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)
STAKEHOLDER COLLABORATION SESSIONS (18 JULY)
BIOPHARMACEUTICAL SECTOR

NETWORKING LUNCH AND BREAK
(11:00-13:00)
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
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
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
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)
Welcome & Brief
Introductions

Name - Organization - Expectations
Understanding the APEC Mexico City Principles and The Nanjing Declaration
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
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

The Mexico City Principles
For Voluntary Codes of Business Ethics in the Biopharmaceutical Sector
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
Representatives from healthcare providers, anti-corruption 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.
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 training areas for industry, governments, healthcare professionals and other stakeholders;
- For non-government organizations, in particular patient organizations: Support partnerships with government agencies, HCPs and industry associations
Facilitated Discussion on Multi-Stakeholder Consensus Frameworks
PRINCIPLES FOR ENGAGEMENT BETWEEN PATIENT ORGANISATIONS AND THE BIOPHARMACEUTICAL AND MEDICAL DEVICE INDUSTRY

- Clarity of Purpose
- Transparency
- Non-interference
- Respect
- Independence
In preparation for today.. we asked 5 questions

1. 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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<th>Presentations from the Economies</th>
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Facilitated Discussion on APEC Mexico City Principles - Toolkit for Patient Organizations
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
Guide to Multi-Stakeholder Collaborations

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<td>Embrace shared values</td>
<td>Convene</td>
<td>Determine scope</td>
<td>Publicise</td>
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<td>Identify stakeholders</td>
<td>Ensure a common understanding</td>
<td>Draft</td>
<td>Maintain commitment</td>
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<td>Commit</td>
<td>Finalize</td>
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<td>Execute joint activities</td>
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<td>Measure</td>
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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...?**
Facilitated Discussion on the development of a Patient Organization Ad-Hoc Support Network to the Patient Co-Chair
Discussion focus on the following questions

- What will we do?
- How will we do this?
- How will we measure success?
- Schedule quarterly calls
- Who will commit?
Who will commit to working on this?
Suggestion of Recommendations for the Plenary Session
Recommendations
STAKEHOLDER COLLABORATION SESSIONS (18 JULY)
BIOPHARMACEUTICAL SECTOR

NETWORKING TEA
(15:45-16:00)
2018 APEC Business Ethics for SMEs Forum
18–20 July 2018 • Tokyo, Japan
2018 APEC Business Ethics for SMEs Forum
18-20 July 2018 • Tokyo, Japan

Industry Co-Chair
Mr. Thomas Cueni
IFPMA

Government Co-Chair
Ms. Rocio Delgado
DIGEMID, Ministry of Health Peru

HCP Co-Chair
Dr. Kenneth Hartigan-Go
College of Physicians Philippines

Patient Co-Chair
Mr. Russell Williams
Diabetes Canada

Members:
Mr. Pan Guangcheng
CPIA

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

Mr. Darodjatun Sanusi,
GP Farmasi Indonesia

Dr. Chairat Shayakui
Mahidol University

Ms. Sabrina Chan
HKAPI

Mr. Jean-Jacques Duhart
CIF Chile

Dr. Juan Francisco Milan Soberanes
CETIFARMA

Mr. Katsumi Kojima
JPMA

MEETING OF THE APEC BIOPHARMACEUTICAL WORKING GROUP ON ETHICS
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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