SME Webinar on APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector

This webinar has been prepared for the Business Ethics for APEC SMEs Initiative as a contribution by: IQVIA
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• Mitigating Challenges and Risks
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Objective of the Guidance

A Guidance that aims to strengthen ethical third party intermediary due diligence and inspires Small and Medium size Enterprises (SMEs) to engage in due diligence by creating achievable and manageable due diligence goals. The Guidance applies to the medical device company as well as the third party intermediary. Both are viewed by APEC as key actors in the medical device sector.
Learning Objectives

- Grasp the importance of due diligence
- Identify third parties
- Recognize risk
- Develop & implement risk-based approach
- Apply consistent approach
- Build trust
- Grasp the importance of due diligence

Objective
APEC

- APEC is the premier Asia-Pacific economic forum
- Asia-Pacific Economic Cooperation (APEC) operates as a cooperative, multilateral economic and trade forum
- Its primary goal is to support sustainable economic growth and prosperity in the Asia-Pacific region
Corruption impedes economic stability
# Business Ethics for APEC SMEs

| Benefits APEC member economies | Provides a platform for effective industry self-regulation  
|                               | Supports government enforcement and anti-corruption efforts |
| Benefits businesses, especially resource-constrained SMEs | Provides companies with clarity and harmonization in rules and practices  
|                                                               | Allows companies to compete across the region at a reduced cost  
|                                                               | In the case of the biopharmaceutical and medical device sectors, facilitates ongoing innovation |
| Benefits patients (in the case of the biopharmaceutical and medical device sectors) | Ethical collaborations fuel advances and promote access to life-saving medicines and technologies  
|                                                                 | Ethical collaborations ensure that decisions are made in the best interest of patients |
Business Ethics for APEC SMEs Initiative

World’s largest public-private partnership to strengthen ethical business practices in the medical device sector

More than doubled the number of medical device industry association codes

Trained over 1,500 stakeholders and expanded high-standards to 18,000+ companies (13,000+ SMEs)

Designed and implemented model consensus agreements to strengthen ethical business practices across health systems
The APEC Kuala Lumpur Principles promote ethical interactions that:

- Promote appropriate interactions between the medical device companies and Healthcare Professional (“HCPs”).
- Enhance patient access to the safe and effective use of medical technologies.
- Promote innovation and the ongoing development of advanced medical technologies.
- Facilitate open and transparent business environments.
- Ensure that medical decision-making is made in the best interest of the patient.
The Kuala Lumpur Principles

- Integrity
- Independence
- Transparency
- Appropriateness
- Advancement
APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector
APEC Guidance for Ethical Third Party Intermediary Relationships

**WHY**

Guidance will help to ensure that third parties, who are critical to the medical device sector and health care systems, and companies can strengthen adherence to high-standard ethical business practices in accordance with the [APEC Kuala Lumpur Principles for Medical Device Sector Codes of Business Ethics](#).

**Collaboration**

Joint work between medical device companies and third parties to develop ethical business practices will strengthen health systems and instill patient confidence that the best treatments are available when needed and delivered in their interest.
Why manage Third Party Relationships

- Protect your organization from risk and damage
- Comply with laws and regulations
- Create a culture of trust and transparency
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
- Consistently applied approach
- Re-catagorizing Risk over time
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
The Meaning of the Guidance in Context
Codes of Ethics and Compliance programs should include the following elements:

1. Written Anti-Bribery Policy/Procedures
2. Risk Assessments
3. Diligence Programs
4. Written Contracts
5. Training and Education Programs
6. Routine Monitoring and Auditing
7. Reporting and Corrective Action
Written Anti-Bribery Policy and Procedures
Anti-Bribery Policy & Procedures

Adopt and implement internal policies that prohibit bribery by Any person or entity acting on behalf of a Company.
Companies and Third Party SMIs should evaluate the risk profile for proposed and utilized Third Party SMI arrangements....
Companies should assess the local risks through:

- Published corruption indices as well as specific risk profiles
- International and local legal requirements
- Information from Third Party SMIs for potentially unusual arrangements
- Information available from public sources or employees
Third Party SMIs should:

• Support companies’ risk assessments
• Assess and communicate international and local legal requirements
• Disclose potentially unusual arrangements; and
• Maintain accurate records for review
Diligence Program
Companies and Third Party SMIs should establish Due Diligence Program.
Written Contracts should include:

- Compliance with international and local laws, ethical principles, and Company policies.
- The ability to conduct independent audits and monitoring, including access to relevant books and records.
- The ability to terminate an engagement for failure to comply with international and local laws, ethical principles, and Company policies; and
- Diligence rights upon renewal.
Communication and Training
Training

- Ethical Principles
- Training in the language most appropriate to the audience
- Joint communication and training with HCPs & other stakeholders
- Company Policies
- International and local laws
- Provide regular Training
Monitor and Audit
Periodic reviews and evaluations of the anti-corruption program

Company and Third Party SMIs should undertake:

- risk-based
- routine monitoring and auditing
- other assessments of their relationship

Assess certification of Company and Third Party SMI personnel

For compliance with international and local laws, ethical principles and Company policies as well as relevant contract terms.
Corrective Action
Corrective measures should be taken if either a Company or Third Party SMI representative fails to comply with:

- *international or local laws*
- *ethical principles*
- *company policies*
- *relevant contract terms or*
- *engages in other impermissible or unethical conduct*
IMPLEMENTATION
Actions for Implementation

Implement Codes of ethics consistent with the principles set out in the guidance and take additional steps to encourage the adoption of this guidance among their respective members and/or employees.

Encourage the development and implementation of high-standard, aligned policies and practices consistent with this guidance.

Undertake joint communication and training on this guidance and other relevant policies.

Encourage medical device sector regulators and enforcement authorities to acknowledge and support this guidance and to support steps by stakeholders to implement effective guidance for ethical Third Party SMI relationships.

Encourage APEC economies to advance ethical collaborations consistent with this guidance through regular communication, joint policies, joint capacity building and other forms of collaboration.

APEC economies to advance guidance

Acknowledgement & Support from regulator

Joint communication & training

High standards & aligned policies

Implement Codes
“If you think compliance is expensive, try non-compliance”
- Former U.S. Deputy Attorney General Paul McNulty
Questions?