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2015 APEC Business Ethics for SMEs Forum

Guide to Implement Multi-Stakeholder Ethical Collaborations in the Medical Device and Biopharmaceutical Sectors

Ethical collaborations among the medical device and biopharmaceutical industry, healthcare professionals¹, patients' organizations and other stakeholders is essential to the delivery of high quality patient care, patient access to life-saving and health-enhancing medical technologies and therapies, and the development of new innovations that meet patient needs. No one group can achieve an ethical environment in these sectors alone. Ethical collaboration among these stakeholders also strengthens the ability of small and medium enterprises (SMEs) to sustainably operate and engage in cross-border trade.

The purpose of this Guide is to support the implementation of multi-stakeholder ethical collaborations for the medical device and biopharmaceutical sectors within APEC member economies². This Guide serves as a tool for medical device and biopharmaceutical enterprises and industry associations; healthcare professionals and their associations; patients' organizations and other relevant stakeholders. The Guide's provisions are aligned with the best practices and provisions endorsed under the Business Ethics for APEC SMEs initiative.³

The implementation of ethical collaborations among relevant stakeholders through this Guide can be used to achieve the following outcomes:

- A platform to build trust and facilitate open communication;
- The development and/or alignment of codes of ethics across different stakeholders;
- Shared capacity-building and practical training programs; and
- The early identification of shared challenges and opportunities.

GUIDE TO IMPLEMENT MULTI-STAKEHOLDER ETHICAL COLLABORATIONS IN THE MEDICAL DEVICE AND BIOPHARMACEUTICAL SECTORS

Step One: Embrace shared values that (a) patients are the priority, b) interactions at all times should be ethical, appropriate and professional; and (c) partners support transparency and accountability in their individual and collaborative activities.

Step Two: Identify key stakeholders within the member economy or local community necessary to facilitate ethical collaborations in the medical device and biopharmaceutical sectors.

Step Three: Identify the individual, group or organization to lead in convening these stakeholders.

¹ The term "Healthcare Professionals" includes those individuals and entities that purchase, lease, recommend, use or arrange for the purchase or lease of, or prescribe medical products. This includes both clinical and non-clinical individuals who make product-related decisions of the type described above. This is a broad definition, intended to encompass anyone with material influence over purchasing decisions. Note that there may be laws and other codes applicable to relationships with Healthcare Professionals, including relationships with government employees.

² APEC member economies include: Australia, Brunei Darussalam, Canada, Chile, China, Hong Kong, Indonesia, Japan, Korea, Malaysia, Mexico, New Zealand, Papua New Guinea, Peru, Philippines, Russia, Singapore, Chinese Taipei, Thailand, United States, and Vietnam.

³ The Kuala Lumpur Principles for Voluntary Codes of Ethics in the Medical Device Sector (The APEC KL Principles), The Mexico City Principles for Voluntary Codes of Ethics in the Biopharmaceutical Sector (The APEC Mexico City Principles), and the Nanjing Declaration to Promote Ethical Business Environments in the Medical Device and Biopharmaceutical Sectors (2014-2020).

Step Four: Convene stakeholders as equal partners. Ensure each partner maintains shared values that are consistent with Step One.

Step Five: Ensure a common basis of understanding. Jointly review current commitments under existing codes of ethics, local laws and regulations, and other organizational guidelines – including the APEC Kuala Lumpur Principles, APEC Mexico City Principles, and the APEC Nanjing Declaration.

Step Six: Commit to developing a consensus-based framework for multi-stakeholder collaboration.

Step Seven: Determine the framework's scope based on the interests / capabilities of the partners.

Step Eight: Establish a drafting group for the framework and determine consultative process.

Step Nine: Finalize framework and undertake individual or collective ratification by the partners.

Step Ten: Publicize and distribute the framework (for example, through the Business Ethics for APEC SMEs initiative website, external stakeholders and the media).

Step Eleven: Maintain shared commitment to the framework's provisions while ensuring active communication to facilitate activities and to identify new opportunities.

Step Twelve: Utilize the framework to identify and execute joint stakeholder activities to promote implementation of ethical business practices.

Step Thirteen: Provide regular updates on milestones under the framework in order to share best practices and support progress in other economies and communities.

COMMITMENT TO IMPLEMENT MULTI-STAKEHOLDER ETHICAL COLLABORATIONS IN THE MEDICAL DEVICE AND BIOPHARMACEUTICAL SECTORS

The representatives of medical device and biopharmaceutical enterprises and industry associations, healthcare professionals and their associations, patients' organizations and other relevant stakeholders convened for the 2015 APEC Business Ethics for SMEs Forum commit to implement multi-stakeholder ethical collaborations within their economy based on this Guide.