

Expert Working Group:
APEC Principles for
Biopharmaceutical Sector
Codes of Ethics

September 26 - 28, 2011

Mexico City, Mexico



Welcome remarks by:

H.E. Mr. Miguel Maron Manzur

**Under Secretary for Small and Medium Enterprises
Ministry of Economy of the Republic of Mexico**



Introduction of Participants

Introductions – Team A

- Dr. Peta O’Connell, Department of Health and Ageing (Australia) – **TABLE MODERATOR**
- Mr. Shaharuddin Khalid, Malaysian Anti-Corruption Commission (Malaysia)
- Ms. Noemi Stolarski Rosenthal, CETIFARMA – Council of Ethics and Transparency of the Pharmaceutical Industry in Mexico (Mexico)
- Mr. Alberto De Lago, Laboratorios Liomont, S.A. de C.V. (Mexico)
- Dr. Niyada Kiatying-Angsulee, Chulalongkorn University (Thailand)
- Ms. Noor Alam, U.S. Department of Commerce (United States)
- Mr. Daniel Brindle, Eli Lilly & Company (United States)

Introductions – Team B

- Mrs. Chrysanti Hasibuan, Indonesia Business Links (Indonesia)
– **TABLE MODERATOR**
- Ms. Chrisoula Nikidis, Rx&D – Canada’s Research-Based Pharmaceutical Companies (Canada)
- Mr. Huai-Lien Chou, Agency Against Corruption, Ministry of Justice (Chinese Taipei)
- Mr. Juan Francisco Millán Soberanes, CETIFARMA – National Chamber of the Pharmaceutical Industry (Mexico)
- Ms. Angelica Morales Quezada, Específicos Stendhal (Mexico)
- Mr. Vladimir Shipkov, AIPM - Association of International Pharmaceutical Manufacturers (Russia)
- Dr. Kitima Yuthavong, PreMA - Pharmaceutical Research and Manufacturers Association (Thailand)
- Ms. Pilar Schultz, Biogen Idec (USA)

Introductions – Team C

- Mr. Jeff Francer, PhRMA - Pharmaceutical Research and Manufacturers of America (United States) — **TABLE MODERATOR**
- Mr. Jose Manuel Cousino, CIFCHILE – Chamber of the Pharmaceutical Industry of Chile (Chile)
- Mr. Xu Ming, CPEA - China Pharmaceutical Enterprises Association (China)
- Mr. Fernando Fon Méndez, AMIIF - Mexican Association of Pharmaceutical Industry Research (Mexico)
- Ms. Mariela Vallejo Paz, Ministry of Public Administration (Mexico)
- Ms. Therese Irynne R. Gonzales, Food and Drug Administration (Philippines)
- Mr. Carlos Garcia, Bristol-Meyers Squibb (United States)

Introductions – Team D

- Dr. Francisco Tranquilino, PHAP - Pharmaceutical & Healthcare Association of the Philippines (Philippines) – **TABLE MODERATOR**
- Mr. Parulian Simanjuntak, IPMG - International Pharmaceutical Manufacturers Group Indonesia (Indonesia)
- Mr. Francisco Kuri Breña, COFEPRIS - Federal Commission for the Protection against Sanitary Risk (Mexico)
- Mr. Rafael Gual Cosío, National Chamber of the Pharmaceutical Industry CANIFARMA (Mexico)
- Ms. Laura Ceron, Consultant, DIGEMID- Ministry of Health (Peru)
- Mr. Sean Roberts, GlaxoSmithKline (United States)
- Mr. Nguyen Duy Ky, TRAPHACO Advanced Technology Joint Stock Company (Vietnam)

Introductions – Team E

- Dr. Patricio Huenchuñir, Ministry of Health (Chile) – **TABLE MODERATOR**
- Mr. Yota Kikuchi, Japan Pharmaceutical Manufacturers Association (Japan)
- Ms. Hayati Hassan, Manager, Strategic Transformation Unit, SME Corporation (Malaysia)
- Mr. Alejandro Sámano Martínez, AMIIF - Mexican Association of Pharmaceutical Industry Research (Mexico)
- Dr. Fabián Lloréns Torres, Takeda Pharmaceuticals (Mexico)
- Mr. Augusto Rey de la Cuba, ALAFARPE – National Association of Pharmaceutical Companies (Peru)
- Dr. Clivetty Martinez, Johnson & Johnson (United States)
- Mr. Nguyen Hoa Cuong, Ministry of Planning and Investment (Vietnam)



Review of Goals and Procedures

Why develop “APEC Principles for Biopharmaceutical Sector Codes of Ethics”?

For patients:

- Ethical promotion of biopharmaceutical products helps to ensure that healthcare professionals have access to the information they need, that patients have access to the medicines they need, and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients

For the biopharmaceutical sector(in particular SMEs):

- A common set of APEC principles for the region provides companies with greater clarity and harmonization in rules and practices, allowing companies to access new APEC markets through lower compliance costs
- Currently only limited code adoption in the region

For APEC Member Economies:

- A common set of APEC principles supports industry self-regulation, which helps economies to attract and grow innovative biopharmaceutical SMEs

How did we arrive here in Mexico City?

October 2010: 17th APEC SME Ministerial Meeting (Gifu, Japan)

- APEC SME Ministers issued a joint statement including a call for the development of APEC codes of ethics in sectors of export interest, beginning with the medical device sector

November 2010: APEC Ministerial Meeting (Yokohama, Japan)

- APEC Ministers welcomed development of APEC codes to improve and better align industry practices across the region

April 2011: Medical Device Expert Working Group (Kuala Lumpur, Malaysia)

- An Expert Working Group drafts the Kuala Lumpur Principles for Medical Device Sector Codes of Ethics (“KL Principles”)

May 2011: 18th APEC SME Ministerial Meeting (Big Sky, Montana, USA)

- APEC SME Ministers endorse the KL Principles and call for the development of additional sets of principles in sectors where SMEs are important stakeholders, including the biopharmaceutical and construction sectors

Co-Chairs' Draft

Basis of Co-Chairs' Draft

- Current code landscape
- Feedback from questionnaires
- Enduring effectiveness and sustainability

Today's Next Steps

- Breakout discussions and feedback
- Discussion to tailor the document
- Advance consensus document for endorsement by APEC

Guiding Principles for our Discussions

Scope

- The term biopharmaceutical sector will encompass companies that manufacture, market, or distribute pharmaceutical or biopharmaceutical products

Nature of Guidance

- Promote ethical standards through voluntary region wide adoption

Approach

- Respect legal and cultural differences but identify best practices and common ethical standards

Morning Breakout Discussions

- Focus on concepts. Word choice discussed this afternoon.

Break Out Session Objectives

Review and provide comment on the Co-Chairs' Draft (table moderators to report on each group's consensus comments):

- Does the draft include appropriate principles to guide ethical promotion of biopharmaceutical products ?
- Does the draft reflect common elements found in existing codes in the APEC region? Does the draft reflect best practices for this industry?
- Does the draft include measures that ensure that any codes developed based on the principles are effective?



Breakout Sessions

9:45 – 11:30 am



Reports of Breakout Outcomes

(10 minutes per team)

11:30 am – 12:30 pm



Photo Session



Keynote remarks by:

H.E. Francisco J. Sánchez
Under Secretary of Commerce
for International Trade
International Trade Administration
U.S. Department of Commerce



Co-Chairs Report on Breakouts and Approach to Finalize Principles

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Co-Chairs Status Report and Approach to Finalize Principles



Co-Chairs Wrap-Up and Next Steps

Endorsement by APEC

- Immediate submission of biopharmaceutical principles to APEC SME Working Group recommending their approval
- If approved by SMEWG, then circulation of three sets of principles (biopharmaceuticals, medical devices, and construction) by SMEWG Chair to APEC Senior Officials for endorsement November 8-9 in Honolulu, Hawaii
- If endorsed by APEC Senior Officials, then circulation of three sets of principles by Chair of APEC Senior Officials for endorsement by APEC Ministers (foreign ministers) November 11 in Honolulu, Hawaii

Capacity Building to Implement the Principles

- Request by the USA, supported by 11 APEC member economies, for multi-year funding by APEC to build the capacity of SMEs to implement the principles, making them functional and operational

Proposal

- Year 1 (anticipated 2012) – Code-writing workshop for industry associations without existing codes, using a twinning or mentor system
- Year 2 (anticipated 2013) – Train-the-trainer program to expand the number of ethics trainers
- Year 3 (anticipated 2014) – Awareness workshop for healthcare professionals, regulators, and anti-corruption authorities



**Concluding Reception & Dinner
At Piso 51 beginning at 8:00 pm**