRINCIPLES

Preamble

1. Companies engage in the development, manufacturing, research, marketing, distribution, and/or sale of medicines to benefit patients.

2. Ethical relationships with healthcare professionals, government officials, patients, and other stakeholders are critical to the mission of Companies to help patients by developing and making medicines available.

11. Companies will respect the independence of patient organizations.

16. Patient Organizations

A. Companies should respect the autonomy of patient organizations and their independence.

B. Support from Companies must not be conditional on the promotion of a specific medicine.
THE NANJING DECLARATION

Nanjing, China, 2 September 2014
2014 APEC Business Ethics for SMEs Forum:
Nanjing Declaration – Promoting Ethical Environments in the Medical Device and Biopharmaceutical Sectors through 2020

1. We, representatives from healthcare providers and professional organizations, anti-corruption agencies, health ministries, health regulatory agencies, economic ministries, medical device and biopharmaceutical associations, industry and patient organizations from across the APEC region, convened in Nanjing, China today to chart the future course of our joint efforts to advance the “Business Ethics for APEC SMEs Initiative” in the medical device and biopharmaceutical sectors. We do so with knowledge that nearly 1,000 stakeholder representatives have engaged in this initiative from all 21 APEC member economies to strengthen ethical business practices for the medical device and biopharmaceutical sectors, including more than 10,000 SMEs, and that this initiative has proven to be an effective model.

Table:

- Support partnerships with government agencies, HCPs and industry associations.

For non-government organizations, in particular patient organizations:
Promote ethical environments in the medical device and biopharmaceutical sectors.
CONSENSUS FRAMEWORKS
TOKYO COMMITMENTS ON PATIENTS (2018)

• PATIENT ORGANIZATIONS TO SUPPORT THE ACHIEVEMENT OF UNIVERSAL CONSENSUS FRAMEWORKS

• PATIENT ORGANIZATIONS TO FORM “ETHICS NETWORK” UNDER BUSINESS ETHICS FOR APEC SMES INITIATIVE TO EXPAND ENGAGEMENT IN BUSINESS ETHICS – WITH INITIAL COMMITMENTS FROM AUSTRALIA, CANADA, CHILE, JAPAN, AND PHILIPPINES.

• PATIENT ORGANIZATIONS TO SUPPORT ONGOING INITIATIVE ACTIVITIES IN BEST PRACTICES AND CAPACITY-BUILDING
BREAKOUT EXERCISE GUIDANCE

• EACH TABLE TO CONSIDER THE FOLLOWING KEY QUESTIONS:
  • ARE PATIENT ORGANIZATIONS KEY TO STRENGTHENING BUSINESS ETHICS IN THE SECTOR?
  • HOW DO WE MAKE PATIENT ORGANIZATION ENGAGEMENT SUCCESSFUL ON ETHICAL BUSINESS PRACTICES?
  • WHAT ROLE SHOULD WE CONSIDER FOR PATIENT ORGANIZATIONS REGIONALLY VS. WITHIN OUR ECONOMIES?

• AFTER 30 MINUTES OF FACILITATED DISCUSSION, RAPPORTEURS TO PROVIDE BRIEF SUMMARY OF THE KEY TAKEAWAYS AS WELL AS SUBMIT WRITTEN SUMMARY TO THE PATIENT CO-CHAIR
BIOPHARMACEUTICAL SECTOR

HEALTHCARE PROFESSIONAL ORGANIZATIONS AND IMPLEMENTING THE APEC PRINCIPLES

Ms. Patricia Wu
Managing Director
Crowell & Moring International
BREAKOUT EXERCISE GUIDANCE

• EACH TABLE SHOULD CONSIDER THE FOLLOWING KEY QUESTIONS:

• WHO IN THE HCP COMMUNITY SHOULD THIS INITIATIVE BE TARGETING TO INCREASE HCP ENGAGEMENT AND COLLABORATION?

• HOW DO WE CREATE AN HCP NETWORK COMMITTED TO CONSISTENTLY WORK WITH THIS INITIATIVE?

• WHAT IN THE INITIATIVE’S CURRENT TOOLBOX MAY BE OF USE TO HCPS?

• WHAT IS NOT IN THE INITIATIVE’S CURRENT TOOLBOX THAT SHOULD BE CO-CREATED WITH AND FOR HCPS?
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AFTERNOON TEA/COFFEE BREAK

15:00 – 15:30
AGENDA:
1. ROLL CALL OF MEMBERS (5 MINUTES)
2. WELCOME REMARKS / SUMMATION OF 2019 WG MEETINGS (5 MINUTES)
3. MEASURING THE POSITIVE IMPACT OF ETHICAL BUSINESS PRACTICES (30 MINUTES)
4. EXPANDING THE SUSTAINABILITY OF RESOURCES (40 MINUTES)
5. SUPPORTING THE SUCCESS OF APEC SME LEIP (30 MINUTES)
6. WORKING GROUP MEMBERSHIP (5 MINUTES)
7. CLOSING REMARKS / SUMMATION OF RECOMMENDATIONS (5 MINUTES)