

Asia-Pacific Economic Cooperation

Business Ethics for APEC SMEs Initiative

Role of Governments in Facilitating Voluntary Ethical Practices



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Economic Cooperation**

Business Ethics for APEC SMEs
Biopharmaceutical Sector

Objective of Exercise Three

- The objective of the exercise is to carry out a discussion on self-regulation and the role governments may play in supporting this process.
- The discussion will focus on the values and challenges around self-regulation and, recognizing that in some instances pure self-regulation is not always an option.
- The relationship of government and stakeholders in industry self-regulations in the Biopharmaceutical sector area varies.
- Industry has the responsibility to earn the respect and trust required for self-regulation.



Process

- The first part of the exercise would require that each economy(Industry, Governments and Stakeholders) identify on the matrix where it believes the Biopharmaceutical Industry exists on the matrix in relation to self-regulation.
- The second exercise would ask “Where the Economy would like to see the Biopharmaceutical Industry exist on the matrix in relation to self-regulation?”.
- All stakeholders in the room would be asked to participate and make their own evaluations of where they see their economy.



Mexico City Principles

APEC Economies should:

- Develop and make known clear, distinctive, accountable and comprehensive policies on procurement processes and procedures.
- Encourage industry regulators and/or anti-corruption enforcement authorities to endorse and support the above Principles and national and local industry codes of ethics, where appropriate.
- Encourage Companies to adhere to the above Principles and national and local industry codes of ethics.
- Formulate and promote clear laws and regulations that are objectively applied.
- Work to advance ethical collaborations consistent with the above Principles regionally, through regular communication, joint policies, joint capacity building activities, and other forms of collaboration.



Nusa Dua Statement

The Nusa Dua Statement issued on 3 September 2013 established that each stakeholder has a unique and important role to promote ethical healthcare environments, including:

- ***Health Ministries and Health Regulatory Agencies*** should recognize the value of industry codes of ethics and encourage all stakeholders to support ethical principles, such as the APEC principles, and national and local industry codes of ethics.



Nanjing Declaration

- **For Governments:** Support and endorse local partnerships in APEC economies between relevant government ministries/agencies and the medical device and biopharmaceutical industries to advance industry's voluntary efforts to strengthen ethical business practices.



Self-Regulation

- Self-regulation is a privilege and not a right;
- The private sector relies on self-regulation to address a range of issues, from establishing industry standards, to developing and applying codes of professional ethics, to ensuring consumer confidence.;
- Despite its widespread use, some policymakers are skeptical of the efficacy and credibility of self-regulation;
- Regulatory styles vary considerably from country to country and industry to industry.



Governments may play a positive role in voluntary self-regulation by

- Encouraging self-regulatory action, by urging businesses to develop self-regulatory schemes;
- Providing advice, by contributing to the development of guidance on how certain issues may best be addressed,
- Supporting compliance, by encouraging adherence
- Authorizing the programs, to ensure their suitability and/or compliance with laws and regulations,
- Monitoring the effectiveness and impact of schemes,
- Promoting multi-stakeholder dialogue, to take part in the development and/or monitoring of schemes and
- Publicly endorse successful self-regulatory efforts



Multi-Stakeholder Ethical Collaborations

DRAFT FOR CONSIDERATION AT
2015 APEC BUSINESS ETHICS FOR SMEs FORUM

Manila, Philippines, 20 August 2015

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 professionals, 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 economies.¹ 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.²

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 provide medical products. This includes both direct and non-direct 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, even if 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).

DRAFT FOR CONSIDERATION AT
2015 APEC BUSINESS ETHICS FOR SMEs FORUM

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, undertaking joint activities as appropriate. Ensure active communication to facilitate activities and to identify new opportunities.

Step Twelve: 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.

- Ethical collaborations among the medical device and biopharmaceutical industry, healthcare professionals, 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.

