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

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ASIA-PACIFIC ECONOMIC COOPERATION (APEC)

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.

To ensure high-standard ethical business practices are implemented for the medical device sector in accordance with the APEC Kuala Lumpur Principles,¹ it is essential that Companies’ interactions with Third Party SMIs, as well as Third Party SMIs’ interactions on behalf of Companies (including with HCPs and government officials) adhere to applicable laws and ethical principles. The *Business Ethics for APEC SMEs Initiative* has prepared the following guidance for Companies and Third Party SMIs in order to support Companies, Third Party SMIs, HCPs, governments, and other health system stakeholders in implementing best practices and ensuring integrity in decision-making.

GUIDANCE

The *Business Ethics for APEC SMEs Initiative* encourages active collaboration within and among Companies, Third Party SMIs, HCPs, and other governmental and non-governmental health system stakeholders in the development and implementation of codes of ethics and compliance programs. Taking into account a variety of risk-based factors, as well as international and local laws, such codes of ethics and compliance programs should include the following elements²:

- A. **Written Anti-Bribery Policy/Procedure:** Companies and Third Party SMIs should adopt and implement internal policies prohibiting all forms of bribery³ by any person or entity acting on a Company’s behalf, including Company personnel, Third Party SMI representatives, HCPs and other agents. Such policies should include more detailed measures for common risk areas such as travel, gifts, hospitality, entertainment, grants or donations, research, and capital equipment. Medical device sector industry associations and their member companies should consider communicating to HCPs and other stakeholders their ethical business practices concerning Third Party SMIs.
- B. **Risk Assessment:** Companies and Third Party SMIs should evaluate the risk profile for proposed and utilized Third Party SMI arrangements including, for example:

¹ APEC Kuala Lumpur Principles: http://mddb.apec.org/documents/2011/MM/SMEMM/11_smemm_009.pdf

² These elements are in addition to an overall compliance program as recommended in the APEC Kuala Lumpur Principles. Where Companies, Industry Codes and other stakeholders already have or may in the future adopt more rigorous self-regulatory policies, nothing in this guidance should be construed to diminish voluntary efforts to commit to a higher ethical objective.

³ The term “bribery” refers to transfers of anything of value, directly or indirectly, to government officials, health care providers or others that may violate applicable international or local laws, ethical principles or Company policies.

- a. **Companies:** Should assess: (1) the local risk through published corruption indices as well as specific risk profiles of planned or utilized Third Party SMIs; (2) international and local legal requirements, (3) information from Third Party SMIs for potentially unusual arrangements, such as unusually high commissions, high degree of interaction with government officials, marketing budgets, health care provider corporate affiliation or ownership, and/or off-shore payment accounts, and (4) information available from public sources or employees for potential issues associated with a Third Party SMI.
- b. **Third Party SMIs:** Should (1) support Companies' risk assessments prior to and throughout engagement in activities conducted on the Company's behalf, (2) assess and communicate international and local legal requirements, (3) disclose potentially unusual arrangements, and (4) maintain accurate records for review.

The Risk Assessment can inform the application of other elements of this guidance.

- C. **Diligence Program:** Companies and Third Party SMIs should establish a risk-based, pre-engagement and renewal due diligence program to identify, prevent, and mitigate risks relating to the market in which the Third Party SMI is engaged to operate, as well as any specific activities the Third Party SMI deploys on behalf of the Company. Third Party SMIs are encouraged to engage with local industry associations to advance compliance and training on local code of ethics principles.
- D. **Written Contract:** Companies and Third Party SMIs should reach contract terms with each other that include controls and implementation of anti-corruption policies, such as:
 - a. Compliance with international and local laws, ethical principles, and Company policies;
 - b. The ability to conduct independent audits and monitoring, including access to relevant books and records;
 - c. The ability to terminate an engagement for failure to comply with international and local laws, ethical principles, and Company policies; and
 - d. Diligence rights upon renewal.
- E. **Training and Education:** Companies and Third Party SMIs should undertake initial and provide regular training and education for relevant Company and Third Party SMI personnel on international and local laws, ethical principles, and Company policies. Training should be conducted in the language most appropriate to the audience. Medical device sector industry associations, their member companies and Third Party SMIs should consider joint communication and training with HCPs and other stakeholders on APEC Third Party SMI ethics guidance and relevant Company and Industry Association ethics policies.
- F. **Monitor/Audit:** Company and Third Party SMIs should undertake risk-based, routine monitoring, auditing, and other assessments of their relationship for compliance with international and local laws, ethical principles, and Company policies as well as relevant contract terms; and regular certification of Company and Third Party SMI personnel on compliance with on international and local laws, ethical principles, and Company policies.

G. Appropriate Corrective Action: Corrective measures should be taken by the relevant party, consistent with applicable international and local laws, if either a Company or Third Party SMI representative fails to comply with international and local laws, ethical principles, or Company policies, relevant contract terms, or engages in other impermissible or unethical conduct.

Implementation

Cooperation among multiple stakeholders is necessary to promote an ethical business environment consistent with this guidance. Therefore, medical device sector industry associations, Companies, Third Party SMIs, HCPs, government authorities, and other stakeholders should consider:

- Implementing codes of ethics consistent with the principles set out above and additional steps to encourage the adoption of this guidance among their respective members and/or employees;
- Encouraging the development and implementation of high-standard, aligned policies and practices consistent with this guidance;
- Undertaking joint communication and training on this guidance and other relevant policies;
- Encouraging medical device sector regulators and enforcement authorities to acknowledge and support this guidance set out above, and to support steps by stakeholders to implement effective guidance for ethical Third Party SMI relationships; and
- Encouraging APEC economies to advance ethical collaborations consistent with this guidance, through regular communication, joint policies, joint capacity building, and other forms of collaboration.

This guidance was prepared by a virtual group of experts selected by the overseer of the *Business Ethics for APEC SMEs Initiative* and tabled for review during the 2017 APEC Business Ethics for SMEs Forum in Hanoi, Viet Nam. The “Joint Guidance for Medical Device and Diagnostics Companies on Ethical Third Party Sales and Marketing Intermediary Relationships”⁴ adopted in July 2014 by medical device industry associations in Australia, Canada, Europe, New Zealand, and the United States serves as a reference document in the preparation and release of this guidance.

⁴ Joint Guidance for Medical Device and Diagnostics Companies on Ethical Third Party Sales and Marketing Intermediary Relationships: https://www.advamed.org/sites/default/files/resource/492_distributorduediligenceresource_english_20140710.pdf