



**Asia-Pacific
Economic Cooperation**

2017/SMEWG44/019
Agenda Item: 14.3a

APEC SME Business Ethics Forum Medical Device and Biopharmaceutical Sectors

Purpose: Information
Submitted by: United States



**44th Small and Medium Enterprises Working Group
Meeting
Sydney, Australia
15-16 March 2017**



APEC SME Business Ethics Forum Medical Device & Biopharmaceutical Sectors

2017 Hanoi, Viet Nam



The Healthcare Sectors

- * 300 participants attended the 2016 SME Healthcare Business Ethics Forum in Lima
- * 19 APEC Economies participated
- * Healthcare ministries, healthcare professionals, association leaders with large, medium and small company members, orthopedic associations, pharmacy and physicians' associations, patient organizations, regulatory agencies and SME delegates.
- * Over 1000 stakeholders are now engaged in this work!



Healthcare Forum Capacity Building to Strengthen & Implement Codes of Ethics

- * Capacity Building workshops on Day 1.
- * Mentors provided assistance to organizations needing support.
- * All associations are actively working to finalize their codes... and most have finished!
- * How do we now augment the private sector with the public sector?

The Multi-Stakeholder Collaborative Framework Public & Private Sector Work Together

- * The multi-stakeholder frameworks serve as a vehicle to bring the private and public sector together.
- * Through the framework agreements the public and private sector will work together under a strategic plan to establish ethical practices across national healthcare systems – opening pathways for discussion & collaborative action.
- * Canada and Peru established the first frameworks!
- * These frameworks are THE FIRST IN THE WORLD!!!!

Congratulations 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





The Updated Biopharmaceutical Expert Working Group

Formed as a Directive of the Nanjing Declaration.

- **Industry Co-Chair: Ms. Chrisoula Nikidis, Vice President, Innovative Medicines Canada (CANADA)**
- **Government Co-Chair: Ms. Rocio Delgado, International Coordinator, DIGEMID, Ministry of Health (PERU)**
- **Health Care Professional Co-Chair: Dr. Kenneth Hartigan-Go, Vice President, Philippine College of Physicians and Former Undersecretary of Health (THE PHILIPPINES)**
- **Patient Co-Chair: Mr. Russell Williams, Vice President, Canadian Diabetes Association (CANADA)**
- **Member: Mr. Pan Guang Cheng, Executive Chairman, China Pharmaceutical Industry Association (PEOPLE'S REPUBLIC OF CHINA)**
- **Member: Dr. Xu Ming, Vice President, China Chamber of Commerce for the Import and Export of Medicines and Health Products (PEOPLE'S REPUBLIC OF CHINA)**
- **Member: Ms. Sabrina Chan, Executive Director, Hong Kong Association of the Pharmaceutical Industry (HONG KONG, CHINA)**
- **Member: Mr. Darodjatun Sanusi, Executive Director, Indonesia Pharmaceutical Association / GP Farmasi (INDONESIA)**
- **Member: Dr. Chairat Shayakul, Member, Rational Drug Use Subcommittee (THAILAND)**
- **Member: Dr. Juan Francisco Millán Soberanes, Executive Director, Council of Ethics and Transparency of the Mexican Pharmaceutical Industry (MEXICO)**
- **Member: Ms. Thuy Nguyen, Policy Director, The Pharma Group, EuroCham Vietnam (VIET NAM)**
- **Member: Mr. Jean Jacques Duhart, Vice President, Chilean Pharmaceutical Chamber (CHILE)**
- **Member: VACANT DUE TO A RETIREMENT (JAPAN)**
- **Project Overseer: Ms. Lynn Costa (THE UNITED STATES)**

SME Ministerial Meeting in Lima, Peru

- * SME Ministers were presented with a status report on where each association, in each economy, stands on developing and implementing codes.
- * Two reports were presented – one for medical devices and one for biopharmaceuticals.
- * We track the number of companies with new codes -- over 19,000 new company codes of which 15,000 are SMEs
- * We also track capacity building workshops delivered to socialize the codes within companies.
- * Surveys will continue each quarter to track outcomes and progress.
- * Surveys will now also include progress made on establishing collaborative frameworks.

Beyond the APEC Region

- * The Medical Device Sector launched in Bogota, Colombia on February 21-23, 2017
- * 140 participants
- * 14 Latin American countries
- * Chile, Peru, Mexico, Canada and the United States provided support
- * Non-APEC Latins are following the path set by the APEC SMEWG SME Business Ethics Initiative

Latin Americans Pledge Their Commitment



Bogota Outcomes

- * Non-APEC Latins agreed to harmonize codes under the *Bogota Principles*, an endeavor they will work on together.
- * Brazil announced it will establish a new *Multi-Stakeholder Collaborative Framework* – a stakeholder working group is assembled and codes are written – Brazil's codes replicate the *KL Principles for the Medical Device Sector*. Peru's *DIGIMED (Ministry of Health)* is assisting Brazil.
- * Colombia and Ecuador will also establish *Multi-Stakeholder Collaborative Frameworks*. Codes are still in progress. Frameworks will follow. The US is providing assistance.
- * Mexico, an APEC member, is already working on its *Multi-Stakeholder Framework Agreement!!*

Feedback – What We're Hearing

- * The Multi-Stakeholder Frameworks are providing a unique space for conversations to take place between the private and public sector -- discussions that were not possible before.
- * Small companies – the innovators of new healthcare technologies – have an equal voice in decisions in the stakeholder framework meetings and now have a pathway to talk to governments.
- * Distributors are joining the discussion in Latin America.
- * Several of your economies not previously noted are drafting Frameworks – you'll find out which ones in Vietnam!



The 2017 SME Business Ethics Forum
Hanoi, Viet Nam



September 7-8 @ the Sheraton Hotel

- * New Distributor Workshop for the Medical Device Sector.
- * Capacity building workshops for every stage of ethics compliance.
- * 60+ mentors available for customized assistance.
- * GREAT networking opportunities to share solutions to challenges.
- * Peru will provide an update on its collaborative framework implementation process.
- * All APEC SMEWG delegates encouraged and WELCOME to attend on the way to Ho Chi Minh City.

Message from the Project Overseer

SME Delegates,

We stood together to fight corruption for SMEs and the APEC SME Business Ethics Forum is now the world's largest ethics compliance event in the world! Over 1,000 stakeholders with many thousands of members are engaged in this work. We have 125+ mentors in place and 50+ are women. The new multi-stakeholder collaborative frameworks are the FIRST in the world and are now being replicated beyond the APEC region! Europe's medical device code will be fully aligned with the United States by the end of this year and APEC is harmonizing codes by 2020. This will bring 3 regions of the world into full alignment. And, Latin America is aligning with the APEC codes and framework agreements.

SMEs are the primary innovators in the medical device and biopharmaceutical sectors and YOU stood up for them to level the playing field.

Thank you for your commitment and resolve! Have a wonderful time in Sydney and I'll see you in Viet Nam.

Lynn Costa
SMALL IS THE NEW BIG!

