



18-20 July 2018 • Tokyo, Japan

STAKEHOLDER COLLABORATION SESSION (18 JULY) BIOPHARMACEUTICAL SECTOR



PART ONE: HEALTHCARE PROFESSIONALS

Introduction/Scene Setting

Dr. Kenneth Hartigan-Go, HCP Co-Chair APEC Biopharmaceutical Working Group on Ethics

PART ONE: HEALTHCARE PROFESSIONALS

Agenda:

- Session One:
 - HCP Code of Conduct Alignment with APEC Mexico City Principles (75 min)
- Session Two:
 - Medical Education Curriculum for APEC Mexico City Principles (45 min)

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STAKEHOLDER COLLABORATION SESSIONS (18 JULY) BIOPHARMACEUTICAL SECTOR

NETWORKING LUNCH AND BREAK (11:00-13:00)

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STAKEHOLDER COLLABORATION SESSION (18 JULY) BIOPHARMACEUTICAL SECTOR



PART TWO: PATIENT ORGANIZATIONS

Introduction/Scene Setting

Mr. Russell Williams, Patient Co-Chair APEC Biopharmaceutical Working Group on Ethics



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BIOPHARMACEUTICAL SECTOR STAKEHOLDER COLLABORATION SESSIONS

(18 JULY 2018)

Manhattan Room One and Two, Tokyo American Club, 2-1-2 Azabudai, Minato-ku, 106-8649 Tokyo, Japan







Business Ethics for APEC SMEs Biopharmaceutical Sector

PART TWO: PATIENT ORGANIZATIONS

13:00-15:35

- Chair: Mr. Russell Williams, Patient Co-Chair, APEC Biopharmaceutical Working Group on Ethics
- **Technical Secretariat:** Mr. Andrew Blasi, Director, C&M International
- **Support:** Mrs. Chrisoula Nikidis, Canadian Head of Compliance and Ethics Solutions, IQVIA



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- 1. Welcome & Brief Introductions (15 minutes)
- 2. Patient Organizations and the APEC Mexico City Principles / Nanjing Declaration (15 minutes)
- 3. Facilitated discussion on Multi-Stakeholder Consensus Frameworks (60 Minutes)
- **4. Building a Toolkit with Patient Organizations** (30 minutes)
- 5. Facilitated discussion on Patient Organization Ad-Hoc Network (30 Minutes)
- 6. Facilitated discussion around a Statement of Recommendations for the Plenary Session (15 minutes)



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Welcome & Brief Introductions

Name - Organization - Expectations





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Understanding the APEC Mexico City Principles and The Nanjing Declaration





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Asia-Pacific Economic Cooperation

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Mexico City Principles

Patients and patient organizations are identified throughout the Mexico City Principles and the Nanjing Declaration

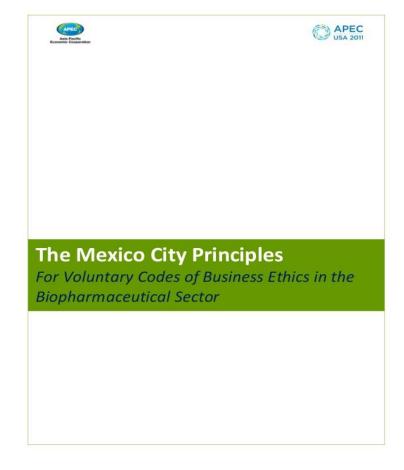
- Preamble
- Section 15 Company Donations for Charitable Purposes
- Section 16 Patient Organizations
- Section 17 Adherence to Principles



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Ethical interactions help ensure that medical decisions are made in the best interests of patients. **Healthcare and Patient Focus** Integrity Independence Legitimate intent Transparency Accountability

Mexico City Principles





Mexico City Principles

Preamble

Engage in the development, manufacturing, research, marketing, distribution, and/or sale of medicines to benefit patients

Ethical relationships with healthcare professionals, government officials, patients, and other stakeholders

Companies are committed to following the highest ethical standards as well as all applicable laws and regulations

Reinforce our intention that Companies' interactions are professional exchanges designed to benefit patients and to enhance the practice of medicine

Companies have an obligation and responsibility to provide objective, accurate, balanced information about their medicines to healthcare professionals

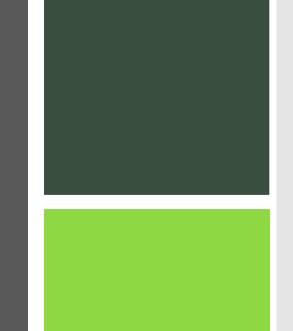
Companies should promote, sell and distribute their medicines in a manner that is ethical, objective, balanced and accountable, and in accordance with all relevant and applicable laws and regulations

Companies are committed to education and training on the safe, appropriate, and effective use of their medicines



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Nanjing Declaration – Promoting Ethical Environments in the Medical Device and Biopharmaceutical Sectors through 2020





Business Ethics for APEC SMEs Biopharmaceutical Sector

Representatives from healthcare providers, anticorruption 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 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.



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Shared Commitment to achieving the Nanjing Declaration Goals

Recognizing our shared commitment to acting in the best interest of patients, we agree on a collective vision for the future of this initiative with recognition that there is more to be done to achieve regional alignment in ethical business practices for both sectors

- Identify priority <u>training areas</u> for industry, governments, healthcare professionals and other stakeholders;
- For non-government organizations, in particular patient organizations: Support <u>partnerships with government</u> agencies, HCPs and industry associations



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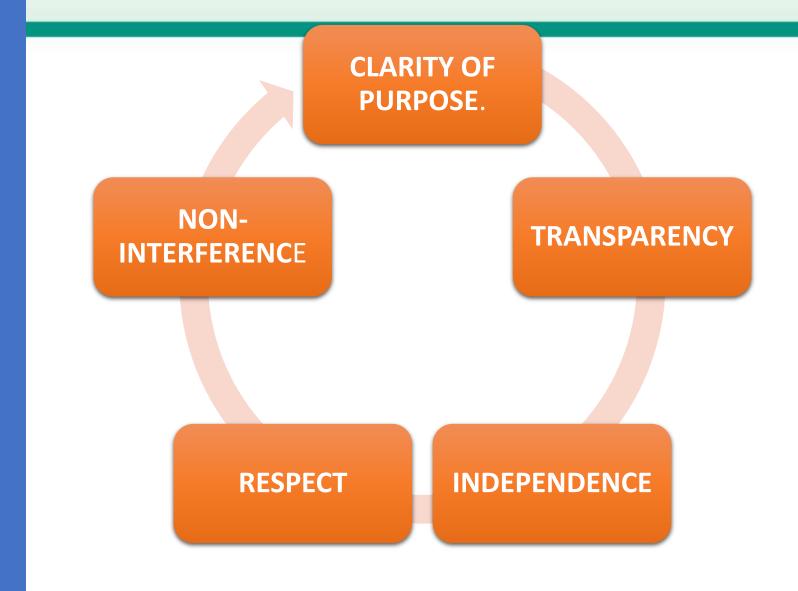


Facilitated Discussion on Multi-Stakeholder Consensus Frameworks



ics for SMEs Forum

PRINCIPLES FOR
ENGAGEMENT
BETWEEN PATIENT
ORGANISATIONS AND
THE
BIOPHARMACEUTICAL
AND MEDICAL DEVICE
INDUSTRY





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In preparation for today.. we asked 5 questions

- What is the status of your Economy's Consensus Framework?
- 2. What is working well and what still needs to be improved?
- 3. Are patient or consumer organization's involved in your Consensus Framework? If so, which ones?
- 4. Why should patient organizations contribute in the next level of Consensus Frameworks?
- 5. How should patient organizations contribute in the next level of Consensus Frameworks?



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Presentations from the Economies

Australia

Canada

Chile

Hong Kong

Japan

Peru

Philippines

Vietnam



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Facilitated Discussion on APEC Mexico City Principles -Toolkit for Patient Organizations



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Guide to Implement Multi-Stakeholder Ethical Collaborations

The implementation of ethical collaborations among relevant stakeholders can be used to achieve the following outcomes:

- A platform to build trust and facilitate open communication;
- The development and/or alignment of codes of ethics across different stakeholders;
- Shared capacity-building and practical training programs; and
- The early identification of shared challenges and opportunities



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Guide to Multi-Stakeholder Collaborations

ENVISION

➤ Embrace shared values

➤ Identify stakeholders

CONVENE

Convene

Ensure a common understanding

Commit

DEVELOP

Determine scope

Draft

Finalize

GROW

Publicise

Maintain commitment

Active communication

Execute joint activities

Measure



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Sample Tool Box Ideas

☐ How do we reach out...?

- Monthly news letter
- Blog
- Tweets
- Linkden
- Etc..

☐ Who do we reach out to..?

- Reach to government officials
- Other patient organizations
- ☐ What do we say..?







Business Ethics for APEC SMEs Biopharmaceutical Sector

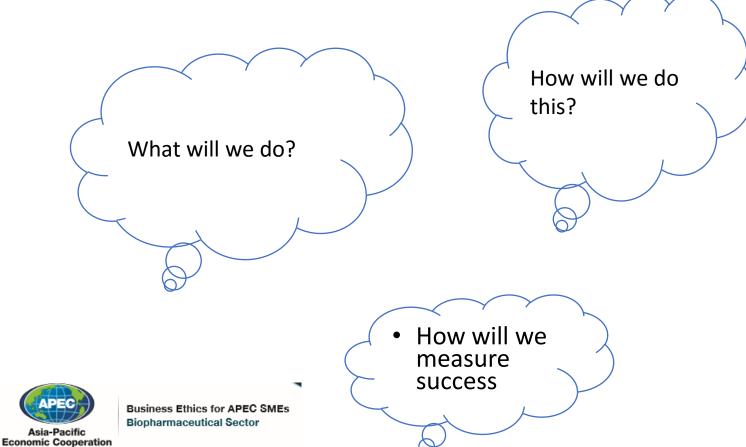






Facilitated Discussion on the development of a Patient Organization Ad-Hoc Support Network to the Patient Co-Chair

Discussion focus on the following questions









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Who will commit to working on this?





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Suggestion of Recommendations for the Plenary Session





Recommendations



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STAKEHOLDER COLLABORATION SESSIONS (18 JULY) BIOPHARMACEUTICAL SECTOR

NETWORKING TEA (15:45-16:00)







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Project Overseer



Ms. Tricia Van Orden, U.S. Department of Commerce

Technical Secretariat:



Mr. Andrew Blasi C&M International

Industry Co-Chair



Mr. Thomas Cueni IFPMA

Government Co-Chair



Ms. Rocio Delgado DIGEMID, Ministry of Health Peru

HCP Co-Chair



Dr. Kenneth Hartigan-GoCollege of Physicians
Philippines

Patient Co-Chair



Mr. Russell WilliamsDiabetes Canada

Members:



Mr. Pan Guangcheng CPIA



Ms. Zhang Beibei On behalf of Dr. Xu Ming CCCMHPIE



Ms. Sabrina Chan HKAPI



Mr. Darodjatun Sanusi, GP Farmasi Indonesia



Dr. Chairat Shayakui Mahidol University



Dr. Juan Francisco Milan Soberanes CETIFARMA



Mr. Jean-Jacques Duhart CIF Chile



Mr. Katsumi Kojima JPMA

MEETING OF THE APEC
BIOPHARMACEUTICAL
WORKING GROUP ON ETHICS



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MEETING OF THE APEC BIOPHARMACEUTICAL WORKING GROUP ON ETHICS (18 JULY)

Discussion Agenda

- 1. Roll Call by Technical Secretariat (CMI) 3 Minutes
- 2. Welcome from the Project Overseer (Ms. Tricia Van Orden, U.S. Department of Commerce) 5 Minutes
- 3. Brief Introductions by Members (Name, Organization, Economy, Length of Involvement) 5 Minutes (30 Seconds Each)
- 4. Readout from WG Meeting on 4 April 2018 by Technical Secretariat (CMI) 5 Minutes
- 5. Summation of Progress in Nanjing Declaration Implementation (by Project Overseer) 5 Minutes
- 6. Member Comments on Remaining Gaps in Nanjing Declaration Goals 15 Minutes

- 7. Facilitated Recommendations (Action Plan) to Achieve Nanjing Declaration Goals 15 Minutes
- 8. Summation of Recommendations (Action Plan) by Technical Secretariat 2 Minutes
- 9. Comments from the Floor (Non-Members) 5 Minutes
- 10. Co-Chair & Member Updates 2 Minutes Each (Time Permitting)
- 11. Closing Thoughts by the Project Overseer (U.S. Department of Commerce) 3 Minutes



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Project Overseer



Ms. Tricia Van Orden, U.S. Department of Commerce

Technical Secretariat:



Mr. Andrew Blasi C&M International

Industry Co-Chair



Mr. Thomas Cueni IFPMA

Government Co-Chair



Ms. Rocio Delgado DIGEMID, Ministry of Health Peru

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