



# 2019 APEC Business Ethics for SMEs Forum

SANTIAGO DE CHILE | 9-10 SEPTEMBER





## BIOPHARMACEUTICAL SECTOR



### OPENING SESSION

*Mr. Patrick Kirwan*

*U.S. Delegate, APEC SME Working Group*

*Director, Trade Promotion Coordinating Committee*

*U.S. Department of Commerce*



## BIOPHARMACEUTICAL SECTOR



### 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)*



## Ethical Business Conduct Matters to SMEs

**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





## The Journey from 2010 to 2017



Asia-Pacific  
Economic Cooperation

2011/CSOM/021  
Agenda Item: 3

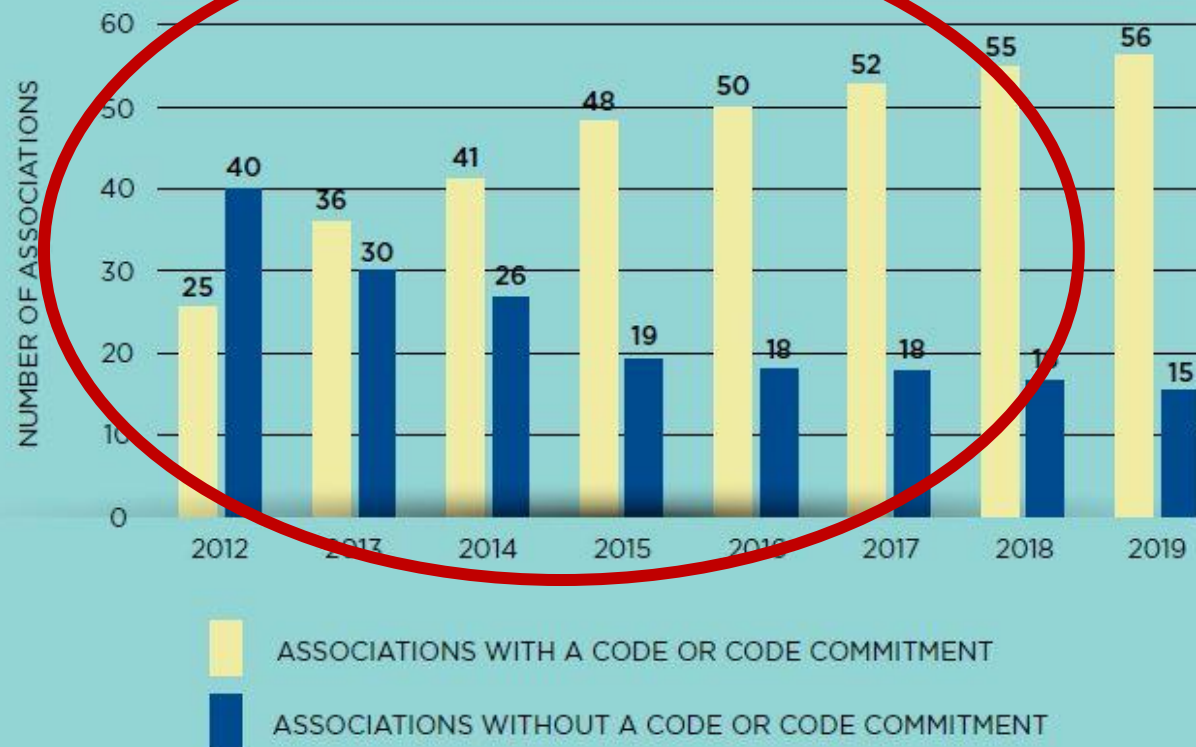
### The Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector

Purpose: Consideration  
Submitted by: SMEWG Chair



Concluding Senior Officials' Meeting  
Hawaii, United States  
8-9 November 2011

### INDUSTRY ASSOCIATIONS WITH A CODE OR CODE COMMITMENT





## The Journey from 2018 to 2019 and Beyond

### SME Guide to the APEC Mexico City Principles

#### Tailoring Resources to Your Enterprise:

User note: Please note that these responses are anonymous (no data will be collected) and this platform is designed towards guiding your enterprise towards the most useful resources and tools for building a compliance program.

##### 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

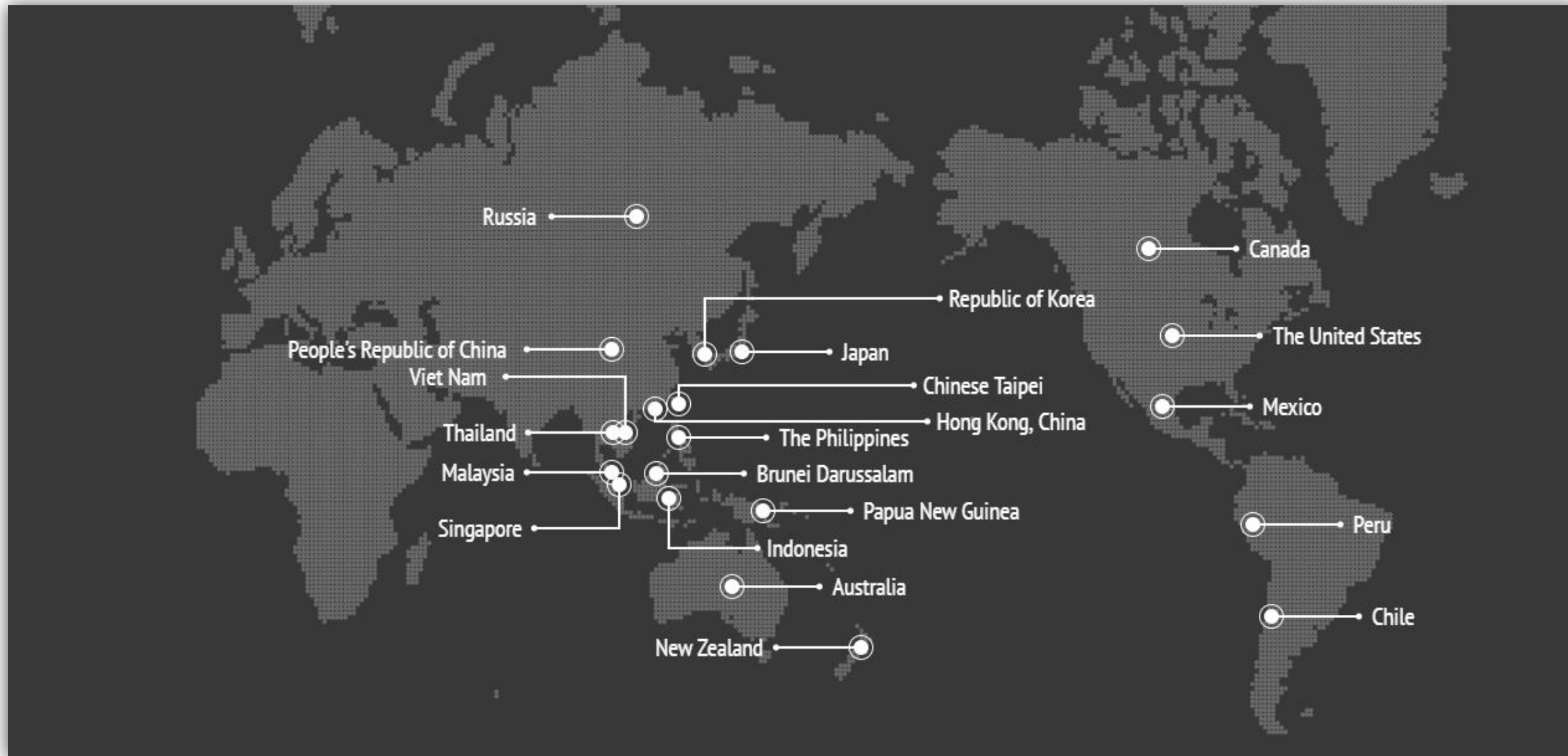
Resource Name	Format
Communicating the Value of High-Standard Business Ethics: Within a Small and Medium Sized Enterprise (SME)	Microsoft PowerPoint   <a href="#">PDF</a>
Compliance Program Outcomes: A tool to build upon the 6 elements of a compliance program including ideas, examples, outcomes, measurements, and materials	Microsoft Word   <a href="#">PDF</a>
The Value from and Responsibility for ensuring Ethical Codes of Conduct: Industry and Association Responsibilities	Microsoft PowerPoint   <a href="#">PDF</a>
Data on Ethical Performance	Microsoft PowerPoint   <a href="#">PDF</a>

## APEC SME Leaders in Ethics and Integrity Program (LEIP)



# 2019 APEC Business Ethics for SMEs Forum

SANTIAGO DE CHILE | 9-10 SEPTEMBER







## BIOPHARMACEUTICAL SECTOR

ESTABLISHING TONE AT THE TOP:  
*INSIGHT FROM SME CHIEF EXECUTIVES AND ASSOCIATIONS*

**Facilitator:**

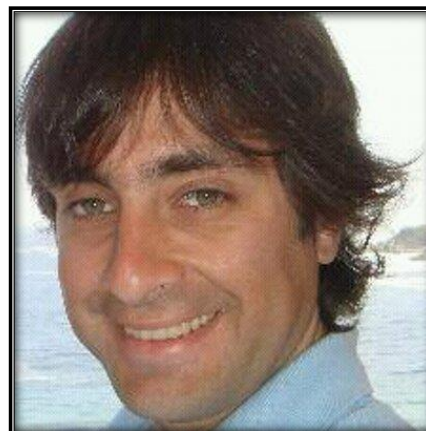


**Ms. Sabrina Chan**  
HONG KONG, CHINA

**Discussants:**



**Mr. Le Quoc Khanh**  
VIET NAM



**Mr. Vicente Astorga**  
CHILE



**Mr. Ma Ensheng**  
CHINA



**Mr. Rafael Andres  
Diaz Granados**  
REGIONAL (LATIN AMERICA)





## BIOPHARMACEUTICAL SECTOR

# MORNING TEA/COFFEE BREAK

## 10:45 – 11:00



## BIOPHARMACEUTICAL SECTOR

### APEC SME LEADERS IN ETHICS AND INTEGRITY PROGRAM (“LEIP”)



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



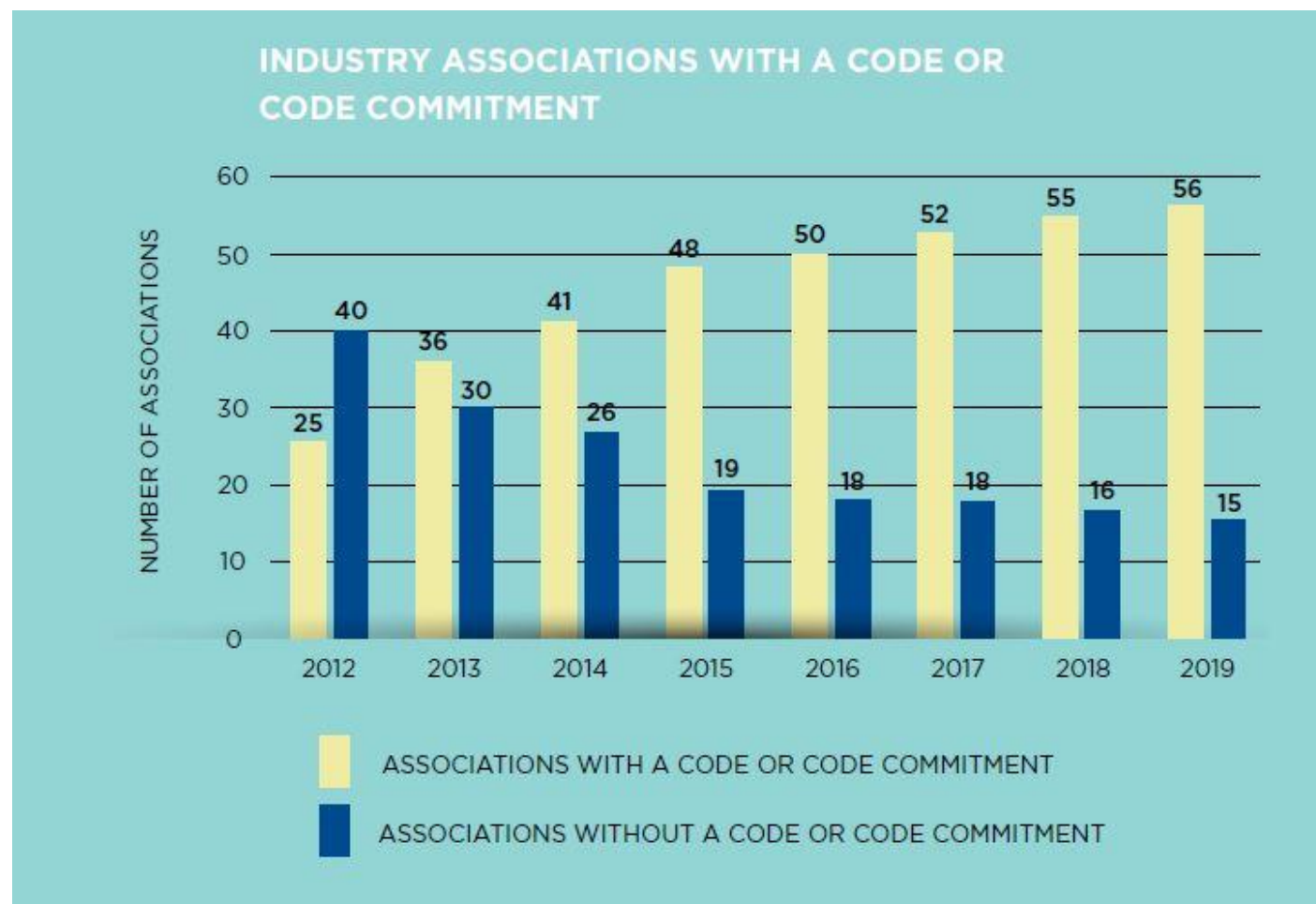
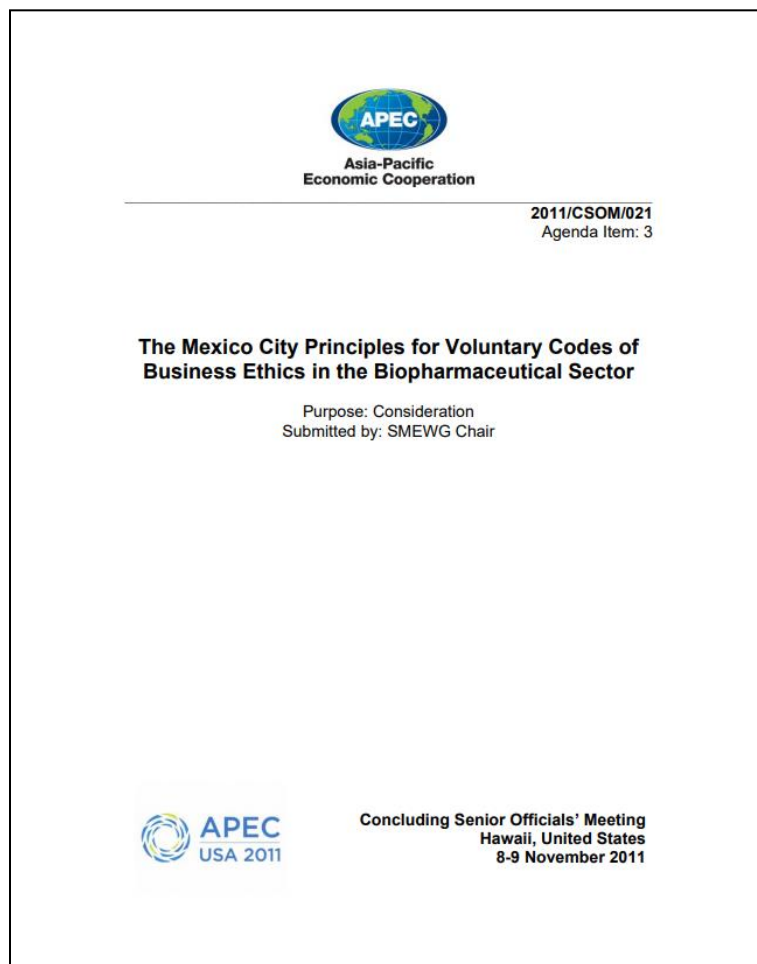
**Ms. Karen Eryou**  
Head, Global Ethics &  
Compliance Programs, UCB



**Ms. Chrisoula Nikidis**  
Head of Ethics and Compliance,  
Takeda (Canada)



## The Journey since 2010





## The Journey from 2018 to 2019 and Beyond

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## APEC SME Leaders in Ethics and Integrity Program (LEIP)







## BIOPHARMACEUTICAL SECTOR

### 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



## BIOPHARMACEUTICAL SECTOR

### 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?**





## BIOPHARMACEUTICAL SECTOR

# LUNCH (SAN CRISTOBAL A)

## 11:45 – 12:45



## BIOPHARMACEUTICAL SECTOR



### 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”**



## BIOPHARMACEUTICAL SECTOR



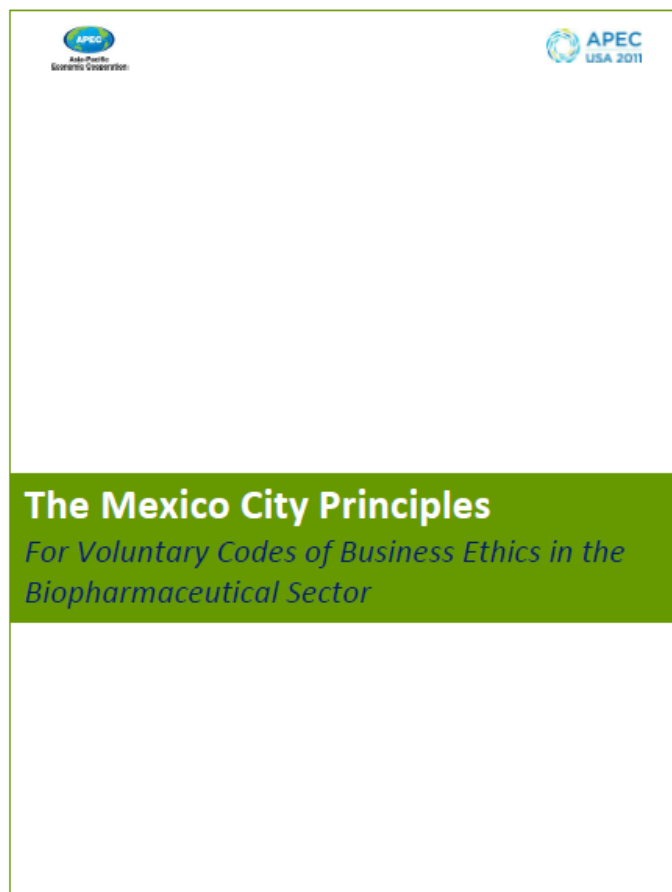
### PATIENT ORGANIZATIONS AND IMPLEMENTING THE APEC PRINCIPLES

*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




Asia-Pacific  
Economic Cooperation

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2014/SMEMM/020a  
Agenda Item: 6.2.8

**2014 APEC Business Ethics for SMEs Forum:  
Nanjing Declaration on Promoting Ethical  
Environments in the Medical Device and  
Biopharmaceutical Sectors Through 2020**

Purpose: Consideration  
Submitted by: United States



APEC  
CHINA 2014

21<sup>st</sup> Small and Medium Enterprises Ministerial  
Meeting  
Nanjing, China  
5 September 2014

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.

For non-government organizations, in particular patient organizations: Promote ethical environments in the medical device and biopharmaceutical sectors.

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



## CONSENSUS FRAMEWORKS

**International Alliance of Patients' Organizations**  
A global voice for patients

**Consensus Framework for Ethical Collaboration between Patients' Organisations, Healthcare Professionals and the Pharmaceutical Industry**

A Consensus Framework established for ethical collaboration between patients' organisations, healthcare professionals and the pharmaceutical industry, in support of high quality patient care. This Consensus Framework and the accompanying resources are intended to serve as a toolkit for those associations, groups and alliances who wish to develop their own policies. It neither aims to be comprehensive nor does it constitute a single common policy of the organisations involved. The individual policies of the participating organisations set out each organisation's detailed commitments and offer more diverse and in depth information and guidance.

**IFPMA**

**fip** International Pharmaceutical Federation

**WMA**

**CANADIAN CONSENSUS FRAMEWORK FOR ETHICAL COLLABORATION**

日本における倫理的連携のための  
コンセンサス・フレームワーク

**JAPANESE CONSENSUS FRAMEWORK FOR ETHICAL COLLABORATION**

**Australian Consensus Framework for Ethical Collaboration in the Healthcare Sector**

A Consensus Statement of Shared Values and Ethical Principles for Collaboration and Interaction Among Organisations in the Healthcare Sector

**EL MARCO CONSENSUADO PERUANO PARA LA COLABORACIÓN ÉTICA MULTISECTORIAL EN LOS SECTORES FARMACÉUTICO Y DE DISPOSITIVOS MÉDICOS**

**PERUVIAN CONSENSUS FRAMEWORK FOR MULTI-STAKEHOLDER ETHICAL COLLABORATION IN THE PHARMACEUTICAL AND MEDICAL DEVICE SECTORS**

2016

**Philippine pharmacists join patients, pharma sector in ethical collaboration**

Philippine pharmacists join patients, pharma sector in ethical collaboration



## 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?**



## BIOPHARMACEUTICAL SECTOR

# AFTERNOON TEA/COFFEE BREAK

## 15:00 – 15:30



## BIOPHARMACEUTICAL SECTOR

### *APEC BIOPHARMACEUTICAL WORKING GROUP ON ETHICS*

#### **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)