



# 2018 APEC Business Ethics for SMEs Forum

18-20 July 2018 • Tokyo, Japan

## 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

UPDATED 17 JULY 2018

TIME	SESSION PROGRAM
08:00-09:00	<p><b>Badge Collection: Fred Harris Gallery (B1 Level)</b></p> <p><b>Networking Tea / Coffee Service: Manhattan Room One and Two (B2 Level)</b></p>
09:00-11:00	<p><b>PART ONE: HEALTHCARE PROFESSIONALS (HCPs)</b></p> <p><b>Objective:</b> Healthcare professionals and their societies serve an integral role in strengthening ethical business practices in the biopharmaceutical sector as well as in realizing full implementation of the APEC Mexico City Principles and Nanjing Declaration. This session will bring together leaders from healthcare professional bodies across the APEC region, in tandem with other industry and non-industry stakeholders, to advance recommendations from the 2017 APEC Business Ethics for SMEs Forum, including (A) the development of a translational tool to support HCP Code of Conduct alignment with the APEC Mexico City Principles and (B) the development of university curriculum for HCP students that incorporates the APEC Mexico City Principles.</p> <ul style="list-style-type: none"> <li>• <b>Chair:</b> Dr. Kenneth Hartigan-Go, HCP Co-Chair, APEC Biopharm. WG on Ethics (Philippines)</li> <li>• <b>Technical Secretariat:</b> Mr. Andrew Blasi, Director, C&amp;M International</li> <li>• <b>HCP Organizations:</b> <i>Japan Medical Association, Chinese Hospital Association, Malaysian Medical Association, Rational Drug Use Subcommittee of Thailand, Philippine College of Physicians, Confederation of Medical Associations in Asia and Oceania, among others.</i></li> <li>• <b>Participants:</b> <i>All stakeholders invited to the Forum are welcome to join this session.</i></li> </ul>
11:00-13:00	<p><b>Networking Lunch: Brooklyn Suite (B2 Level)</b></p> <p><b>Tea / Coffee Service: Manhattan Room One and Two (B2 Level)</b></p>
13:00-15:45	<p><b>PART TWO: PATIENT ORGANIZATIONS</b></p> <p><b>Objective:</b> Ethical business practices are at the heart of patient-centered healthcare where thousands of small and medium-sized enterprises operate. Patient organizations have served a key role across numerous APEC member economies in advancing multi-stakeholder ethical collaborations as called for by the APEC Mexico City Principles and APEC Nanjing Declaration. This session will bring together leaders from patient organizations, in tandem with other industry and non-industry stakeholders, to advance recommendations from the 2017 APEC Business Ethics for SMEs Forum, including (A) specific strategies for patient organizations to support universal adoptions and implementation of consensus frameworks, (B) the development of an APEC Principles toolkit for patient organizations, and (C) the formation of an ad hoc network to exchange best practices.</p> <ul style="list-style-type: none"> <li>• <b>Chair:</b> Mr. Russell Williams, Patient Co-Chair, APEC Biopharm. WG on Ethics (Canada)</li> <li>• <b>Technical Secretariat:</b> Mr. Andrew Blasi, C&amp;M International (United States)</li> <li>• <b>Presentation on APEC Principles / Nanjing Declaration:</b> Ms. Chrisoula Nikidis, Polaris (Canada)</li> <li>• <b>Patient Organizations:</b> <i>Consumers Health Forum of Australia, Diabetes Canada / Health Charities Coalition of Canada, Japan Federation of Cancer Patient Groups, Fundación Me Muevo (Chile), Philippine Alliance of Patients Organizations (PAPO), Rare Cancers Philippines, and Medicines Transparency Alliance (MeTA) Philippines, among others.</i></li> <li>• <b>Participants:</b> <i>All stakeholders invited to the Forum are welcome to join this session.</i></li> </ul>
15:45-16:00	<p><b>Networking Tea / Coffee Service: Manhattan Room One and Two (B2 Level)</b></p>



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<b>16:00-17:30</b>	<p><b>Part Three: APEC Biopharmaceutical Working Group on Ethics</b></p> <p><i>Project Overseer to facilitate agenda outlined below. Discussion and interventions during this session are limited to sitting members of the Working Group or their designee(s). Other 2018 Forum participants are welcome to observe.</i></p> <ol style="list-style-type: none"> <li>1. Roll Call by Technical Secretariat – 3 Minutes</li> <li>2. Welcome from the Project Overseer (Ms. Tricia Van Orden, U.S. Dept. of Commerce) – 5 Minutes</li> <li>3. Brief Introductions by Members (Name, Organization, Economy) – 5 Minutes (30 Seconds Each)</li> <li>4. Readout from WG Meeting on 4 April 2018 by Technical Secretariat – 5 Minutes</li> <li>5. Summation of Progress in Nanjing Declaration Implementation (by Project Overseer) – 5 Minutes</li> <li>6. Member Comments on Remaining Gaps in Nanjing Declaration Goals – 15 Minutes</li> <li>7. Facilitated Recommendations (Action Plan) to Achieve Nanjing Declaration Goals – 15 Minutes</li> <li>8. Summation of Recommendations (Action Plan) by Technical Secretariat – 2 Minutes</li> <li>9. Comments from the Floor (Non-WG Attendees) – 5 Minutes</li> <li>10. Co-Chair &amp; Member Updates – 2 Minutes Each (Time Permitting)             <ul style="list-style-type: none"> <li>o <u>Industry</u>: Mr. Thomas Cueni (IFPMA)</li> <li>o <u>Government</u>: Ms. Rocio Delgado (DIGEMID, Ministry of Health of Peru)</li> <li>o <u>Patient</u>: Mr. Russell Williams (Diabetes Canada / Health Charities Coalition of Canada)</li> <li>o <u>HCP</u>: Dr. Ken Hartigan-Go (Philippine College of Physicians / Asian Institute of Mgt)</li> <li>o Mr. Pan Guangcheng, CPIA (China)</li> <li>o Ms. Zhang Beibei on behalf of Dr. Xu Ming, CCCMHPIE (China)</li> <li>o Ms. Sabrina Chan, HKAPI (Hong Kong, China)</li> <li>o Mr. Darodjatun Sanusi, GP Farmasi Indonesia</li> <li>o Dr. Chairat Shayakul, Rational Drug Use Subcommittee / Mahidol University (Thailand)</li> <li>o Dr. Juan Francisco Millan Soberanes, CETIFARMA (Mexico)</li> <li>o Ms. Geraldine Dufresne, Pharma Group (Viet Nam)</li> <li>o Mr. Jean-Jacques Duhart, CIF Chile</li> <li>o Mr. Katsumi Kojima, JPMA (Japan)</li> </ul> </li> <li>11. Closing Thoughts by the Project Overseer (U.S. Department of Commerce) – 3 Minutes</li> </ol>
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## **BIOPHARMACEUTICAL SECTOR**

### **MULTI-STAKEHOLDER TRAINING WORKSHOP (19 JULY 2018)**

*Leveraging Technologies to Scale Code of Ethics Implementation for Small and Medium Enterprises  
Manhattan Room One and Two, Tokyo American Club, 2-1-2 Azabudai, Minato-ku, 106-8649 Tokyo, Japan*

TIME	WORKSHOP PROGRAM
<b>7:30-8:30</b>	<p><b>Badge Collection: Fred Harris Gallery (B1 Level)</b></p> <p><b>Networking Tea / Coffee Service: Manhattan Room One and Two (B2 Level)</b></p>
<b>8:30-9:00</b>	<p><b>Opening Session</b></p> <p><i><u>Introductory Remarks:</u> Tricia Van Orden, Project Overseer, Business Ethics for APEC SMEs Initiative &amp; Deputy Director, Trade Promotion Coordinating Committee Secretariat, U.S. Dept. of Commerce</i></p> <p><i><u>Welcome Remarks:</u> Melissa Stapleton Barnes, Senior Vice President, Enterprise Risk Management, and Chief Ethics and Compliance Officer, Eli Lilly and Company</i></p> <ul style="list-style-type: none"> <li>• <u>Participant Introductions:</u> Name, Position, Organization, &amp; Economy</li> <li>• <u>Official Workshop Photograph</u></li> </ul>



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<p>9:00-10:00</p>	<p><b>2018 Report on Code of Ethics Implementation by APEC Biopharmaceutical Industry Associations Roundtable on Tracking Progress with the Nanjing Declaration &amp; Looking Ahead</b></p> <p><i>Objective:</i> Following a brief presentation on the outcomes of the 2018 Report on Code of Ethics Implementation by APEC Biopharmaceutical Industry Associations, the Co-Chairs of the APEC Biopharmaceutical Working Group will provide perspectives on how the region can continue to realize universal adoption and widespread implementation of the APEC Mexico City Principles. Thoughts will also be provided on Nanjing Declaration implementation before opening the floor for questions.</p> <p><i>Presentation &amp; Facilitator:</i> Mr. Andrew Blasi, Director, C&amp;M International</p> <p><i>Panel Discussants:</i></p> <ul style="list-style-type: none"> <li>• Mr. Thomas Cueni, Industry Co-Chair, APEC Biopharmaceutical Working Group on Ethics</li> <li>• Ms. Rocio Delgado, Government Co-Chair, APEC Biopharmaceutical Working Group on Ethics</li> <li>• Dr. Kenneth Hartigan-Go, HCP Co-Chair, APEC Biopharmaceutical Working Group on Ethics</li> <li>• Mr. Russell Williams, Patient Co-Chair, APEC Biopharmaceutical Working Group on Ethics</li> </ul>
<p>10:00-11:30</p>	<p><b>Spotlight on Japan: Multi-Stakeholder Collaboration to Strengthen Ethical Business Practices</b></p> <p><i>Session Introduction / Closing:</i> Sabrina Chan, Senior Executive Director The Hong Kong Association of the Pharmaceutical Industry (HKAPI)</p> <p><i>Keynote Remarks (10 Minutes):</i> Dr. Isao Teshirogi President, Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ) Vice President, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) President and Chief Executive Officer, Shionogi &amp; Co., Ltd.</p> <p><i>Multi-Stakeholder Panel Session: "Building Trusted Relationships for Japan Society –Transparency between Healthcare Professionals and the Industry" (80 Minutes)</i> <i>Note:</i> Introduction by panel moderator and five minute remarks by each panelist followed by facilitated discussion. Topics include: transparency, clinical data integrity, industry self-regulation, IFPMA Code, and multi-stakeholder consensus framework.</p> <ul style="list-style-type: none"> <li>• <i>Panel Moderator:</i> Mr. Junichi Asatani, Vice President, Chief Compliance Officer, Eisai Co., Ltd.</li> <li>• Dr. Shigeki Shiiba, Counsellor of Health Policy Bureau, Ministry of Health, Labor, and Welfare</li> <li>• Ms. Naomi Sakurai, Executive Director, Japan Federation of Cancer Patient Groups</li> <li>• Prof. Saburo Sone, Chair, Conflicts of Interest Committee, Japanese Assn of Medical Sciences</li> <li>• Mr. Tokuo Tanaka, Managing Director, Japan Pharmaceutical Manufacturers Association</li> </ul>
<p>11:30-13:30</p>	<p><b>Presentation on the Pilot Module: "APEC Virtual Ethics for SMEs Compliance Program (Biopharmaceutical Sector)" &amp; Breakout Testing Exercises with Feedback Sessions</b></p> <p><i>Lead Facilitator:</i> Karen Eryou, Head, Global Ethics &amp; Compliance Programs, UCB</p> <p><i>Note:</i> Coffee, tea, and pastry service will be offered during the testing exercises</p>
<p>13:30-14:30</p>	<p><b>Networking Lunch: Brooklyn Suite (B2 Level)</b></p>
<p>14:30-15:30</p>	<p><b>Interactive Session: Heightening External Stakeholder Engagement on Industry Association and Enterprise Codes of Ethics – Strategies for Success across the APEC Region</b></p> <p><i>Co-Facilitators:</i></p> <ul style="list-style-type: none"> <li>• Dr. Kenneth Hartigan-Go, HCP Co-Chair, APEC Biopharmaceutical Working Group on Ethics</li> <li>• Mr. Russell Williams, Patient Co-Chair, APEC Biopharmaceutical Working Group on Ethics</li> </ul>



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	<p><i>Objective:</i> Following a short review of the “External Stakeholder Engagement” outcomes from the 2018 Report on Code of Ethics Implementation by APEC Biopharmaceutical Industry Associations, Dr. Hartigan-Go and Mr. Williams will facilitate one or two interactive exercises that provide strategies for all organizations to successfully heighten engagement with external stakeholders on codes. Building upon the recommendations concluded on 18 July, the learnings from this session may also help to inform plenary deliberations on implementation of consensus frameworks across the region.</p>
<p><b>15:30-15:45</b></p>	<p><b>Networking Tea / Coffee Service: Manhattan Room One and Two (B2 Level)</b></p>
<p><b>15:45-17:45</b></p>	<p><b>Interactive, Multi-Stakeholder Sessions</b></p> <p><i>Objective:</i> Undertake two interactive sessions using a train-the-trainer approach:</p> <ul style="list-style-type: none"> <li>• <u>Session One: Case Study on a Mainstream Issue: International best practices in Industry-Healthcare Professional (HCP) gift giving: What does the APEC Mexico City Principles say and what is the international consensus?</u></li> <li>• <u>Session Two: Assessing an Emerging Issue: Ethical third party intermediary relationships: How significant is this risk area for biopharmaceutical sector entities? What are the global and regional trends in other sectors that should be understood in considering future actions?</u></li> </ul> <p><u>Session One Facilitators:</u></p> <ul style="list-style-type: none"> <li>• Mr. Howard Lin, Eli Lilly (China)</li> <li>• Mr. Neil Pratt, PhRMA (United States)</li> <li>• Ms. Sofie Melis, IFPMA (Switzerland)</li> <li>• Mr. Kunio Kawajiri, JPMA (Japan)</li> <li>• Mr. Teodoro Padilla, PHAP (The Philippines)</li> </ul> <p><u>Session Two Facilitators:</u></p> <ul style="list-style-type: none"> <li>• Ms. Maru Quindimil, UCB (The Philippines)</li> <li>• Ms. Chrisoula Nikidis, IQVIA (Canada)</li> <li>• Mr. Reiner Gloor, PHAP (The Philippines)</li> <li>• Ms. Duangduen Sahavechaphan, PReMA (Thailand)</li> </ul>
<p><b>17:45-18:00</b></p>	<p><b>Closing Session</b></p> <p><u>Closing Observations:</u> Mr. Thomas Cueni, Industry Co-Chair APEC Biopharmaceutical Working Group on Ethics &amp; Director-General, IFPMA</p> <p><u>Guidance for Plenary (20 July):</u> Andrew Blasi, Director, C&amp;M International</p>