

GOVERNMENT STRATEGIES TO ENCOURAGE ETHICAL BUSINESS CONDUCT

*A RESOURCE GUIDE FOR ECONOMIES FROM THE
BUSINESS ETHICS FOR APEC SMES INITIATIVE*

DRAFT / NOTIONAL - UPDATED 5 SEPTEMBER 2019

Prepared for the 2019 APEC Business Ethics for SMEs Forum

Santiago de Chile | 9-10 September 2019

Introduction

Ethical business conduct is vital to the sustainable growth of APEC economies, the competitiveness of the region's businesses, and patient access to medical products. High-standards in business ethics are especially crucial to creating an enabling environment for small and medium-sized enterprises, as indicated by APEC Economic Leaders.¹ They also contribute to the sustainable growth of small and medium-sized enterprises, as indicated by APEC Ministers.² Ethical business conduct strengthens the quality of and confidence in health systems while fostering innovation by enhancing trusted collaboration and spurring new investment. The collective prosperity of the APEC region is supported when ethical business conduct is implemented through high-standard, sector-specific best practices.

As the leaders of society, governments have an important role in supporting ethical business conduct. During the 2018 APEC Economic Leaders' Meeting, the Chair's Statement reaffirmed the commitment by member economies to foster integrity in the public and private sectors, recognizing the importance of efforts to combat and prevent corruption, promote transparency and good governance while strengthening the rule of law.³

While it is necessary for governments to ensure consistent enforcement actions are taken against those who violate laws designed to prevent unethical business conduct, governments can also take proactive steps to encourage ethical business conduct before unethical conduct occurs.

The Business Ethics for APEC SMEs Initiative is pleased to present member economies this resource guide of strategies that governments are already taking around the world to encourage ethical business conduct across six unique areas:

- (1) Convening Power,*
- (2) Procurement,*
- (3) Regulatory Practices,*
- (4) Enforcement Recognitions and Incentives,*
- (5) Government Supported Business Ethics Training, and*
- (6) Trade Agreements.*

¹ See 2017 Leader's Declaration (Da Nang Vietnam, Nov. 11th 2018), Asia-Pacific Economic Cooperation, available at: https://www.apec.org/Meeting-Papers/Leaders-Declarations/2017/2017_aelm.

² See 2018 APEC Ministerial Meeting Declaration (Port Moresby, Papua New Guinea, Nov. 15th 2018), Asia-Pacific Economic Cooperation, available at: https://www.apec.org/Meeting-Papers/Annual-Ministerial-Meetings/2018/2018_amm

³ See 2018 Chair's Statement (Port Moresby, Papua New Guinea, Nov. 18th 2018), Asia-Pacific Economic Cooperation, available at: https://apec.org/Meeting-Papers/Leaders-Declarations/2018/2018_aelm

Section One: Convening Power

Government bodies can serve as a neutral authority to voluntarily convene diverse, even at times adverse, parties within their economy to encourage collaboration and/or alignment for the benefit of society. This is particularly relevant for ethical business conduct, where trust between diverse parties within the economy may be limited and they may have difficulty coming together independently to collaborate. This “convening power” is one that few stakeholders in our societies possess. Notably, governments themselves are not monolithic and can contain diverse structures. As such, there is no uniform approach for governments in leveraging convening power. Different bodies can and have served to convene local stakeholders in different contexts to support ethical business conduct.

An example where governments are leveraging their convening power is in bringing health stakeholders together under “Consensus Frameworks” for ethical collaboration.⁴ Since 2014, hundreds of medical device and biopharmaceutical industry associations, healthcare professional and hospital groups, patient organizations, health regulators, and other stakeholders across nearly a dozen APEC member economies have committed to heightening collaboration on ethical business conduct through Consensus Frameworks. Not to be misunderstood as a code of ethics, a Consensus Framework is a voluntary and principles-based agreement or commitment by different parties across an economy’s healthcare system to convene on a routine basis and facilitate discussions / action items that support ethical business conduct.

Consensus Frameworks encourage diverse parties to align their codes of ethics, moving an economy toward universal adoption of harmonized and high-standard ethical business conduct. Examples of other activities stakeholders are performing under Consensus Frameworks include cross-organizational education and training; joint communication and advocacy activities; public-private dialogue on emerging challenges and opportunities; joint industry association code of ethics harmonization; and shared monitoring.⁵

Examples of Consensus Frameworks include:

- **Australian Ethical Healthcare Alliance:** Chaired by a healthcare professional society with direct support from the Department of Health and Therapeutic Goods Administration, the “Australian Ethical Healthcare Alliance” – originally titled Australian Consensus Framework – convenes over 70 national and regional parties covering nearly all aspects of Australia’s health system (professional societies, industry associations, hospital and health service providers, government bodies, patient organizations, and civil society, among others). Publicly supported by the Minister of Health and State Ministers of Health, the Australian Ethical Healthcare Alliance is the largest ethics accord of its kind in the world as of this Guide’s release. The platform has leveraged the convening power of government to support code of ethics alignment, implementation, and capacity-building on a grand scale.
- **Peruvian Consensus Framework:** Launched in 2016 by the Minister of Health and Director-General of DIGEMID, the Peruvian Consensus Framework has assembled 23 public and private bodies across the health system (industry associations, government bodies, healthcare professionals, hospitals, patient organizations, and civil society) in a collective action to strengthen ethical business practices in alignment with the APEC Kuala Lumpur Principles and APEC Mexico City Principles. The Peruvian Consensus Framework is managed by the Ministry of Health and maintains a work plan to drive code of ethics alignment and implementation.⁶

As of this Guide’s release, eight APEC economies have launched Consensus Frameworks (Australia, Canada, Chile, China, Japan, Peru, The Philippines, and Viet Nam). To support these efforts, the *Business Ethics for APEC SMEs Initiative* issued the 2018 Guide to Facilitate Multi-Stakeholder Ethical Collaborations in the Medical Device and Biopharmaceutical Sectors outlining steps to form / implement Consensus Frameworks.⁷

⁴ See 2019 Status Report on Consensus Frameworks in the APEC Region, available at:

<http://mcprinciples.apec.org/CMFiles/StatusReportonConsensusFrameworksIntheAPECRegion.pdf>

⁵ Please see Appendix 1 for suggested steps to form a consensus framework.

⁶ See *generally Peruvian Consensus Framework for Multi-Stakeholder Ethical Collaboration in the Pharmaceutical and Medical Device Sectors*, available at: <http://mcprinciples.org/CMFiles/MS%20Ethical%20Collaborations/EIMarcoConsensuadoPeruano-EnglishandCastellano.pdf>.

⁷ See 2018 APEC Business Ethics for SMEs Forum – Guide to Facilitate Multi-Stakeholder Ethical Collaborations in the Medical Device and Biopharmaceutical Sectors, Asia-Pacific Economic Cooperation, available at:

http://mddb.apec.org/Documents/2018/SMEWG/SMEWG47/18_smeWG47_014.pdf

Section Two: Procurement

Government bodies are often the largest procurers of goods and services. Such purchases can be substantial and can influence market behaviors. For some economies, direct government spending on goods and services can account for up to 20% of Gross Domestic Product (GDP). As such, government bodies are leveraging this “purchasing power” to encourage ethical business conduct. Some examples from across the APEC region and beyond include:

- **New Zealand:** NZ Health Partnerships – a Crown subsidiary that is owned and operated by New Zealand’s 20 District Health Boards – requires all suppliers of clinical products to: (A) be a member of the Medical Technology Association of New Zealand (MTANZ), which has an obligatory Code of Practice; or (B) adhere to the MTANZ Code of Practice.⁸
- **Chile:** Launched in 2003, “La Dirección ChileCompra” serves as the economy’s e-procurement system for the public sector.⁹ The platform serves to increase transparency and accountability for all goods and services procured by the Government of Chile. Through ChileCompra, suppliers looking to sell goods and services to the government are provided online ethics training.
- **Argentina:** Enacted by the National Congress of Argentina, Law No. 27401 sets a legal framework for corporate criminal and administrative liability for domestic and transnational bribery, influence peddling, participation in the illicit enrichment of public officials, as well as falsification of books and records.¹⁰ The Law requires entities to have an adequate integrity program before contracting with the government.
- **United States:** The U.S. Federal Acquisition Regulations (FAR), Section Three requires all contractors to maintain business practices with the highest level of integrity and honesty and are required to implement a written code of business ethics and conduct. The FAR also suggests a training program and internal control system associated with the code of business ethics and conduct that is suitable to the organization’s size and involvement in government contracting, facilitates timely disclosure of improper conduct to the government client, and ensures corrective measures are in place and followed.
- **Brazil:** Several states in Brazil have enacted regulations requiring companies to implement an integrity program in order to participate in public tenders of a certain value and duration.¹¹ These integrity programs should include a set of internal integrity and audit mechanisms, procedures for reporting irregularities and applying codes of ethics, as well as conduct, policies and guidelines to detect and remedy unethical business conduct.

The **OECD Principles for Integrity in Public Procurement** have also drawn attention to the role of governments in encouraging ethical business practices through procurement.¹² Principle Six encourages close co-operation between government and industry to maintain high standards of integrity, encouraging governments to consider requiring potential suppliers to make declarations of integrity or entering into “Integrity Pacts” that require mutual ethical commitments.

⁸ See *NZ Health Partnerships*, available at: <http://www.nzhealthpartnerships.co.nz/operating-model/#our-structure>.

⁹ *Chile Compra Sistema de Contratacion y Compras Publicas*, Gobierno de Chile Ministerio de Hacienda, available at: <https://www.chilecompra.cl/wp-content/uploads/2016/11/strategic-plan-public-procurement-system-2002-2004-2.pdf>

¹⁰ See Argentine Law that Establishes Corporate Criminal and Administrative Liability for Corruption Enters Into Force March 2018, Luis Inacio Lucena Adams (Feb. 01, 2018), available at: <https://www.mayerbrown.com/en/perspectives-events/publications/2018/02/argentine-law-that-establishes-corporate-criminal>.

¹¹ See, e.g., *Brazil: New mandatory compliance programs between companies and Rio de Janeiro State*, Francisco Todorov et. al., *Global Compliance News* (Dec. 4, 2017), available at: <https://globalcompliancenews.com/brazil-mandatory-compliance-programs-20171204/>.

¹² See *OECD Principles for Integrity in Public Procurement*, OECD, available at: <https://www.oecd.org/gov/ethics/48994520.pdf>

Section Three: Regulatory Practices

Regulatory practices can be structured to encourage ethical business conduct. Some examples from across the APEC region and beyond include:

- **Mexico:** By embracing Good Regulatory Practices (also referred to as good regulatory design and regulatory coherence) through the General Law of Regulatory Improvement, Mexico has focused on the mandatory deployment of quality and consistent rulemaking.¹³ This internal coordination and review process under which the whole-of-government works helps to realize rules and regulations that are crafted in an open, transparent, and participatory manner. As such, all enterprises in the economy are subject to the same regulations without the ability to deploy shortcuts that could lead to unethical business conduct.
- **Philippines:** In 2015, the Philippines Department of Health issued Administrative Order No. 2015-0053: Implementing Guidelines on the Promotion and Marketing of Prescription Pharmaceutical Products and Medical Devices (Order).¹⁴ The Order requires all entities in the economy related to the pharmaceutical and medical device sectors to adhere to high standard ethical business practices as embodied in the APEC Kuala Lumpur Principles and the APEC Mexico City Principles. The Order followed the release of Food and Drug Administration Circular No. 2014-007 and Circular No. 2013-024 seeking the adoption and implementation of these APEC Principles.
- **South Africa:** Under South Africa's Medicines and Related Substances Act 101 of 1965 the Minister of Health is empowered to consult with the pharmaceutical industry and other stakeholders to make regulations on the marketing of medicines, scheduled substances, medical devices or in vitro diagnostics (IVDs).¹⁵ This includes maintaining together an enforceable code of practice.
- **United States:** Over the last ten years, several state legislatures (such as Vermont, Nevada, Massachusetts, and California) have enacted a series of regulations which require medical device and biopharmaceutical manufacturers operating within their respective states to train company employees on ethical marketing practices to the standards set by their industry's code of conduct.

¹³ See *Ley General De Mejora Regulatoria*, available at: http://www.diputados.gob.mx/LeyesBiblio/pdf/LGMR_180518.pdf.

¹⁴ See *Implementing Guidelines on the Promotion and Marketing of Prescription Pharmaceutical Products and Medical Devices*, available at: https://www.pcom.ph/sites/default/files/downloads/ao_on_marketing_of_drugs.pdf,

¹⁵ Medicines and Related Substances Act 101 of 1965, available at: https://www.hpcs.co.za/Uploads/editor/UserFiles/downloads/legislations/acts/medicines_and_related_sub_act_101_of_1965.pdf.

Section Four: Enforcement Recognition and Incentives

Governments serve an important role in undertaking investigations and enforcement action against organizations and/or individuals for violation of laws against unethical business conduct. This role is a deterrent against unethical business conduct. In addition, some governments offer enforcement recognition and incentives that encourage organizations and/or individuals to prevent unethical business conduct before it occurs or to voluntarily cease / disclose unethical conduct before the situation worsens. Some examples from the APEC region and beyond include:

- **Effective Codes and Compliance Programs:** Some governments offer recognition to enterprises that encourage the proactive implementation and enforcement of effective codes of conduct and compliance programs. The aim of this recognition is to prevent unethical business conduct before it occurs while reducing the consequences faced by enterprises who take proactive steps to strengthen ethical business conduct. In several instances, governments have included such recognition within anti-corruption laws.

The **United Kingdom** issued guidance in 2011 on “procedures which relevant commercial organizations can put into place to prevent persons associating with them from bribing” alongside enactment of the 2010 Bribery Act.¹⁶ If an enterprise has implemented a compliance program that satisfies the Act’s “Six Principles” of an effective system at the time of an individual’s crime, the enterprise may obtain certain recognition of their efforts, such as penalty and fine reductions.

Mexico reinforced a series of anti-corruption reforms in 2016 with the General Law of Administrative Responsibility (GLAR) that mitigates corporate liability if an enterprise has implemented a robust compliance integrity program.¹⁷ The Clean Companies Act 2014 in **Brazil** provides exemptions from sanctions, including reductions of fines by up to two-thirds, if an enterprise’s ethics and compliance program is in accordance with the law.¹⁸

Spain amended its Criminal Code in 2015 to provide enterprises protection from liability for crimes committed by their officers or employees if certain requirements are met including directors having adopted an effective ethics and compliance program. Article 33 bis 5 enumerates six key elements on which officers and employees must demonstrate that they have been properly trained for the enterprise to gain legal defense against criminal liability.

Although the Penal Code in **Sweden** does not specifically recognize compliance programs,¹⁹ having an effective compliance program in place could partly mitigate their criminal liability.²⁰

The **United States** updated guidance on the Evaluation of Corporate Compliance Programs in April 2019 to help prosecutors make informed decisions as to whether an enterprise’s compliance program was effective at the time an offense occurs.²¹ This guidance provides that prosecutors ask whether the corporation’s compliance program was well designed; if the program was applied earnestly and in good faith; and if the corporation’s compliance program works in practice.²² It also provides details on how prosecutors should evaluate these questions.

- **Advance Disclosure:** Many governments offer incentives that encourage enterprises to voluntarily cease and disclose unethical business conduct. The aim of these incentives is to prevent unethical business conduct from becoming more severe over time and, as a result, curtailing the systemic implications that can face entire

¹⁶ See *The Bribery Act 2010: Guidance about procedures which relevant commercial organisations can put into place to prevent persons associated with them from bribing* (section 9 of the Bribery Act 2010), Ministry of Justice (March 2011), available at: <https://www.justice.gov.uk/downloads/legislation/bribery-act-2010-guidance.pdf>.

¹⁷ Ley General de Responsabilidades Administrativas, (July 18, 2016), available at: http://www.diputados.gob.mx/LeyesBiblio/pdf/LGRA_120419.pdf.

¹⁸ Lei No. 12.846, de 1 de Agosto de 2013, available at: <https://www.cov.com/files/upload/E-Alert-Attachment-Brazilian-Clean-Companies-Act-Original.pdf>.

¹⁹ See Swedish Penal Code, Chapter 10, Section 5 (a)-(e).

²⁰ See *Anti-Corruption in Sweden*, Global Compliance News, Mattias Hedwall & Olof Konig, available at: <https://globalcompliancenews.com/anti-corruption/anti-corruption-in-sweden/>.

²¹ See *Evaluation of Corporate Compliance Programs*, U.S. Department of Justice Criminal Division (April 2019), available at: <https://www.justice.gov/criminal-fraud/page/file/937501/download>. See also *Criminal Division Announces Publication of Guidance on Evaluating Corporate Compliance Programs*, United States Department of Justice, Press Release (Apr. 30, 2019), available at: <https://www.justice.gov/opa/pr/criminal-division-announces-publication-guidance-evaluating-corporate-compliance-programs>.

²² See *Evaluation of Corporate Compliance Programs*, U.S. Department of Justice Criminal Division (April 2019), available at: <https://www.justice.gov/criminal-fraud/page/file/937501/download>.

industries and the public when there is sustained unethical business conduct. These incentives also reduce the enforcement burden faced by governments who might otherwise have investigated the enterprise. For example, Legislative Decree 231/2001 (Decree) in **Italy** codified the benefit of advance disclosure by specifying that an effective ethics and compliance program worthy of legal defense would include clear informational channels for reporting wrongdoing and internal protections for those employees who report wrongdoing (“whistleblowing”). The Decree was amended further through Law No. 3/2019.

Section Five: Government Supported Business Ethics Training

Governments increasingly recognize that enterprises adhering to high standard ethical business conduct are more competitive and sustainable, provide stronger protections for their workers and customers, and are more attractive for local partnerships and international supply chains. As such, several economies offer government sponsored business ethics training and related resources, in particular for small and medium sized businesses.

There are a range of government entities that may champion such efforts, including those seeking to promote economic growth and commerce, SME development, and anti-corruption programs, among others. Some examples from across the APEC region and beyond include:

- **Hong Kong, China:** The Independent Commission Against Corruption (ICAC) of Hong Kong, China embraces a three-pronged approach in its work to reduce corruption: law enforcement, prevention, and education. Aligned with this approach, in 1994 the ICAC launched a “Campaign on Business Ethics” in co-operation with business associations and professional bodies. In 1995, the ICAC established the Hong Kong Business Ethics Development Centre under the ICAC’s Community Relations Department. Since 2015, representatives from ten major chambers of commerce in Hong Kong have formed the Hong Kong Business Ethics Development Advisory Committee (BEDAC) to steer the Centre’s work. The Centre offers consultancy services for individual enterprises (such as business ethics training, code of conduct formation, system controls, and customized resources), as well as a broad range of free resources, including training packages and practical guides, for all enterprises in Hong Kong, China.
- **Malaysia:** SME Corporation Malaysia partners with the Malaysian Anti-Corruption Commission (MACC) and other government bodies to promote business ethics and integrity for the benefit of small and medium-sized businesses. This collaboration started with the creation of the SME Pledge to foster ethical business practices and was followed by the promotion of integrity pacts and well-designed contract support to include anti-corruption clauses. SME Corporation Malaysia also works with practitioners, regulators and academic representatives to publish works or references for anti-bribery and anti-corruption efforts as well as assisting regulators to develop Codes of Ethics on a sectoral basis in order to support SME development.

Section Six: Trade Agreements

Trade agreements between two or more economies serve as mechanisms to improve the volume and quality of cross-border commerce. The APEC region has seen a rapid proliferation in the number and scope of trade agreements since the inter-governmental forum was established in 1989. Trade agreements can also serve as a mechanism for governments to promote and align ethical business conduct for parties within their respective economies. In fact, enterprises seeking to expand international market access (especially SMEs), forge new partnerships, participate in international supply chains, and pursue foreign investment all benefit from formalized efforts to strengthen and align ethical business conduct.

Economies such as Australia, Indonesia, Mexico, and the United States, among others have adopted provisions within trade agreements to address bribery and foster collaboration to reduce unethical and criminal business conduct. Examples in trade agreements include:

- Criminalization of active and passive domestic public sector bribery and active transnational public sector bribery, including the application of effective sanctions;
- Adoption of measures to protect persons who report acts of bribery in good faith (i.e., whistleblower protections);
- Government training to promote business ethics and integrity;
- Promoting ethical conduct among public officials and those who interact with them; and
- Promoting the role of the private sector and other stakeholders to help prevent corruption, including the use of effective compliance programs.

APEC economies will likely continue to use trade agreements to promote criminalization of public sector corruption and to strengthen ethical business practices.

Appendix 1

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

PART ONE – 11 STEPS TO FORM A CONSENSUS FRAMEWORK

Step 1: 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 2: Identify key stakeholders within the member economy or the local community necessary to facilitate ethical collaborations in the medical device and biopharmaceutical sectors.

Step 3: Identify the individual, group, or organization to lead in convening these stakeholders.

Step 4: Convene stakeholders as equal partners. Ensure each partner maintains shared values that are consistent with Step One.

Step 5: 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 *Business Ethics for APEC SMEs Initiative*.

Step 6: Commit to developing a consensus-based framework for multi-stakeholder collaboration.

Step 7: 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.

Step 8: Establish a drafting group for the framework and determine consultative process.

Step 9: Finalize framework and undertake individual or collective adoption by the partners.

Step 10: 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.

Step 11: Publicize and distribute the framework (for example, through the *Business Ethics for APEC SMEs Initiative* website, external stakeholders and the media).