Introductory Remarks

Ms. Lynn Costa
Project Overseer, Business Ethics for APEC SMEs Initiative,
U.S. Department of Commerce

Participant Introductions and Status Updates by Associations
Progress and Emerging Trends in Ethical Business Practices

Mr. Russell Williams
Industry Co-Chair, APEC Biopharmaceutical Working Group on Ethics
Complex Environment

- UK Bribery Act
- Individual Company Codes
- US Foreign Corrupt Practices Act
- IFPMA Code of Practice
- EFPIA Transparency Guidelines
- Government Regulation
- Local Industry Association Codes
- Health Care Professional Associations
- Patient Group Codes
- Canadian Corruption of Foreign Public Officials Act
- APEC and Mexico City Principles
• The first part of the exercise would require that each economy (Industry, Governments and Stakeholders) identify on the matrix where it believes the Biopharmaceutical Industry exists on the matrix in relation to self-regulation.

• The second exercise would ask “Where the Economy would like to see the Biopharmaceutical Industry exist on the matrix in relation to self-regulation?”.

• All stakeholders in the room would be asked to participate and make their own evaluations of where they see their economy.
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The table above illustrates the relationship between government participation and industry self-regulation. Each cell represents a combination of high and low levels in the two dimensions.
Communicating the Value of High Standard Ethics in Enterprise & Successful Strategies for Low Cost Implementation of your Code of Ethics

Perspectives from Enterprise

Mr. Beau Agana, President, Pharex HealthCorp (The Philippines)

Dr. José Roberto C. Pereira, Business Development and Innovation Director, Biolab, Inc. (Brazil)

Perspectives from Industry Associations

Dr. Xu Ming, Vice President, CCCMHPIE (China)

Dr. Juan Francisco Millán Soberanes, CETIFARMA (México)

Session Facilitator

Karen Eryou, Senior Director, Corporate Compliance (APAC), UCB Pharma (China)

Session Exercise

Rotating Breakout Tables
30 Minutes Per Rotation
APEC Biopharmaceutical Workshop Structure for Session 1

Pre-Workshop

Needs Assessment Survey Results:
- Mentors needed in all areas
- Identified Areas: Tool Kits, Communications, Handling Objections, Government Relations, Reputation, Next Steps for Code Implementation

Workshop

Based on outcome of survey, set up “expert forums” (i.e. 2-3 of our industry mentors) who are expertise on a topic identified in survey (i.e. influencing skills) listen to association/s challenges and troubleshoot, offer advice.

Association completes and “action card” listing 2-3 actions based on expert advice.

After 30 minutes, facilitator rings a bell, and association physically move to another table for their next consultation with a new expert forum.

In an hour, an association could rotate through 2 experts forums to seek advice on 2 different challenges.

Output, Challenges, Benefits

Session Output: each association develops 2-3 actions per challenge area that will move them along on the road to code effectiveness once back to their country.

Challenges:
- Clear explanation for Associations on module
- Table cards to identify table topics
- Good classroom organisation and instructions (slides and mentors prepared)

Benefits:
- Attendees moving about and meeting many people in short timeframe
- Will help socialize the group for later conversations
Workshop Topic: Successful Strategies for Low Cost Implementation of your Codes of Ethics

Pre-workshop survey of Associations to determine challenges *

Workshop Day: Scene-Setting Remarks (2-3 minutes each)

First Matching – Associations move to their mentor tables per selected topic (30 min)

Associations completes actions cards with take-away suggestions from mentor discussions

Associations move to their second matching per selected topic (30 min)

Associations completes actions cards with take-away suggestions from mentor discussions

Wrap Up (5 min)

* Suggested Topics - see word doc
APEC Biopharmaceutical Workshop Structure for Session 1 Workshop Day

Workshop Topic: Successful Strategies for Low Cost Implementation of your Codes of Ethics

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- Associations completes actions cards with take-away suggestions from mentor discussions
- Wrap Up (5 min)
# Mentor Assignments and Tables

<table>
<thead>
<tr>
<th>Topic</th>
<th>Tables</th>
<th>Mentor</th>
<th>Mentor</th>
<th>Mentor/Floaters</th>
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<tbody>
<tr>
<td>Handling objections</td>
<td>A, B</td>
<td>Neil (A)</td>
<td>Katsumi (B)</td>
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<tr>
<td>Government relations</td>
<td>C, D</td>
<td>Isabela (C)</td>
<td>Sabrina Chan (D)</td>
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<tr>
<td>Next Steps on Code Implementation</td>
<td>E, F</td>
<td>Chrisoula (E)</td>
<td>Ricardo Moreno (F)</td>
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<td>Tool kits</td>
<td>G-H</td>
<td>Ricardo Muza (G)</td>
<td>Silvia (H)</td>
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<td>I, J</td>
<td>Claudia (I)</td>
<td>Reiner (J)</td>
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<tr>
<td>Reputation</td>
<td>K, L</td>
<td>Rosina (K)</td>
<td>Sujata (L)</td>
<td></td>
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<tr>
<td>Additional Support: (in case of extra table or support needed)</td>
<td>M-O</td>
<td>Irina (M)</td>
<td>Laura (N)</td>
<td>Cecilia (O)</td>
</tr>
</tbody>
</table>

30 minutes session and Attendees move to another table. Mentors remain at assigned table.
Leading Multi-Stakeholder Perspectives in Peru

Industry Association Perspectives
Mr. Gabriel Apestegui Castro, Board of Directors, ADIFAN
Ms. Maria Aste, President, ALAFARPE
Mr. Carlos Leigh Vigil, Executive President, ALAFAL

Health Care Professional Perspectives
Dr. Alberto Gayoso Villaflor, President, Medicines Committee, College of Physicians of Peru
Dra. Amelia Villar López, Dean, College of Pharmacists

Patient Perspectives
Ms. Karla Ruiz de Castilla Yabar, Chief Executive Officer, Esperantra
Mr. Julio Cesar Cruz Requenes, President, PROSA

Government Perspectives
Dr. Ruben Espinoza, Director-General, DIGEMID, Ministry of Health

Moderator
Ms. Kathleen Hamann
Partner, Pierce Atwood,
Former International Policy Counsel, U.S. Department of Justice
The United States
LUNCH BREAK
NEXT SESSION AT 1:00 PM
CASE STUDY ONE (30 Minutes):
Interactions with Healthcare Professionals

Presented by: Mr. Katsumi Kojima, JPMA (Japan)
Ms. Isabella Pires, Eli Lilly (Brazil)

Case Review: 15 Minutes
Case Feedback by Tables: 15 Minutes
Interactive Case Exercises

CASE STUDY TWO (45 Minutes):
Interactive, Multi-Stakeholder Scenario

Presented by: Ms. Laura Giussani, Eli Lilly (United States)
Ms. Sabrina Chan, HKAPI (Hong Kong, China)
Mr. KP Tsang, IAPO (Hong Kong, China)
Dr. Philip Ashok, Malaysian Medical Association (Malaysia)
Ms. Claudia Hernandez Loustalot Laclette, AbbVie (Mexico)
Ms. Silvia Rodriguez, Eli Lilly (Mexico)
Overview

1. In this exercise, you will receive information and sketches framing the case scenario

2. Case questions will be presented and each table will discuss the response

3. We will conclude the case by sharing feedback from each tables and highlighting our key takeaways
Exercise / Scenario

• A small biopharmaceutical company (Farma-Star) in your economy is about to launch a new product.

• Given the nature of the disease this product treats, and how the product works, Farma-Star is not only focused on the patient but also on the caregivers.

• It is important this new product be a commercial success, based on the revenue expectations Farma-Star leaders have expressed to the board and their investors.
Dialogue

- **Patient Organization #1:**
  The new medication is so exciting for all of us!

- **Patient Organization #2:**
  It will be critical to understand the roles of caregivers and also be actively engaged on how the medicine will be priced.

- **Health Care Professional Organization #1:**
  When is the National Congress? It will be an opportunity to continue our medical education and ensure we remain key players. Perhaps the biopharmaceutical company can help.

- **Health Care Professional Organization #2:**
  I am sure the company with this new product will want to invest.
Questions (15 Minutes)

• What are some possible plans the Patient Organizations, the Medical Associations and Farma-Star could undertake to ethically achieve their goals? Discuss for 5-7 minutes.

• What are your thoughts on the proposals below? Each group should pick one and discuss for 5-7 minutes.

1. Farma-Star considers funding and partnering with the Patient Organizations for a disease-awareness fair; says patients’ willingness to give testimonials would increase the chance of product success.

2. Farma-Star invites the Patient Organizations to a focus group for both patients and caregivers, to better understand their needs; reasonable expenses for participants would be covered by Farma-Star.

3. The Medical Associations ask Farma-Star to sponsor its directors (HCPs) to the National Congress; in the request letter they mention the HCPs can have a key role in government formulary decisions.

4. The Patient Organization reach out to Farma-Star for a grant to create educational materials on disease awareness.
GAME CHANGER!

• Development #1: A reputable newspaper has released an expose on how HCPs are being given special privileges by biopharmaceutical companies to speak well about new products.

• Development #2: The Patient Organizations mention they would prefer not to disclose grant funding from Farma-Star to avoid the impression of undue influence in their activities.

Do these developments impact the plans your group has suggested or the proposals you have discussed? If yes, what alternatives can you offer to help the parties ethically achieve their goals?
Interactive Case Exercises

EXERCISE THREE (45 Minutes):
Role of Government in Facilitating Voluntary Ethical Practices

Presented by: Mr. Russell Williams, Co-Chair, APEC Biopharm WG on Ethics
Ms. Chrisoula Nikidis, Innovative Medicines Canada
The objective of the exercise is to carry out a discussion on self-regulation and the role governments may play in supporting this process.

The discussion will focus on the values and challenges around self-regulation and, recognizing that in some instances pure self-regulation is not always an option.

The relationship of government and stakeholders in industry self-regulations in the Biopharmaceutical sector area varies.

Industry has the responsibility to earn the respect and trust required for self-regulation.
• The first part of the exercise would require that each economy (Industry, Governments and Stakeholders) identify on the matrix where it believes the Biopharmaceutical Industry exists on the matrix in relation to self-regulation.

• The second exercise would ask “Where the Economy would like to see the Biopharmaceutical Industry exist on the matrix in relation to self-regulation?”.

• All stakeholders in the room would be asked to participate and make their own evaluations of where they see their economy.
Mexico City 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.
Nusa Dua Statement

The Nusa Dua Statement issued on 3 September 2013 established that each stakeholder has a unique and important role to promote ethical healthcare environments, including:

- **Health Ministries and Health Regulatory Agencies** should recognize the value of industry codes of ethics and encourage all stakeholders to support ethical principles, such as the APEC principles, and national and local industry codes of ethics.
Nanjing Declaration

- For Governments: Support and endorse local partnerships in APEC economies between relevant government ministries/ agencies and the medical device and biopharmaceutical industries to advance industry’s voluntary efforts to strengthen ethical business practices.
Self-Regulation

• Self-regulation is a privilege and not a right;
• The private sector relies on self-regulation to address a range of issues, from establishing industry standards, to developing and applying codes of professional ethics, to ensuring consumer confidence.;
• Despite its widespread use, some policymakers are skeptical of the efficacy and credibility of self-regulation;
• Regulatory styles vary considerably from country to country and industry to industry.
Governments may play a positive role in voluntary self-regulation by

- Encouraging self-regulatory action, by urging businesses to develop self-regulatory schemes;
- Providing advice, by contributing to the development of guidance on how certain issues may best be addressed,
- Supporting compliance, by encouraging adherence
- Authorizing the programs, to ensure their suitability and/or compliance with laws and regulations,
- Monitoring the effectiveness and impact of schemes,
- Promoting multi-stakeholder dialogue, to take part in the development and/or monitoring of schemes and
- Publicly endorse successful self-regulatory efforts
Ethical collaborations among the medical device and biopharmaceutical industry, healthcare professionals, patients’ organizations and other stakeholders is essential to the delivery of high quality patient care, patient access to life-saving and health-enhancing medical technologies and therapies, and the development of new innovations that meet patient needs.

No one group can achieve an ethical environment in these sectors alone.
PERU

Industry Self-Regulation

Government Participation

High

Low

Low

High

Industry

HCP

Patient
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COFFEE BREAK
NEXT SESSION AT 4:00 PM
Breakout Sessions

MENTORS AT EACH TABLE TO PROVIDE GUIDANCE ON BEST PRACTICES, CODES OF ETHICS, & HEIGHTENING ETHICAL COLLABORATIONS
Closing Remarks:

Mr. Alejandro Torrendell, Regional General Counsel, LatAm, Merck KGaA

Guidance for Plenary Session (Tuesday, 6 September)

Workshop Group Photograph