OPENING SESSION

Ms. Tricia Van Orden
Overseer
Business Ethics for APEC SMEs Initiative

DISTRIBUTORS PORTAL SESSION
DISTRIBUTORS PORTAL SESSION

A DECADE IN REVIEW: MEDICAL DEVICE SECTOR AND ETHICAL BUSINESS CONDUCT

Ms. Nancy Travis, Vice President, International Compliance and Governance, The Advanced Medical Technology Association (AdvaMed)
A Remarkable 10 Year Journey (2010-2011)
A Remarkable 10 Year Journey (2011-2012)
A Remarkable 10 Year Journey (2012)

We recognize the important role of business and public-private partnerships in promoting the elaboration of codes of conduct in the private sector and measures to fight corruption, especially measures that support the promotion of ethical business practices in interactions between government, business and other stakeholders. We welcome efforts by our SME Ministers, industries and academics to promote voluntary, industry-specific APEC principles that aid in this effort.

http://klprinciples.apec.org
A Remarkable 10 Year Journey (2013-2014)
A Remarkable 10 Year Journey (2018)
Rapid Uptake of Medical Device Sector Codes of Ethics
A HISTORY OF STRENGTHENING ETHICAL THIRD PARTY INTERMEDIARY RELATIONSHIPS IN THE MEDICAL DEVICE SECTOR

Ms. Faye Sumner
Chief Executive Officer
Medical Technology Association of New Zealand
THIRD PARTY INTERMEDIARIES AND ETHICS
JOINT GUIDANCE FOR MEDICAL DEVICE AND DIAGNOSTICS

COMPANIES ON ETHICAL THIRD PARTY SALES AND MARKETING INTERMEDIARY ["SMI"] RELATIONSHIPS

Version July 10, 2014
• Written Policy and Procedure
• Risk Assessment
• Diligence Programs
• Written Contract
• Training and Education
• Monitor/ Audit
• Appropriate Collective Action
Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector

Purpose: Information
Submitted by: United States
2018 APEC Business Ethics for SMEs Forum - Tokyo Declaration: Promoting Ethical Third Party Intermediary Relationships in the Medical Device Sector Through 2021 (Endorsed)

Purpose: Information
Submitted by: United States
DISTRIBUTORS PORTAL SESSION

WORK PLAN PRESENTATION OF THE MEDICAL DEVICE DISTRIBUTOR’S ETHICAL PORTAL

Ms. Michelle Wagner, Global Lead, Third Party Intermediary and Supply Chain Compliance, Johnson & Johnson
2018 APEC Business Ethics for SMEs Forum

Tokyo Action Plan: Recommendations to Promote Ethical Third Party Intermediary Relationships in the Medical Device Sector through 2021

1. We, representatives from medical device researchers and manufacturers, third party intermediaries (such as distributors, wholesalers, and sales agents), industry and third party intermediaries' associations, healthcare providers and professional organizations, government agencies, health regulatory authorities and patient groups from across the APEC region, convened in Tokyo, Japan from 18-20 July 2018 for the APEC Business Ethics for SMEs Forum.

2. We note that it may often be considered necessary for medical device researchers and manufacturers ("Companies") to contract with third party sales and marketing intermediaries ("Third Party SMIs") to support their activities, enabling ongoing access for patients and healthcare professionals ("HCPs") to innovative, reliable, and effective medical devices. Third Party SMIs may serve an integral role in the medical device sector, and a majority of them are small and medium-sized enterprises that contribute to employment and commercial activity in the APEC region.

3. We reaffirm the APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector ("the Guidance"), recognized by APEC SME Ministers in Ho Chi Minh City, Viet Nam on 15 September 2017. The Guidance advances ethical business practices for SMEs as called for by the APEC Kuala Lumpur Principles (the "KL Principles"), the APEC Nanjing Declaration, and the Business Ethics for APEC SMEs Initiative (the "Initiative"). The Guidance states that Companies and Third Party SMIs should develop and adhere to codes and compliance programs that embrace the KL Principles and include the following elements: written anti-bribery policy/procedure; risk assessment; diligence program; written contract; training and education; monitor/audit; and appropriate corrective action.

4. Recognizing our shared commitment to ethical interactions that are in the best interest of patients and to the ability of the region’s Third Party SMIs to be able to sustainably grow and trade, we agree on a collective vision to promote ethical third party intermediary relationships in the medical device sector.

5. We declare our intention to APEC SME Ministers, APEC Ministers, and APEC Leaders to work towards achieving the following goals. We call upon APEC economies and stakeholders to consider undertaking the following recommendations, respecting the diversity of healthcare systems:
MEDICAL DEVICE DISTRIBUTORS ETHICS PORTAL

Phase 1: Code Adoption
Phase 2: Communication Tools
Phase 3: Template Policies
Phase 4: Working with Sub-Distributors
Phase 5: Sophistication of Procedures
Phase 1: Code Adoption

Materials and guidance for the company to create its own code of ethics in alignment with relevant industry association codes while also building the company’s own compliance and training program.
Phase 2: Communication Tools

Materials and guidance for internal and external communication concerning the adoption process and adherence details of the company’s code of ethics
Phase 3: Template Policies

Materials and guidance for creating template policies and contracts concerning consultant agreements, meeting sign-in sheets, payment for booth space forms, and anti-trust disclosure language, among others.
Phase 4: Working with Sub-Distributors

Template policies, contracts and guidance geared toward working with sub-distributors
Phase 5: Sophistication of Procedures

Materials and guidance on sophisticated record keeping, expense claims, detailed Code provisions, and other related resources
Distributor Compliance Portal

1. Phase 1 - Code Adoption
   - Sample Slides Deck - Working with a Code of Ethics - Key Areas for Distributors - PDF
   - APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector
     - English - PDF
     - Japanese - PDF
     - Chinese - PDF
     - Spanish - PDF
     - Vietnamese - PDF
   - Basic Recordkeeping - PDF
   - Employee Training Attendance Form - PDF
   - Sample Code of Conduct Template - PDF
   - Sample Quiz With Answers from MEDEC - PDF
   - Written Contract Guidance - PDF

2. Phase 2 - Communication Tools
   - Sample Code of Ethics Brochure - PDF
   - Form TPS Certification - PDF
   - Sample Postcard - PDF
   - HCP Invitation - PDF
   - Notification to Employer Training - PDF

3. Phase 3 - Template Policies
   - Sample Compliance Checklist New Hire - PDF
   - Consultant Contract - PDF
   - Form Request Consultant Services - PDF
   - Payment Booth Fees Form - PDF
   - Grants and Donations Form - PDF
   - Sign in sheet HCPs Training - PDF
   - Template Funding Agreement - PDF
   - Written Contract Guidance - PDF

4. Phase 4 - Working with SubDistributors
   - Due Diligence Guide Sub Distributor 21 - PDF
   - Sample Compliance Certification Form - PDF
   - TPS Sponsorship Form - PDF
   - Template Agreement Sub Distributors - PDF
   - Pilot Webinar on the Guidance
     - PowerPoint Presentation - PDF
     - Script Overview - PDF
     - Note: Delivered 9 July (Auckland, New Zealand) and 10 July (Toronto, Canada)

5. Phase 5 - Sophistication of Procedures
   - Accounts Payable Red Flags - PDF
   - 5 Steps to Monitor a Compliance Program - PDF
   - Expenses Form - PDF
   - Sample Quick Reference Common Interactions - PDF
   - Policy Template - PDF

6. Other Documents
   - Tokyo Action Plan Recommendations to Promote Ethical Third Party Intermediary Relationships
   - Sample Illustrative Code Flow Charts - PDF
   - Sample Info Notice - PDF
   - Sample Business Conduct Reminders - PDF
   - Speaker Agreement - PDF
   - Speaker Agreement - PDF
   - Notification to Employer Consulting - PDF
   - PCPA FAQs - PDF
   - UK Bribery Act Guidance - PDF
   - UK Bribery Act Quick Start - PDF
CONSIDERATIONS

• Does this approach make sense? Are the five phases of the resources appropriately segmented? Would you make any adjustments or expand upon the kinds of materials that are already indicated?

• Who are the right users within SME distributors and third party intermediaries for these resources?

• What approaches should be considered in order for industry associations to routinely utilize this resource for the benefit of their member companies? What do associations need to make it work?

• The Tokyo Action Agenda calls for a third party intermediary certification model by 2021. How can this be achieved together?
DISTRIBUTORS PORTAL SESSION

MORNING TEA / COFFEE BREAK
10:45 – 11:15
DISTRIBUTORS PORTAL SESSION

DISTRIBUTOR PERSPECTIVES AND CHALLENGES

Facilitator:

Roundtable Discussants:

Ms. Michelle Wagner
AUSTRALIA

Mr. Eduardo Del Solar
CHILE

Mr. Ma Ensheng
CHINA

Mr. Omar Neyra
PERU

Mr. Bruno Boldrin
BRAZIL
DISTRIBUTORS PORTAL SESSION

NON-INDUSTRY PERSPECTIVES ON DISTRIBUTORS

Ms. Bronwen Taylor
UNITED STATES

Mr. Adrian Cosenza
AUSTRALIA

Ms. Jo Watson
AUSTRALIA
DELEGATES
NETWORKING LUNCH
(SAN CRISTOBAL A)
13:00 – 14:00
WELCOMING REMARKS AND CODE OF ETHICS LAUNCH BY ASOCIACIÓN DE DISPOSITIVOS MÉDICOS DE CHILE (ADIMECH)

The Honorable Gilbert Kaplan
Under Secretary for International Trade
U.S. Department of Commerce
WELCOMING REMARKS AND CODE OF ETHICS LAUNCH BY ASOCIACIÓN DE DISPOSITIVOS MÉDICOS DE CHILE (ADIMECH)

Mr. Tulio Oliveira, President, ADIMECH

Regional Vice President – Latin America South Johnson and Johnson
COALITION PHOTO WITH THE HONORABLE GILBERT KAPLAN
CHILEAN MULTI-STAKEHOLDER PERSPECTIVES ON STRENGTHENING ETHICAL BUSINESS PRACTICES

Facilitator: Mr. Alberto Martinez

Roundtable Discussants:
- Hon. Javier Macaya Danus
- Ms. Cecilia Rodriguez
- Dr. Eghon Guzmán
- Mr. Jorge Jaraquemada Roblero
AFTERNOON TEA / COFFEE BREAK
15:30 – 16:00
COALITION MEETING READOUT
FROM BUENOS AIRES (24 JULY 2019)

Mr. Sergio Pinto
Chair, Latin America Compliance Committee, The Advanced Medical Technology Association
BEST PRACTICES SESSION ON “EXTERNAL STAKEHOLDER ENGAGEMENT ON THE CODE”
BY MEDICAL DEVICE ASSOCIATIONS

Ms. Diane Biagianti
Chief Responsibility Officer
Edwards Lifesciences
WHY should medical device industry associations care about external stakeholder engagement?

✓ Because your members have committed to follow the code and the association is their collective voice.

✓ Because external stakeholders can be an ally in promoting ethical business practices.

✓ Because external stakeholders may want to align their own ethical business practices with yours.

✓ Because it may be the only way to address the “non-member dilemma”
57% Distributed the code beyond the association’s members

29% Making code trainings open to non-members

36% Building code awareness through multi-stakeholder initiatives

71% Keen to heighten external stakeholder engagement

http://klprinciples.apec.org
HOW should medical device industry associations care about external stakeholder engagement?

- **Prioritize** as a core activity in effective code implementation
- Set **measurable commitments** in external engagement on the code
- Make strong effort to **invite non-member companies** to the association code trainings
- Meet with peak **healthcare professional organizations and government agencies** at least once per year on the code AND **ask for their views/input** – build genuine collaboration
- Take the **non-member dilemma** seriously and take action.

[http://klprinciples.apec.org](http://klprinciples.apec.org)
DISCUSSION ON WHY AND HOW

✓ Do you see other reasons why an association should prioritize external engagement on the code?

✓ Do you see other ways in which an association can undertake external engagement on the code?

I LOOK FORWARD TO YOUR IDEAS!
PUBLIC-PRIVATE PERSPECTIVES ON ETHICAL COLLABORATION
FROM THE COMPTROLLER GENERAL OF THE UNION AND THE
HEALTH ETHICS INSTITUTE (BRAZIL)

Mr. Alexandre Krügner Constantino
Comptroller General of the Union

Mr. Carlos Gouvea, Etica Saude
SUMMARY OF CONCLUSIONS
PREVIEW OF PLENARY

BRING YOUR ID’S TO RECEPTION!

Mr. Andrew Blasi, Director
Crowell & Moring International