

**Tokyo, Japan, 20 July 2018**

## **2018 APEC Business Ethics for SMEs Forum**

### **Guide to Facilitate Multi-Stakeholder Ethical Collaborations in the Medical Device and Biopharmaceutical Sectors (Version 2018)**

**Background:** Ethical collaboration among medical device and biopharmaceutical enterprises, their industry associations and third party intermediaries, healthcare professionals<sup>1</sup> and providers, patients' organizations, health regulators, 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 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.

**Purpose:** The purpose of this Guide is to facilitate multi-stakeholder ethical collaborations for the medical device and biopharmaceutical sectors within APEC member economies<sup>2</sup> and beyond. The implementation of formalized, consensus framework agreements by two or more stakeholders to collaborate in strengthening ethical business practices within these sectors can serve as a lasting platform to facilitate the identification and communication of best practices, the undertaking of cross-organizational capacity building for mutual benefit, and the shared monitoring and evaluation of changes in the ethical business environment. The APEC Nanjing Declaration<sup>3</sup>, endorsed by APEC Ministers, calls on every member economy to develop a consensus framework by 2020.

**Overview:** This Guide serves as a tool for all organizations involved in or that interface with the medical device and/or biopharmaceutical sectors. It builds upon the initial Guide launched at the 2015 APEC Business Ethics for SMEs Forum<sup>4</sup> and is aligned with the best practices and provisions endorsed under the *Business Ethics for APEC SMEs Initiative*.<sup>5</sup> It has been updated to include steps for organizations to pursue the formation of a consensus framework (Part One) and strategies to realize mutual benefits once a consensus framework is adopted (Part Two). Economies recognize that consensus frameworks are inclusive platforms for lasting collaboration to strengthen ethical business practices. While they are not intended to replace local laws and regulations, high-standard codes of ethics, or other organizational requirements, consensus frameworks can serve as a platform to inform, implement, and/or update these items for the mutual benefit of stakeholders.

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<sup>1</sup> 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.

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

<sup>3</sup> APEC Nanjing Declaration on Promoting Ethical Business Environments in the Medical Device and Biopharmaceutical Sectors through 2020: [http://mddb.apec.org/Documents/2014/MM/SMEMM/14\\_smemm\\_020a.pdf](http://mddb.apec.org/Documents/2014/MM/SMEMM/14_smemm_020a.pdf)

<sup>4</sup> Guide to Implement Multi-Stakeholder Ethical Collaborations in the Medical Device and Biopharmaceutical Sectors (2015 APEC Business Ethics for SMEs Forum): [http://mddb.apec.org/Documents/2015/SMEWG/SMEWG41/15\\_smewg41\\_029.pdf](http://mddb.apec.org/Documents/2015/SMEWG/SMEWG41/15_smewg41_029.pdf)

<sup>5</sup> The Kuala Lumpur Principles for Voluntary Codes of Ethics in the Medical Device Sector (APEC KL Principles): [http://mddb.apec.org/Documents/2011/MM/SMEMM/11\\_smemm\\_009.pdf](http://mddb.apec.org/Documents/2011/MM/SMEMM/11_smemm_009.pdf)

& The Mexico City Principles for Voluntary Codes of Ethics in the Biopharmaceutical Sector (APEC Mexico City Principles): [http://mddb.apec.org/Documents/2011/SOM/CSOM/11\\_csom\\_021.pdf](http://mddb.apec.org/Documents/2011/SOM/CSOM/11_csom_021.pdf)

PART ONE	11 STEPS TO FORM A CONSENSUS FRAMEWORK
<p><b>Step 1:</b> 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.</p> <p><b>Step 2:</b> Identify key stakeholders within the member economy or the local community necessary to facilitate ethical collaborations in the medical device and biopharmaceutical sectors.</p> <p><b>Step 3:</b> Identify the individual, group, or organization to lead in convening these stakeholders.</p> <p><b>Step 4:</b> Convene stakeholders as equal partners. Ensure each partner maintains shared values that are consistent with Step One.</p> <p><b>Step 5:</b> 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, APEC Nanjing Declaration, and other best practices identified by the <i>Business Ethics for APEC SMEs Initiative</i>.</p> <p><b>Step 6:</b> Commit to developing a consensus-based framework for multi-stakeholder collaboration.</p> <p><b>Step 7:</b> Determine the framework’s scope of activities based on the interests / capabilities of the partners. Partners are encouraged to review Part Two of this Guide for strategies in determining the scope of activities that will realize mutual benefits.</p> <p><b>Step 8:</b> Establish a drafting group for the framework and determine consultative process.</p> <p><b>Step 9:</b> Finalize framework and undertake individual or collective adoption by the partners.</p> <p><b>Step 10:</b> Partners may consider effective governance strategies for the framework. This includes a designated or rotating secretariat or convener. The partners may support routine internal communication, virtually or in-person, facilitated by the convener. The partners may embrace an inclusive approach to welcome new organizations as well as changes in leadership by existing partners. Partners may maintain collaborative intent to preserve the platform’s underlying purpose. Partners may maintain routine external communication for their constituents, the general public, and the international community to build awareness and support for their activities. The partners may commit themselves to routine modernization of the framework so that it continues to reflect its original intent and motivates strengthened ethical business practices over time.</p> <p><b>Step 11:</b> Publicize and distribute the framework (for example, through the <i>Business Ethics for APEC SMEs initiative</i> website, external stakeholders and the media).</p>	

**PART TWO**

**STRATEGIES TO REALIZE SUSTAINABLE, MUTUAL BENEFITS**

**1. Identification and Communication of Best Practices:**

- The development of new codes of ethics for individual partners, the alignment of existing codes among partners, and/or the integration of codes between partners;
- Joint discussions and/or recommendations on existing, proposed, or potential laws and regulations or other local standards; and
- Joint communications on established best practices to each partner's respective constituents as well as the public and international community.

**2. Implementation of Cross-Organizational Capacity Building:**

- Ethics training curriculum, such as sharing existing resources or jointly developing new resources for dissemination to each partner's constituents;
- Ethics training activities, such as jointly convening or delivering training sessions to each partner's constituents (virtually and/or in-person);
- Ethics training feedback, such as each partner communicating back to other partners what their constituents are reporting during capacity building activities; and
- Ethics training incentives, such as enablers that encourage capacity building by all partners.

**3. Shared Monitoring and Evaluation of Changes:**

- An agreed process for partners to mutually track the dissemination of capacity building;
- A common recognition process across partners for their constituents who receive ethics training, such as a logo and/or other validation mechanism; and
- An early warning or opportunity detection process for partners to quickly exchange views and/or develop strategies for new or changed circumstances in the environment.

*Note: Depending on the nature of the framework, not all partners need to undertake each strategy together. Some strategies may be undertaken for the mutual benefit of all partners, while some may be undertaken for the benefit of a sub-group of partners. This should only apply when a certain strategy is not relevant to all partners, rather than as a means to exclude partners where there is mutual benefit. All partners should be welcomed to join each strategy that is pursued.*