



Asia-Pacific
Economic Cooperation

2018 APEC Business Ethics for SMEs Forum

18-20 July 2018 • Tokyo, Japan





MULTI-STAKEHOLDER TRAINING WORKSHOP (19 JULY) BIOPHARMACEUTICAL SECTOR



Introductory Remarks

*Ms. Tricia Van Orden, Project Overseer
Business Ethics for APEC SMEs Initiative
U.S. Department of Commerce*



MULTI-STAKEHOLDER TRAINING WORKSHOP (19 JULY) BIOPHARMACEUTICAL SECTOR



Welcome Remarks

Ms. Melissa Stapleton Barnes

*Senior Vice President, Enterprise Risk Management and
Chief Ethics and Compliance Officer
Eli Lilly and Company*



MULTI-STAKEHOLDER TRAINING WORKSHOP (19 JULY) BIOPHARMACEUTICAL SECTOR

Participant Introductions

<i>NAME</i>	<i>POSITION</i>	<i>ORGANIZATION</i>	<i>ECONOMY</i>
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2018 REPORT ON CODE OF ETHICS IMPLEMENTATION BY APEC BIOPHARMACEUTICAL INDUSTRY ASSOCIATIONS ROUNDTABLE

Roundtable Discussants:



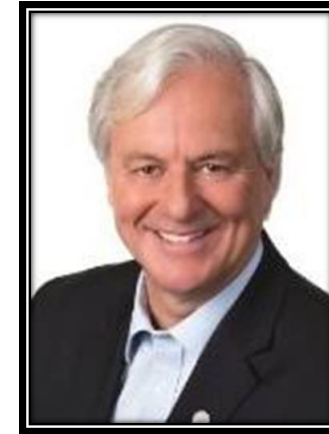
Mr. Thomas Cueni
Industry Co-Chair
APEC
Biopharmaceutical
Working
Group on Ethics



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



Ms. Rocio Delgado
Government Co-Chair
APEC
Biopharmaceutical
Working
Group on Ethics



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



Mr. Andrew Blasi
C&M International

Presentation & Facilitator:



SPOTLIGHT ON JAPAN: MULTI-STAKEHOLDER COLLABORATION TO STRENGTHEN ETHICAL BUSINESS PRACTICES



SESSION INTRODUCTION/CLOSING

Ms. Sabrina Chan

Senior Executive Director

The Hong Kong Association of the Pharmaceutical Industry



SPOTLIGHT ON JAPAN: MULTI-STAKEHOLDER COLLABORATION TO STRENGTHEN ETHICAL BUSINESS PRACTICES



KEYNOTE REMARKS

*Dr. Isao Teshirogi, President, FPMAJ
Vice President, IFPMA
President and Chief Executive Officer,
Shiongi & Co., Ltd.*



SPOTLIGHT ON JAPAN: MULTI-STAKEHOLDER COLLABORATION TO STRENGTHEN ETHICAL BUSINESS PRACTICES

Facilitator:



Mr. Junichi Asatani
Eisai Co., Ltd.

Roundtable Discussants:



Ms. Naomi Sakurai
Japan Federation of
Cancer Patient Groups



Mr. Tokuo Tanaka
Japan Pharmaceutical
Manufacturers
Association



Prof. Saburo Sone
Japanese Association of
Medical Societies



Ms. Keiko Moritsu
Ministry of Health,
Labor, and
Welfare, Japan



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PILOT MODULE: APEC VIRTUAL ETHICS FOR SMEs COMPLIANCE PROGRAM

Project Lead & Technical Secretariat:



Ms. Karen Eryou
UCB



Ms. Katherine Nunner
C&M International

Expert Team:



Ms. Deborah Monk
Medicines Australia



Mr. Y.S. Kwon
Johnson & Johnson



Ms. Sofie Melis
IFPMA



Mr. Howard Lin
Eli Lilly

Sounding Board Team:



Ms. Hui Chen
Ethics &
Compliance Consultant



Prof. Muel Kaptein
Erasmus University
Rotterdam



Ms. Kathleen Hamann
Pierce Atwood



Ms. Chrisoula Nikidis
Polaris



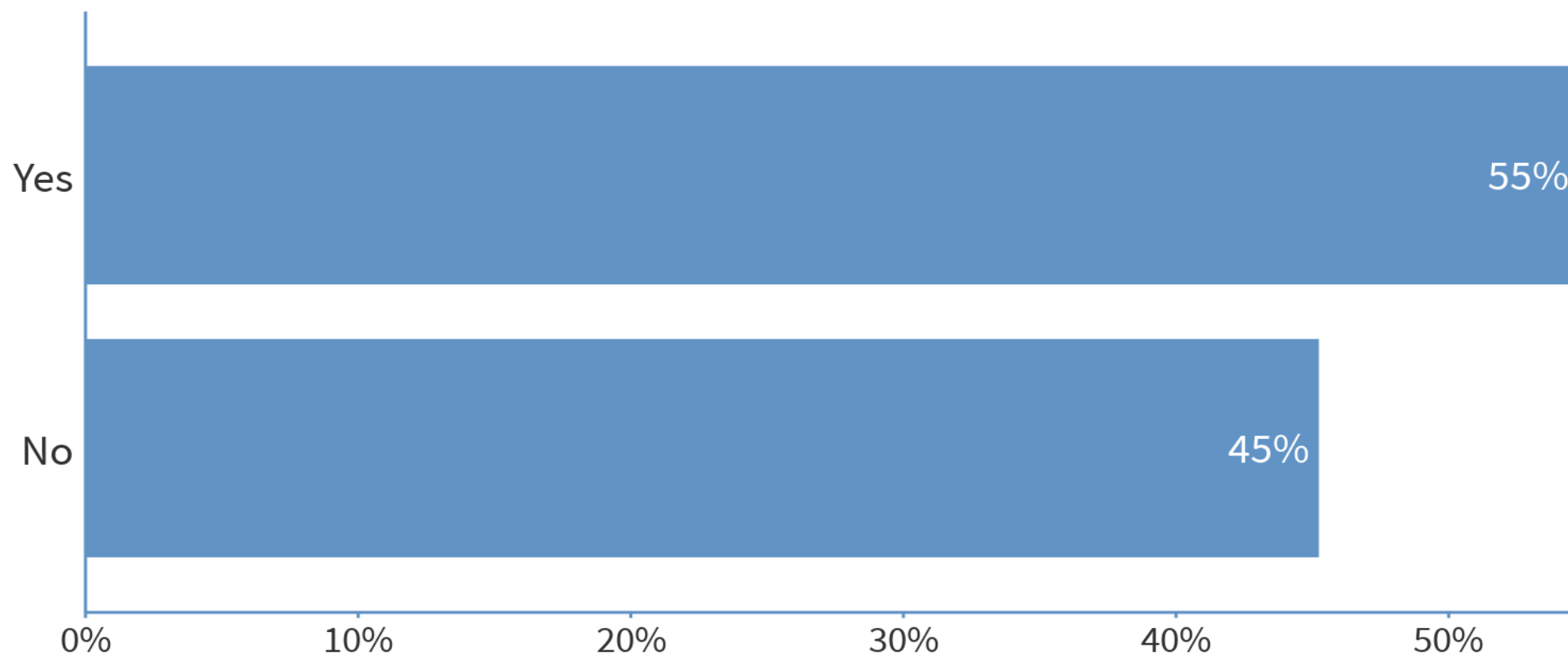
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Have you previously attended the APEC Ethics for SMEs Forum?



When poll is active, respond at **PollEv.com/apecethics**



[illegible]



PILOT MODULE: APEC VIRTUAL ETHICS FOR SMES COMPLIANCE PROGRAM

Objective:

- Simple, foundational virtual ethics and compliance program
- Open-sourced to all SMEs
- Disseminated in partnership with APEC industry associations

Audience:

- SMEs in the biopharmaceutical sector with minimal or no ethics and compliance programs



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Tailoring Resources to Your Enterprise:

User note: Please note that these responses are anonymous and this platform is designed towards guiding your enterprise towards the most useful resources and tools for building a compliance program.

Need/Motivation

What is your need/motivation for using the site?



Does your company have a code of ethics?



Are you aware of the Mexico City Principles?



Does your industry association have a code of ethics?



Enterprise Segmentation

What is the size of your enterprise?



What type of business is your enterprise?



Governance

What is your role in the company?





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Results

Resource Name	Format
Communicating the Value of High-Standard Business Ethics: Within a Small and Medium Sized Enterprise (SME)	Microsoft PowerPoint PDF
Compliance Program Outcomes: A tool to build upon the 6 elements of a compliance program including ideas, examples, outcomes, measurements, and materials	Microsoft Word PDF
The Value from and Responsibility for ensuring Ethical Codes of Conduct: Industry and Association Responsibilities	Microsoft PowerPoint PDF
Data on Ethical Performance	Microsoft PowerPoint PDF
Mexico City Principles: A guide for the ethical conduct and interaction between the healthcare sector and the biopharmaceutical industry to ensure that medical decisions are made in the best interests of the patients.	Website



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mcprinciples.org/smeecp.asp




PILOT MODULE: APEC VIRTUAL ETHICS FOR SMES COMPLIANCE PROGRAM

Testing:

- Facilitated by mentors (2 at each table)
- 11:50-12:25: Viewing platform, complete survey (30 minutes)
- 12:25-12:55: Discussion on Mexico City Principles and guide to implementation (30 minutes)



Given your review of the beta version of the platform, what additional resources would you include for SMEs?

 When poll is active, respond at **PollEv.com/apecethics**





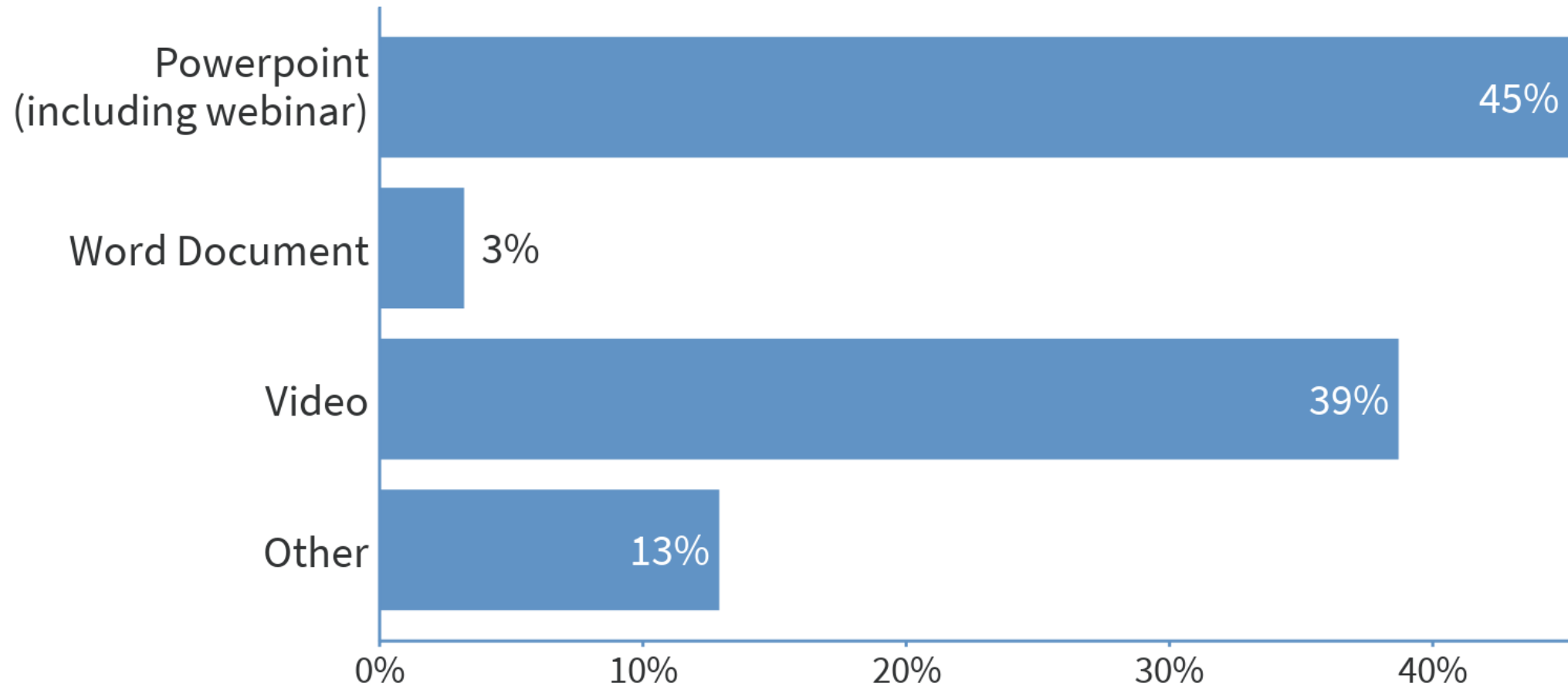
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How might this information be best packaged?




When poll is active, respond at **PollEv.com/apecethics**





What is one word or phrase to describe what you are going to take away from this session?

 When poll is active, respond at **PollEv.com/apecethics**





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MULTI-STAKEHOLDER TRAINING WORKSHOP (19 JULY)
BIOPHARMACEUTICAL SECTOR

NETWORKING LUNCH
(13:30-14:30)



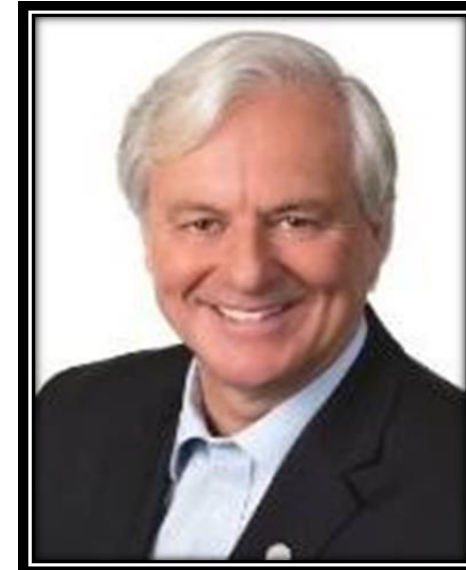
INTERACTIVE SESSION: HEIGHTENING EXTERNAL STAKEHOLDER ENGAGEMENT



Dr. Kenneth Hartigan-Go

HCP Co-Chair

*APEC Biopharmaceutical Working
Group on Ethics*



Mr. Russell Williams

Patient Co-Chair

*APEC Biopharmaceutical Working
Group on Ethics*




INTERACTIVE SESSION: HEIGHTENING EXTERNAL STAKEHOLDER ENGAGEMENT

- Brief Introductions / Scene-Setting (Russell Williams and Ken Hartigan-Go)
- Interactive Exercise: Strategies for Heightening External Stakeholder Engagement
 - Breakout Table Question One (12 Minutes): Why and how should enterprises and industry associations coordinate with patient organizations to advance implementation of the APEC Mexico City Principles?
 - Breakout Table Question Two (12 Minutes): Why and how should enterprises and industry associations coordinate with healthcare professional organizations to advance implementation of the APEC Mexico City Principles?
 - Breakout Table Question Three (12 Minutes): Why and how should enterprises and industry associations coordinate with governments to advance implementation of the APEC Mexico City Principles?
 - Report Out Session: One representative from each table (mentor or attendee) will update the workshop on one suggestion from their small group for each question.




What do we do to improve engagement with HCPs?

 When poll is active, respond at **PollEv.com/apecethics**





What do we do to improve engagement with patient organizations?

 When poll is active, respond at **PollEv.com/apecethics**



A word cloud visualization of terms related to patient engagement. The most prominent words are 'respect' and 'simplicity', both in large, dark purple font. Other significant words include 'communication', 'education', 'listen', 'trust', 'involvement', 'participation', 'information', 'building', 'dialogue', 'science', 'accountable', 'stand', 'navigate', 'balance', 'build', 'listening', 'share', 'understanding', 'purpose', 'segment', 'organize', 'inclusive', 'support', 'practices', 'transparency', 'value', 'empathy', 'partnership', 'codes', 'communicate', 'provide', 'better', 'safety', 'activities', 'tools', 'dialogues', 'workshops', 'access', 'tageting', 'proposition', 'shoes', 'centric', 'needs', 'set', 'equals', 'treat', 'best', 'supportive', 'target', 'issues', 'knowledge', 'reap', 'medicines', 'medical', 'segmentation', 'patient', 'respect', 'simplicity', 'communication', 'education', 'listen', 'trust', 'involvement', 'participation', 'information', 'building', 'dialogue', 'science', 'accountable', 'stand', 'navigate', 'balance', 'build', 'listening', 'share', 'understanding', 'purpose', 'segment', 'organize', 'inclusive', 'support', 'practices', 'transparency', 'value', 'empathy', 'partnership', 'codes', 'communicate', 'provide', 'better', 'safety', 'activities', 'tools', 'dialogues', 'workshops', 'access', 'tageting', 'proposition', 'shoes', 'centric', 'needs', 'set', 'equals', 'treat', 'best', 'supportive', 'target', 'issues', 'knowledge', 'reap', 'medicines', 'medical', 'segmentation', 'patient', 'respect', 'simplicity', 'communication', 'education', 'listen', 'trust', 'involvement', 'participation', 'information', 'building', 'dialogue', 'science', 'accountable', 'stand', 'navigate', 'balance', 'build', 'listening', 'share', 'understanding', 'purpose', 'segment', 'organize', 'inclusive', 'support', 'practices', 'transparency', 'value', 'empathy', 'partnership', 'codes', 'communicate', 'provide', 'better', 'safety', 'activities', 'tools', 'dialogues', 'workshops', 'access', 'tageting', 'proposition', 'shoes', 'centric', 'needs', 'set', 'equals', 'treat', 'best', 'supportive'.



What do we do to improve engagement with governments?



When poll is active, respond at **PollEv.com/apecethics**





INTERACTIVE SESSION: HEIGHTENING EXTERNAL STAKEHOLDER ENGAGEMENT

- Brief Introductions / Scene-Setting (Russell Williams and Ken Hartigan-Go)
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MULTI-STAKEHOLDER TRAINING WORKSHOP (19 JULY)
BIOPHARMACEUTICAL SECTOR

NETWORKING BREAK
(15:30-15:45)



INTERACTIVE MULTI-STAKEHOLDER SESSION:

SESSION ONE: CASE STUDY ON A MAINSTREAM ISSUE

FACILITATORS:



Mr. Howard Lin
Eli Lilly (China)



Mr. Neil Pratt
PhRMA
(United States)



Ms. Sofie Melis
IFPMA (Switzerland)



Mr. Kunio Kawajiri
JPMA (Japan)



Mr. Teodoro Padilla
PHAP
(The Philippines)



The Mexico City Principles

Biopharmaceutical Sector Codes of Ethics

Ethical Interactions help ensure that medical decisions are made in the best interests of patients

- **Healthcare and Patient Focus** means everything we do is intended to benefit patients.
- **Integrity** means dealing ethically, honestly, and respectfully in everything we do.
- **Independence** means to respect the need of autonomous decision-making of all parties, free from improper influence.
- **Legitimate intent** means everything we do is for the right reasons, is lawful, and aligns with the spirit and values of these Principles.
- **Transparency** means a general willingness to be open about our actions while respecting legitimate commercial sensitivities and intellectual property rights.
- **Accountability** means a willingness to be responsible for our actions and interactions.



Article 1 – Interactions with Healthcare Professionals

- A. Interactions between Companies and healthcare professionals provide valuable scientific, clinical, product, and policy information about medicines that may lead to improved patient care.

- C. All interactions with healthcare professionals are to be conducted in a professional and ethical manner.
 - 1. Healthcare professionals must not be improperly influenced by Companies.
 - 2. Nothing should be offered or provided by a Company in a manner that inappropriately influences a healthcare professional's prescribing practices.



Article 4 – Symposias and Congresses

- C. Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, or promote any medicine.
- D. All Events should be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. Companies should avoid using extravagant venues or resorts.
- E. Hospitality should be limited to refreshments and/or meals incidental to the main purpose of the Event and should only be provided:
 - 1. to participants of the Event and not their guests; and
 - 2. is moderate and reasonable as judged by local standards.
- F. Companies should not pay any costs associated with individuals accompanying invited healthcare professionals.



Article 5 – Informational Presentations by Company Representatives

- A. In order to provide important scientific information and to respect healthcare professionals' abilities to manage their schedules and provide patient care, Company representatives may take the opportunity to present information during healthcare professionals' working day, including mealtimes, in accordance with applicable laws and regulations.
 - 1. In connection with such presentations or discussions, it is appropriate for occasional meals to be offered as a business necessity to the healthcare professional as well as members of their staff attending presentations, so long as the presentations provide scientific or educational value and the meals (a) are reasonable as judged by local standards; (b) are not part of an entertainment or recreational event; and (c) are provided in a manner conducive to informational communication.
 - 2. Inclusion of a healthcare professional's spouse or other guest in a meal accompanying an informational presentation made by or on behalf of a Company is not appropriate. Offering "take-out" meals or meals to be eaten without a Company representative being present is not appropriate.



Article 6 – Entertainment

- A. Company interactions are professional in nature and are intended to facilitate the exchange of medical or scientific information that will benefit patient care.
 - 1. To ensure the appropriate focus on education and informational exchange and to avoid the appearance of impropriety, Companies should not provide any form of entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any healthcare professional. Such entertainment or recreational benefits should not be offered, regardless of (1) the value of the items; (2) whether the Company engages the healthcare professional as a speaker or consultant, or (3) whether the entertainment or recreation is secondary to an educational purpose.
 - 2. No standalone entertainment or other leisure or social activities should be provided or paid for by Companies. At events, entertainment of modest nature, which is secondary to refreshments or meals, is allowed.



Article 7 – Educational Items and Gifts

- A. Payments in cash or cash equivalents (such as gift certificates) or gifts for the personal benefit of healthcare professionals should not be provided or offered to healthcare professionals.
 - 1. It is appropriate for Companies, where permitted by law or local codes of ethics, to offer items designed primarily for the education of patients or healthcare professionals if the items are of modest value and do not have value to healthcare professionals outside of his or her professional responsibilities.
 - 2. These items should not subsidize normal routine operations of a medical practice.



Article 10 – Consultant and Speaker Arrangements

- A. Consulting arrangements with healthcare professionals allow companies to obtain information or advice from medical experts on such topics as the marketplace, products, therapeutic areas and the needs of patients. Companies use this advice to inform their efforts to ensure that the medicines they develop, produce and/or market are meeting the needs of patients. In addition, healthcare professionals participate in Company sponsored speaking programs in order to help educate and inform other healthcare professionals about the benefits, risks, and appropriate uses of medicines.
1. Companies should continue to ensure that consultant and speaking arrangements are neither inducements nor rewards for prescribing or recommending a particular medicine or course of treatment.
 2. It is appropriate for consultants and speakers who provide services to be offered reasonable compensation for those services and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Any compensation or reimbursement made in conjunction with a consulting or speaking arrangement should be reasonable and based on fair market value.



Article 15 – Company Donations for Charitable Purposes

- A. As a demonstration of good corporate citizenship, Companies recognize their responsibility to support worthwhile activities both within and outside our communities.
 - 1. Donations including donations in kind, may be provided to organizations and institutions involved in promoting activities such as artistic, charitable, cultural, community, educational, humanitarian, health, philanthropic, and sporting activities in accordance with applicable laws and regulations.
 - 2. Companies should ensure that such support is not undertaken solely for product promotional reasons, and is not directed solely for product promotion purposes.
 - 3. Funding and donations in-kind should be directed to organizations and documented in a manner that outlines the nature of the donation provided.
 - 4. Acknowledgement by the recipient organization of such support should be restricted to appropriate recognition of support.
 - 5. Companies should ensure that there are no incentives to prescribe, recommend, purchase, supply or administer a product based on financial support and that nothing should be offered or provided which would interfere with the independence of a healthcare professional's prescribing or dispensing practices.



Gifts Case Study

- Images of items of varying value are in the container. Each table will select **three** images from the container.
- Discuss at table:
 1. Could the item be given to an HCP (or an HCO) under the Mexico City Principles?
 - **Yes:** Fine to give to an HCP
 - **Maybe:** Under certain circumstances/with appropriate controls
 - **No:** Cannot be given to an HCP
 2. What is the relative risk of giving the item to an HCP (very low to very high)?
- Select a representative from each table to post items on relevant flipcharts at front of the room. The representative will explain the table's thought-process behind the decision.



INTERACTIVE MULTI-STAKEHOLDER SESSION:

SESSION TWO: ASSESSING AN EMERGING ISSUE, Ethical and Third Party Relationships
FACILITATORS:



Ms. Maru Quindimil
UCB
(The Philippines)



Ms. Chrisoula Nikidis
IQVIA
(Canada)



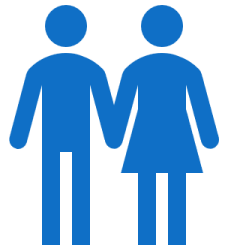
Mr. Reiner Gloor
PHAP
(The Philippines)



**Ms. Duangduen
Sahavechaphan**
PReMA
(Thailand)



Ms. Laura Giussani
(United States)

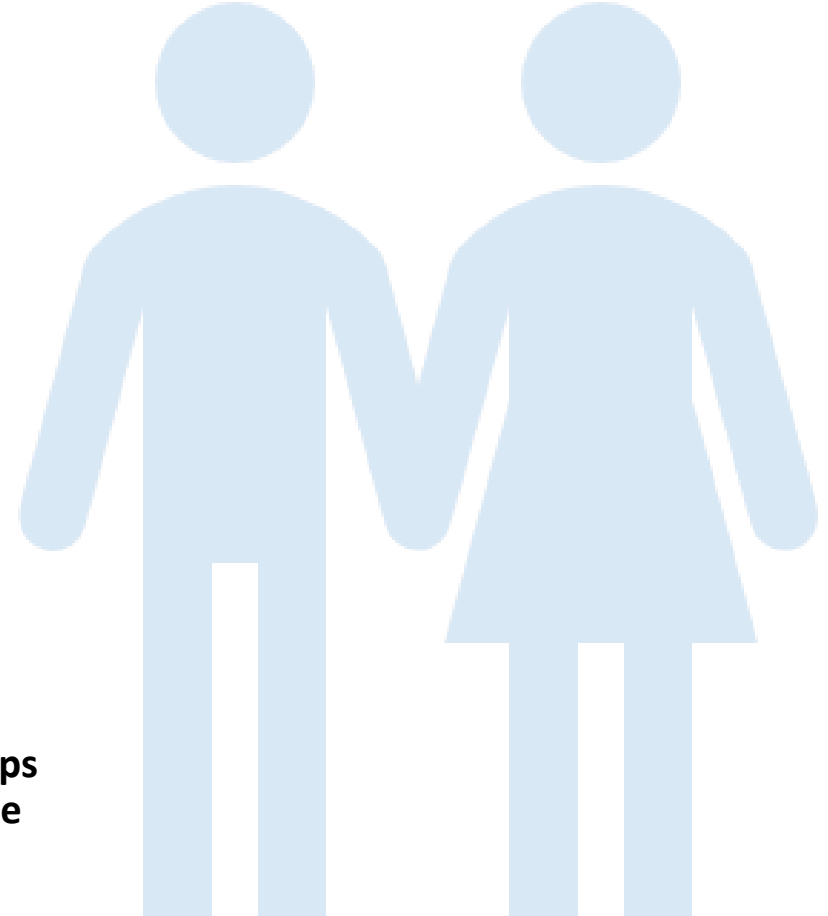


Third Party Intermediaries Courtship- Marriage – (?)Divorce(?)

16:15-18:15

Interactive Workshop

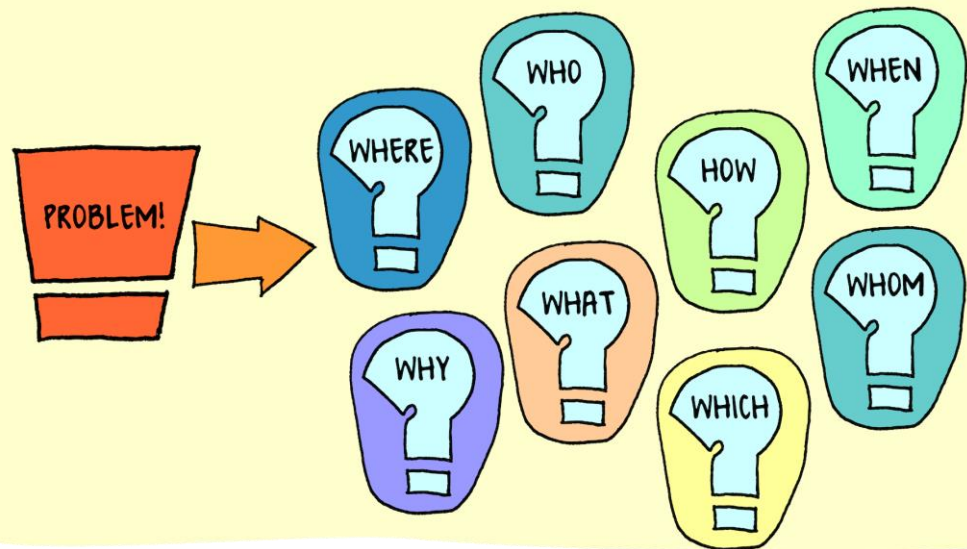
Guidance for Ethical Third Party Intermediary Relationships
in the Biopharmaceutical Sector (Distributors / Sales Force
Guidance)





Problem statement

- As business models become more complex across the entire product life-cycle, third party intermediaries (TPIs) have gradually become key assets in delivering results. It is therefore necessary to understand how laws and regulations define and view the relationship between the TPIs and the originating company, to ensure appropriate risk- management and guardrails by both entities, during the entire relationship.
- FCPA enforcement actions involving TPI impact all industries, and both the medical devices and biopharma sectors continue to face this type of legal actions.





Overview

Defining and Framing Third Party Relationships

Relevancy and considerations

Current Landscape: Adopted Guidance by the Medical Device Sector and potential applicability to the Pharmaceutical Sector





Why manage Third Party Relationships

Protect

Protect your
organization from
risk and damage

Comply

Comply with laws
and regulations

Create

Create a culture
of trust and
transparency





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INCREASING EXPECTATIONS- what the regulator is looking at

While regulators may have different priorities and focus areas when it comes to anti-corruption compliance and third party management there are a number of commonalities

**Careful consideration
and
Sound decisions**



**Process of continual
monitoring**



**Re-categorizing
Risk over time**



**Consistently applied
approach**



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What is Third Party Risk Management and Third Party Due Diligence?

Third Party Risk Management

- Refers to all activities related to your third parties, including risk ranking, screening data collection, documentation and ongoing monitoring

Third Party Due Diligence

- Refers to the assessment of third parties and their principals before and during an engagement



Who is a Third Party Intermediary?

Distributors

Wholesalers

Distribution or sales agents

Marketing agents \ consultants

Brokers

Commission Agents

Independent sales representatives (Third party SMIs)

Service providers

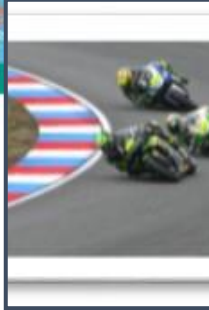




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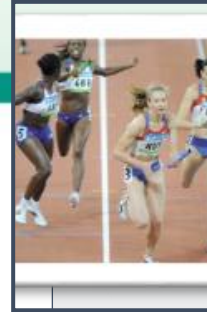
Co-marketing



Parties seen as competitors, requiring full independence between them

No joint activities, budget, business planning or interference in each other's activities

Each company runs with its own business codes and processes



Other party purchases product; once the product changes title (i.e. product moves to their books) a hand-over occurs

As a result, certain distance must be preserved in strategic and operational matters, but there is still a potential for liability by originating company

Co-promotion



Parties are not seen as competitor and are potentially at risk for each other's activities

Strategies are usually jointly developed, and while each party has full control of their own activities there are likely joint activities and shared budgets therefore some joint rules of engagement are required



Other party is seen an extension of the originating company which retains responsibility for both strategy and execution oversight

For the activities in scope, both parties are subject to the same requirements and procedures; other considerations (e.g. labor laws) may apply



Depth of Due Diligence, contractual requirements and oversights depends on the individual nature of the relationship: is it internal or externally focused? - and if externally focused who are the parties with whom it interacts: are these influencers, decision makers, government officials?

Distribution and Promotion

Contract Sales Force(CSO) and CRO



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Other Services



Assessing and Understanding Risk

To adequately assess the risk when undertaking Third Party Relationships it is critical to understand

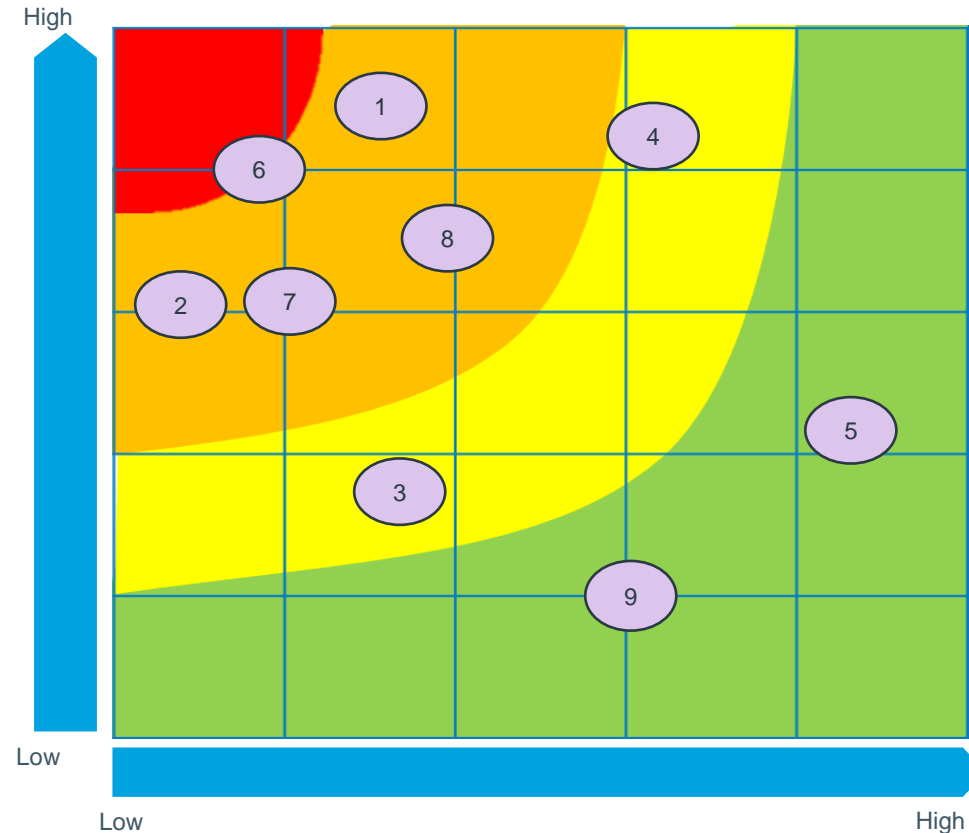
- How laws and regulations view those relationships, **both**
 - in the country (ies) where the third party plans to operate **and**
 - in the country where the company seeking the services is based in.

Once determined, then it is possible to assess the type of Due Diligence required in engaging and if/ what kind of strategic and operational requirements must be in place to ensure identified risks are addressed while the relationship is ongoing.





Break-out Session: Assessing Third Party Intermediaries





- What is needed so we can work together?
- What would simplify our relationship?





What already exists today as guidance

We must adhere to the Code in both the spirit and the letter and, as such, we must ensure that all relevant Member employees and agents acting on our behalf are appropriately trained in the requirements of the Code and abide by it.
(IMC CODE)

IFPMA member companies and anyone acting on their agents behalf must comply directly with applicable national codes of member associations where such codes exist....

Agents and Third Party Partners shall extend to agents, third party partners interacting with healthcare professionals on behalf of the member company (PHAP Code)





What exists today from Pharmaceutical companies codes

It is critically important to us that the **Third Party** we work with share our values and ensure that any work on our behalf upholds our ethical standards. Only together can we maintain and enhance the trust of our customers and stakeholders deliver our purpose: to push the boundaries

We never direct or authorize any **third party** to provide improper payments, gifts, meals, or other items of value on behalf of XXX. Recognizing that many bribery cases involve payments through third parties, we conduct anti-bribery/corruption due diligence on our third-party representatives in accordance with our code

Our Values and Standards for Business Partners

Our Business Partner Code of Conduct presents basic principles for our business partners, including those that provide us with services, raw materials, active ingredients, components, finished goods or other products. We expect all our business partners to firmly adhere to these principles and operate in full compliance with all applicable laws, rules and regulations.





Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector

To ensure and improve ongoing access for patients and health care professionals (“HCPs”) to innovative, reliable, and effective medical devices, it is often necessary for medical device researchers and manufacturers (“Companies”) to contract with third parties to support their commercial activities.

These third parties operate as distributors, wholesalers, distribution or sales agents, marketing agents or consultants, brokers, commission agents, and/or independent sales representatives (“Third Party SMIs”).

They serve an integral role in the medical device sector and health systems, connecting Company products and services to HCPs and other end-users. A significant majority of Third Party SMIs in the medical device sector across APEC member economies are small and medium-sized enterprises.



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**Working together to develop a Standard for the
Biopharmaceutical Industry**



MULTI-STAKEHOLDER TRAINING WORKSHOP (19 JULY) BIOPHARMACEUTICAL SECTOR



Closing Observations

*Mr. Thomas Cueni
Industry Co-Chair, APEC Biopharmaceutical
Working Group on Ethics
Director General, IFPMA*



GUIDANCE FOR PLENARY (20 JULY)



Mr. Andrew Blasi
Director
C&M International