

# **OPENING CEREMONY**

***FACILITATING TRANS-PACIFIC  
COLLABORATION TO STRENGTHEN  
ETHICAL BUSINESS PRACTICES***

## Introductory Remarks

John Andersen, Chair, APEC SME Working Group,  
Deputy Assistant Secretary of Commerce  
for the Western Hemisphere,  
U.S. Department of Commerce

# Keynote Remarks

Dr. Patricia García Funegra  
Minister of Health, Peru

# Announcement of the 2016 APEC Business Ethics Lighthouse Award

*Presented by:*  
*Lynn Costa, Project Overseer*  
*Business Ethics for APEC SMEs Initiative*

# SIGNING CEREMONY

## PERU CONSENSUS FRAMEWORK FOR MULTI-STAKEHOLDER ETHICAL COLLABORATION IN THE MEDICAL DEVICE & PHARMACEUTICAL SECTORS

*Presented by:*

*Lynn Costa, Project Overseer*

*Business Ethics for APEC SMEs Initiative*

*Rocio Delgado Montero, International Coordinator*

*DIGEMID, Ministry of Health, Peru*

# 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

# PLENARY PHOTOGRAPH

# REGIONAL PROGRESS UPDATE

*Presented by:*  
*Andrew Blasi, C&M International*



## UPDATE FOCUS AREAS

1. Industry Association Code Adoption and Implementation
2. Nanjing Declaration Implementation
3. Other Emerging Considerations



Asia-Pacific  
Economic Cooperation

## Business Ethics for APEC SMEs Plenary Dialogue

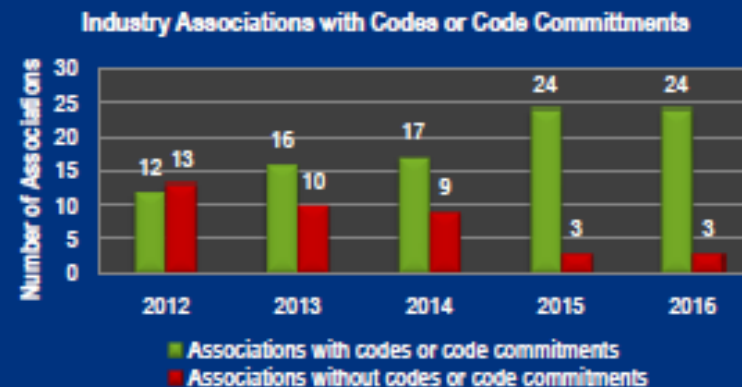
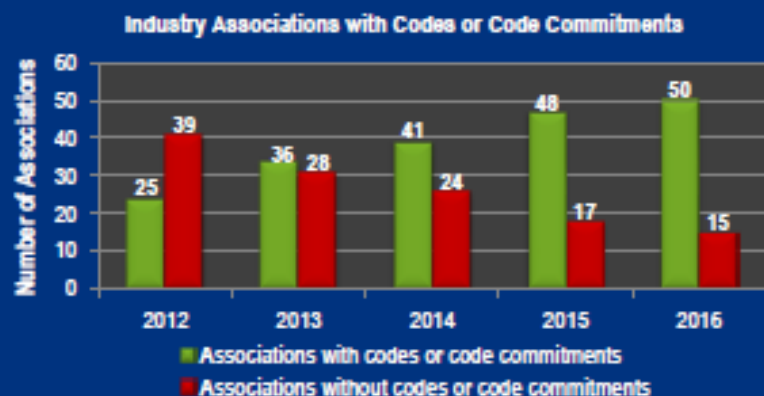


APEC PERU  
2016

# INDUSTRY CODE ADOPTION AND IMPLEMENTATION

## BIOPHARMACEUTICAL

## MEDICAL DEVICE



## **KEY TAKEAWAYS ON ASSOCIATION CODE ADOPTION**

- 1. Rapid progress is naturally slowing, as there are much fewer associations without a code of ethics**
- 2. Some associations reluctant or slow to adopt codes**
- 3. At least 3 medical device associations and 15 biopharmaceutical associations in the APEC region that remain without a code or commitment**

# THE “BIG THREE” IN ASSESSING ASSOCIATION CODE IMPLEMENTATION

1. Governance
2. Alignment
3. Member Implementation

## **KEY TAKEAWAYS ON ASSOCIATION CODE GOVERNANCE**

- 1. Leadership commitments are firmly in place**
- 2. Code distribution to members and non-industry stakeholders is seeing notable improvement**
- 3. Code resources and local trainings lagging**

## **KEY TAKEAWAYS ON ASSOCIATION CODE ALIGNMENT**

- 1. New and existing codes are intently being aligned with the APEC Principles**
- 2. For the biopharmaceutical sector, code provisions on public sector relationships, clinical trials, and patient organizations are most likely to not be aligned with the APEC Principles**

## KEY TAKEAWAYS ON ASSOCIATION MEMBER IMPLEMENTATION

- 1. While both sectors are confident in overall code performance, biopharmaceutical associations report feeling more confident**
- 2. At least half of the associations in both sectors with codes report a majority of their members have implemented the association's code**

## **NANJING DECLARATION 2020 GOALS**

- 1. Universal industry association codes of ethics**
- 2. Implementation of industry association codes by a majority of their member companies**
- 3. Consensus Frameworks for Multi-Stakeholder Ethical Collaboration in every APEC economy**



## **OTHER EMERGING CONSIDERATIONS**

- 1. Rapid evolution of health care systems and emergence of new stakeholders**
- 2. Industry changes impacting associations**
- 3. Heightened role of health care professionals in serving as active partners with industry to strengthen ethical business practices**




**Asia-Pacific  
Economic Cooperation**

**Business Ethics for APEC SMEs**  
**Medical Device Sector**




**Report on Code of Ethics Implementation by  
APEC Medical Device Industry Associations, 2012-2016**

Prepared for the:  
2016 APEC Business Ethics for SMEs Forum | Lima, Peru | 5-6 September 2016  
43rd APEC Small & Medium Enterprise Working Group | Lima, Peru | 7-8 September 2016  
23rd APEC Small & Medium Enterprise Ministerial Meeting | Lima, Peru | 9 September 2016



**Asia-Pacific  
Economic Cooperation**

**Business Ethics for APEC SMEs**  
**Biopharmaceutical Sector**



**Report on Code of Ethics Implementation by  
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# NETWORKING COFFEE BREAK

*Plenary Dialogue to Recommence at 11:00 AM*

# PROGRESS DIALOGUE BY APEC ECONOMIES

*Session Chair:*

*Datuk Hafsah Hashim, Chief Executive Officer  
Malaysia SME Corporation*

# NETWORKING LUNCH BREAK

*Plenary Dialogue to Recommence at 2:00 PM*

# **DIALOGUE SESSION ONE**

## *Designing and Launching Multi-Stakeholder Ethical Collaborations*

*Scene-Setting Remarks:* *Ms. Maria Lourdes C. Santiago, Deputy Director General, Philippines FDA*

*Session Chair:* *Mr. Russell Williams, Co-Chair, APEC Biopharmaceutical Working Group on Ethics*

## SESSION ONE RECOMMENDATIONS

1. Prepare Roadmap by 2017 that outlines steps through 2020;
2. Identification of champions from member economies;
3. Provide continued guidance to economies that conclude multi-stakeholder ethical collaborations;
4. Recruit economies who conclude collaborations to serve as mentors to economies who pursue one; and
5. Collaborations should consider best practices unique to the biopharmaceutical and medical device sectors.



# DIALOGUE SESSION TWO

*Promoting Strong Ethical Business Practices  
with Distributors / Third Party Intermediaries*

Scene-Setting Remarks: Ms. Bronwen Taylor, Vice  
President, Compliance and Risk Management, Stryker

Session Chair: Ms. Faye Sumner, Chief Executive  
Officer, Medical Technology Association of New Zealand



# Manufacturer – Third Party Intermediary Relationships

Companies (especially SME's) engage third parties in overseas markets to:

- Ensure patient and HCP access to innovative, reliable and patient-appropriate medical technology
- Ensure appropriate technology support and service
- Ensure HCP access to education and training in overseas markets

However, these crucial engagements can bring legal and ethical risk...



# Third-Party Corruption Liability: Companies Are Accountable for Acts of Agents

- Organizations may be held liable for acts of corruption by their third parties, i.e. their agents, consultants, suppliers, distributors, joint-venture partners, or any individual or entity that has some form of business relationship with the organization.
- Before entering into relationships with third parties, organizations must take active steps to ensure that potential corruption risks stemming from these relationships are responsibly evaluated and managed.
- Conducting risk-based due diligence on third parties has become a legal expectation in many countries that have ratified the OECD Anti-Bribery Convention and/or the United Nations Convention against Corruption.
- Conducting adequate due diligence may help organizations decrease, and even avoid, the risk of criminal culpability for corrupt third-party conduct.



# Recent Company Headlines

- 2016: Medical device company must pay \$623.2 million to resolve criminal and civil allegations about kickbacks paid to Latin America's doctors and hospitals, and pay a \$22.8 for criminal bribery law violations.
- 2013: Medical device company paid \$13.2 million to resolve FCPA violations including bribing doctors and administrators at government controlled hospitals in Argentina, Greece, Mexico, Poland, and Romania.
- 2012: Medical device company paid a criminal fine of \$17.3 million in its settlement with the DOJ, and \$5.5 million in disgorgement of profits and pre-judgment interest to the SEC. Alleged that company bribed doctors at government hospitals in Argentina, Brazil, and China from 2000 to 2008.
- 2012: Medical device company charged with violating FCPA when a subsidiary paid routine bribes referred to as "chocolates" to Mexican officials in order to obtain lucrative sales contracts with government hospitals. Company to pay \$5.2 million to settle the SEC's charges.
- 2012: PhRMA agreed to pay the U.S. government \$29,398,734, in disgorgement of profits, interest and penalties related to bribes paid to government officials to secure business with the government in four countries, including Brazil, in violation of the FCPA. In the case of Brazil, company, through a third-party distributor, paid approximately \$70,000 to bribe state government officials so that the state would purchase certain products.





## Current KL Principles Text Addresses Third Parties:

**“Companies to communicate company policies consistent with the industry code to their third-party intermediaries with the expectation that intermediaries will comply with the industry code. ”**

But, can we do more?.....

Should the APEC business ethics initiative pursue the development of best practice principles on promoting ethical business practices with third party intermediaries to...

- *Ensure medical decision making in best interest of patient;*
- *Mitigate risky legal environments that impede SME access to markets;*
- *Reinforce self-regulatory approach to manage known legal risk; and*
- *Maintain industry credibility and public confidence.*



# Guidance on Compliance Controls



[www.advamed.org/Distributor-Relations](http://www.advamed.org/Distributor-Relations)

AdvaMedDx | AdvaMedEGCC | AdvaMedMTLI | AdvaMed2015 | LifeChangingInnovation

**40 YEARS** **AdvaMed**  
Advanced Medical Technology Association  
1975 - 2015

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## JOINT GUIDANCE ON RELATIONSHIPS WITH DISTRIBUTORS

AdvaMed and Eucomed encourage medical technology companies to adopt a Third Party Sales and Marketing Intermediary (SMI) Management Compliance Program in addition to an overall Health Care Professional (HCP) Compliance Program

**AdvaMed**  
**Eucomed**  
Medical Technology

Home > Issues > Issues Overview

### DISTRIBUTOR GUIDANCE

#### BACKGROUND

AdvaMed and Eucomed have developed joint compliance guidance and tools on Distributor Relations as part of an ongoing commitment to provide ethical guidance on appropriate industry interactions. We believe clear, established compliance programs will safeguard the integrity of medical decision making and promote further public confidence in our industry.

To ensure and improve ongoing patient and clinician access to innovative, reliable and effective medical technologies, it is often necessary for medical device and diagnostics companies ("Companies") to engage third parties to assist with marketing, sales and distribution of advanced medical technology overseas. These third parties may include distributors, wholesalers, distribution or sales agents, marketing agents, brokers, commissionary commercial agents and independent sales representatives ("Third Party Sales and Marketing Intermediaries" or "Third Party SMIs").

#### QUICK LINKS

AdvaMed Code of Ethics  
English  
Chinese - Simplified  
Chinese - Traditional  
German  
Italian  
Portuguese  
Spanish

Eucomed Code  
Article by Aline Lautenberg and Christopher White in Life Science Compliance





# Best Practices and Compliance Tools

- Joint Guidance on Managing Third Party SMI Risk
  - Industry's Top FCPA Risk
  - Industry Wide Tools
    - Compliance Policy
    - Distributor Training Slides
    - Due Diligence Tool



[www.advamed.org/Distributor-Relations](http://www.advamed.org/Distributor-Relations)



# Compliance Training Slides (translated)



[www.advamed.org/Distributor-Relations](http://www.advamed.org/Distributor-Relations)

## Training Topics

- Why Compliance with Global Anti-Bribery Laws Matters
- What is Bribery?

Matters

## Disclaimer and Purpose of Distributor Training Guide

- This training tool is prepared in consultation with, and for the benefit of,

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KAYE SCHOLER

## Distributor Training Tool



This training tool was prepared by Amy Conway-Hatcher and Greg Jaeger of Kaye Scholer LLP, in consultation with the Joint AdvaMed and Eucomed Distributor Working Group.



# Distributor Due Diligence Tool



[www.advamed.org/Distributor-Relations](http://www.advamed.org/Distributor-Relations)

Third Party SMI Compliance Diligence Resource  
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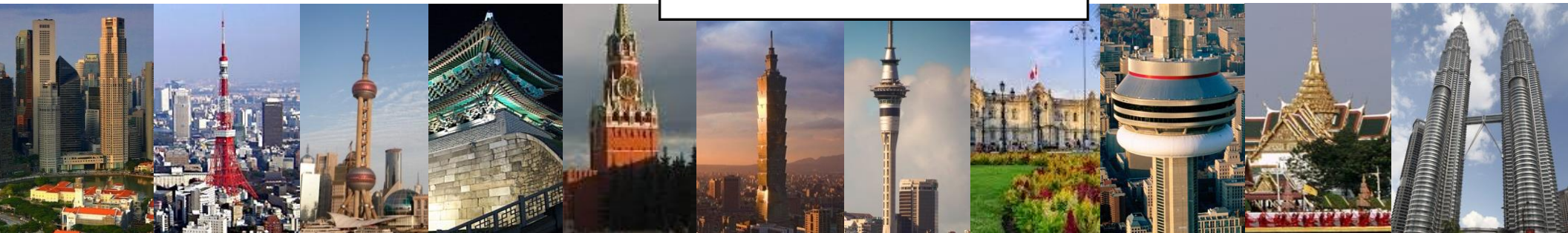
Example Questions for Potential Inclusion Within an SMI Compliance Questionnaire

Please complete the following questions as completely and thoroughly as possible. All questions must be completed or a written response of "not applicable" must be provided.

**SMI Information**

- SMI Name
- Has your company or any of your company's principals done business with our Company in the last 10 years? If so, under what names?
- Has your company or any of your company's principals done business in a similar field in the last 5 years? If so, under what names?
- Your Name and Title
- Full Address
- Telephone
- Fax
- Email
- Your Company Website

<sup>1</sup> Please list in English and the local language.  
<sup>2</sup> Please list in English and the local language.





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- *Reinforce self-regulatory approach to manage known legal risk; and*
- *Maintain industry credibility and public confidence.*



## **SESSION TWO RECOMMENDATIONS**

1. Expert working group should be convened before the 2017 APEC Business Ethics Forum to prepare draft best practice principles for ethical partnerships with third parties;
2. Organizations have been nominated to coordinate next steps;
3. APEC should ensure inclusive approach that accounts for all third party intermediaries;
4. APEC should drive activities that include (A) alignment of best practices between third parties, manufacturers, and other stakeholders, and (B) capacity-building trainings and resources.

# NETWORKING COFFEE BREAK

*Plenary Dialogue to Recommence at 4:30 PM*

# READOUT & ENDORSEMENT OF DIALOGUE RECOMMENDATIONS

*Emcee: Andrew Blasi, C&M International*

## **GLOBAL SHOWCASE SESSION**

### **Ensuring an Inclusive and Consultative Approach**

Dr. Kenneth Hartigan-Go,  
Vice President, Philippine College of Physicians

### **Harmonizing & Sustaining One Code of Ethics for Multiple Industry Groups**

Dr. Juan Francisco Millán Soberanes,  
Director, CETIFARMA (Mexico)

### **Novel Strategies for Code of Ethics & Capacity-Building Collaboration between Industry Associations & Healthcare Professional Bodies**

Dr. Andreas Loeffler, President, A  
Australian Orthopaedic Association

### **Digital Strategies to Strengthen Ethical Practices for Third Party Intermediaries**

Dr. Sergio Alcântara Madeira, Technical Director,  
ABRAIDI (Brazil)

### **Assuring Ethical Collaborations between Industry & Patient Organizations**

Ms. Leanne Wells, CEO, Consumer Health Forum of Australia  
<https://www.youtube.com/watch?v=iDTI3M1nTb0>



Council of Ethics and Transparency of the Pharmaceutical Industry

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**AGREEMENT FOR TRANSPARENCY IN  
THE RELATIONSHIP  
BETWEEN PHYSICIANS AND HEALTH  
CARE INSTITUTIONS  
WITH THE PHARMACEUTICAL  
INDUSTRY  
MEXICO**

Mexico, October 2007

# **Agreement for Transparency Mexico Consensus**

- Signed in 2007 with endorsement of the Government
- Head: General Council of Health (GCH)
- Enforcement mechanism:
  - On 2008 the Health Ministry issued and published an act to enforce the Agreement in all the public sector.
  - 12 public and private signatories are part of the Compliance Committee, which receive complaints.
  - Once the GCH investigates, enforce the comply with the signatories

# Positive impact to the Health Sector

## Mexican population: 125,235 million

### Stakeholders

### Impact

- |   |   |   |
|---|---|---|
| • Public and Social Security Institutions       | ⇒ | 95% affiliates to the health system                 |
| • National Academies and Colleges of physicians | ⇒ | 275,517 physicians                                  |
| • National Association of Private Hospitals     | ⇒ | 23,269 health units                                 |
| • Pharma Industry and Medical Devices Sector    | ⇒ | 204 global and local companies, 95% of market value |
| • Schools of Medicine                           | ⇒ | 10,000 students                                     |



## **CLOSING SESSION**

Ms. Melissa Stapleton Barnes,  
Senior Vice President, Enterprise Risk Management  
and Chief of Ethics and Compliance Officer /  
Executive Committee, Eli Lilly & Company

## **Announcement of 2017 APEC Business Ethics for SMEs Forum**

Mr. Nguyen Hoa Cuong, Deputy Director-General,  
Agency for Enterprise Development, Ministry of Planning and Investment  
APEC Small and Medium Enterprise Working Group Chair – Designate

## **Takeaways & Farewell**

Ms. Lynn Costa, Project Overseer,  
Business Ethics for APEC SMEs Initiative (The United States)

## **Economy Groups:**

Group A: Peru, Indonesia, Malaysia, Mexico, The United States

Group B: Australia & The Philippines (Limatambo Three)

Group C: China, Canada, & Hong Kong, China (Limatambo Three)

Group D: Viet Nam, Thailand & Japan (Limatambo Three)

Group E: Chile, Brazil, Colombia, New Zealand & Korea (Limatambo Three)

*All Other Economies May Select Preferred Group*

## **Emcee**

Ms. Kate Hamann  
Partner, Pierce Atwood LLP,  
Former Intl Policy Counsel,  
U.S. Department of Justice