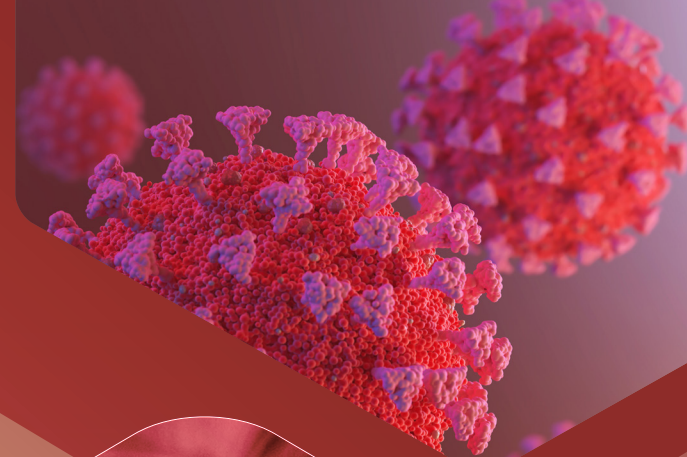


2021 Report on

Code of Ethics Implementation

by Biopharmaceutical
Industry Associations
in the APEC Region



Business Ethics for APEC SMEs
Biopharmaceutical Sector

APEC Small and Medium Enterprises
Working Group (SMEWG)

Table of Contents

EXECUTIVE SUMMARY	2
PART ONE CODE OF ETHICS ADOPTION	4
PART TWO CODE OF ETHICS IMPLEMENTATION	5
PART THREE MULTI-STAKEHOLDER AND NON-MEMBER ENGAGEMENT	8
APPENDIX CODE OF ETHICS COMPENDIUM OF BIOPHARMACEUTICAL INDUSTRY ASSOCIATIONS IN THE APEC REGION	11

Executive Summary

Launched in 2011, the Business Ethics for APEC SMEs Initiative is the world's largest public-private partnership to strengthen ethical business practices for small- and medium-sized enterprises (SMEs). Comprised of industry associations representing thousands of SMEs in the biopharmaceutical sector and endorsed by APEC Economic Leaders and Ministers, this initiative sets best practices through the APEC Mexico City Principles (APEC MC Principles). This report serves as the final review under the original principles as, for the first time, the Principles will undergo a modernization process in 2021

to incorporate the latest high standards and embrace the expanded role of industry and non-industry stakeholders.

Code implementation efforts are one of the initiative's core activities. This is monitored through an annual survey of 70 biopharmaceutical industry associations across the APEC region. This report highlights core components of the survey results: (1) code of ethics adoption; (2) code of ethics implementation; and (3) code of ethics adherence.

KEY SURVEY FINDINGS

CODE ADOPTION

- Since 2018, APEC has achieved near-universal code adoption. We still see challenges with code adoption in Chile; Hong Kong, China; Korea; Mexico; Singapore; Russia; and Chinese Taipei.
- The COVID-19 pandemic caused association membership to increase and decrease in some APEC economies, as reported by industry associations in China, Mexico, and Chinese Taipei.

CODE IMPLEMENTATION

- 90% of associations in the APEC region with a code have adopted all six of the fundamental principles underlying the APEC MC Principles.
- Associations holding annual discussions with member companies are more likely to report the highest level of code adherence (76-100%).
- Association code of ethics trainings decreased in 2020, but rebounded to an all-time high in 2021.

MULTI-STAKEHOLDER AND NON-MEMBER ENGAGEMENT

- New Zealand is working toward the launch of a new consensus framework agreement by October 2021.
- Industry associations reporting engagement with patient organizations rose from 40% to more than 63% in 2021.

To learn more about the initiative, please visit <http://mcprinciples.apec.org>

Disclaimer: The data presented in this Report is based on survey responses provided by biopharmaceutical industry associations in the APEC region. The data has not been independently validated nor does the initiative conduct audits of the region's industry associations or their member companies.

PART 1

Code of Ethics Adoption

Since they were endorsed in 2012, the APEC Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector have inspired industry associations to establish similar codes or code commitments. In less than a decade, the *Business Ethics for APEC SMEs Initiative* has achieved near-universal adoption of industry codes of ethics among biopharmaceutical industry associations in the APEC region. As of 2021, at least 55 biopharmaceutical industry associations representing nearly 10,000 companies and over 5,000 SMEs in the APEC region have established a code or code commitment.

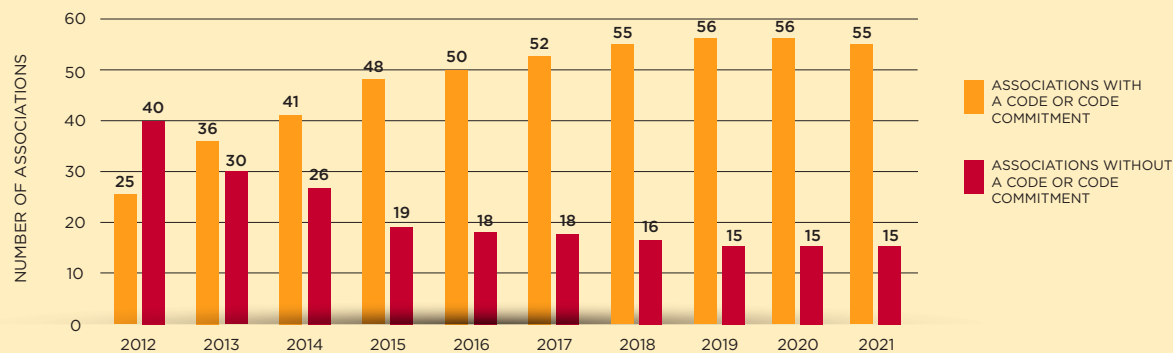
The COVID-19 pandemic caused some fluctuation in association membership across the APEC region. In particular, membership in China consolidated by 200 enterprises while membership expanded in Mexico by 60 companies and in Chinese Taipei by almost 30.

The remaining fifteen biopharmaceutical associations without a code of ethics are located in seven APEC economies: Chile; Hong Kong, China; Korea; Mexico; Singapore; Russia; and Chinese Taipei (see table in Appendix for further details). When asked what difficulties they face in adopting the APEC Mexico City Principles, many cite challenges in coordinating member companies and non-member stakeholders as hindrances to adoption. The *Business Ethics for APEC SMEs Initiative* has shifted its efforts toward code implementation now that near-universal code adoption is achieved. Training and resources to adopt an enterprise-level code of ethics are still continually available to thousands of businesses, including SMEs.

A MAJORITY OF INDUSTRY ASSOCIATIONS AND SMEs ARE COVERED BY A CODE OF ETHICS AS OF 2021



IN LESS THAN A DECADE, APEC HAS ACHIEVED NEAR-UNIVERSAL CODE ADOPTION

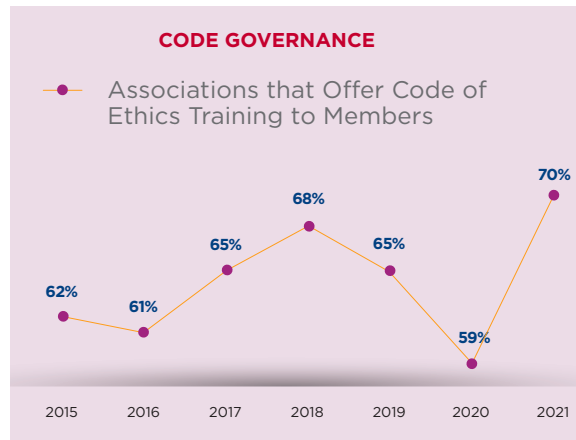


PART 2

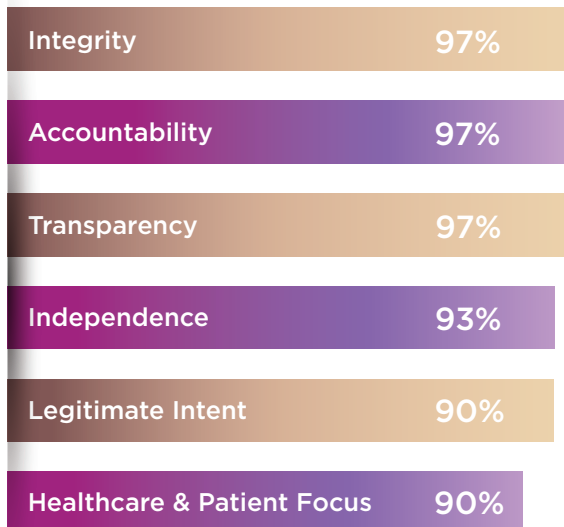
Code of Ethics Implementation

While adopting a code of ethics is an important step toward raising ethical standards in the biopharmaceutical industry, proper implementation of that code is essential to effectively advance ethical business practices. Successful code implementation by an industry association consists of code governance, code alignment, and code adherence.

Code Governance - Maintaining sound governance around a code of ethics promotes accountability and encouragement among association members, creating an environment in which ethical business practices thrive. As of 2021, over 83% of industry associations in the APEC region have a code complaint or violation procedure, and 60% of associations report that this system has been actively used in the past two years. Additionally, since 2015, over 60% of industry associations responding to the survey have offered code of ethics training to members. The COVID-19 pandemic caused training availability to fall in 2020, but associations corrected this with a significant influx of trainings in 2021.



90% OF INDUSTRY ASSOCIATIONS EMBRACE ALL SIX FUNDAMENTAL PRINCIPLES



Code Alignment - Many industry associations choose to align their code or code commitment with the APEC Mexico City Principles; at times associations include the entire document's text. Other associations incorporate certain provisions into their own ethics codes to better align with local requirements. There are six fundamental principles which motivate the APEC Mexico City Principles and address member company relationships with healthcare professionals and other stakeholders. They are Healthcare and Patient Focus, Integrity, Independence, Legitimate Intent, Transparency, and Accountability. While there may be a plurality of association codes of ethics, 90% of associations in the APEC region with a code or code commitment still report adopting all six principles, with 97% highlighting Integrity, Transparency, and Accountability.

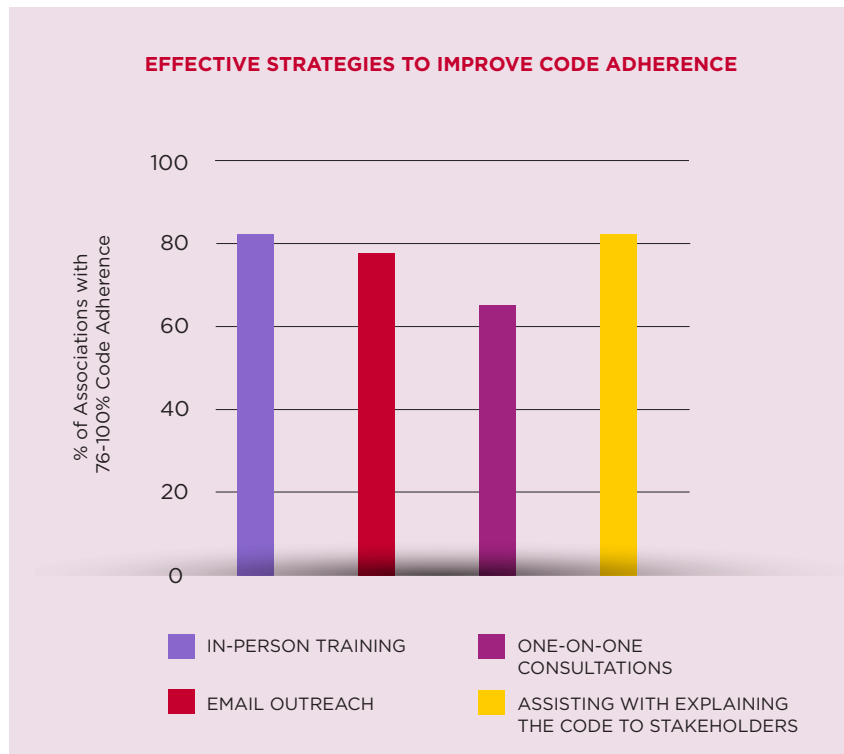
Code of Ethics Implementation continued

Code Adherence - Industry associations pursue diverse strategies to bolster code adherence among biopharmaceutical companies in the APEC region. There is a strong correlation between high code adherence and routinely convening member companies (at least twice a year) to discuss ethical and non-ethical matters. Industry associations which hold annual discussions with member companies are more likely to report the highest level of code adherence (76-100%). In 2021, 87% of industry associations

which convene these annual discussions reported between 76-100% code adherence. Similarly, associations which offer code of ethics training to their members indicate high levels of code adherence; 86% of industry associations which offer member training on their code of ethics reported 76-100% code adherence.

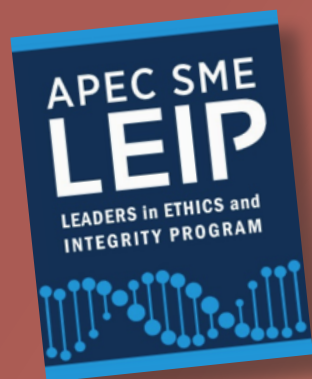
Other association activities for reaching members include targeted communications and outreach about the code with stakeholders,

one-on-one consultations, and email outreach in addition to in-person training. Of those industry associations which have achieved 76-100% code adherence, 83% report that providing in-person code of ethics training for members and assisting with explaining the code of ethics to stakeholders are the most effective strategies to improve code adherence in the biopharmaceutical industry.



SPOTLIGHT ON CAPACITY BUILDING:

APEC SME Leaders in Ethics and Integrity Program (LEIP)



The APEC SME Leaders in Ethics and Integrity Program (LEIP) is designed to help bi-pharmaceutical industry associations equip leaders of their small and medium enterprise (SME) members with resources and a valued network to reinforce a culture of integrity within their enterprise. Using a “tone-at-the-top” approach, the mission of LEIP is to support the integration of the APEC Mexico City Principles into the daily business practices of every SME that develops, manufactures, markets, or distributes any pharmaceutical and/or biologic product. LEIP is offered to SMEs through industry association partners that have implemented a code of ethics.

LEIP supports associations’ code implementation efforts and strengthens the value associations provide to member companies. This offering for smaller member companies can also include non-member companies as a way to introduce them to the association. The Initiative works closely with associations in collaboration with industry experts to provide guidance on the structure, curriculum, and sustainability of LEIP. In 2021, LEIP premiered in two APEC economies: Chile and Canada.

KEY INSIGHTS FROM 2021 LEIP

LEIP CHILE	LEIP CANADA
<p>Host: National Chamber of Laboratories in Chile, a local association with 12 members</p> <p>Partners included: Industry (including medical technology association), government, academia, patient organizations</p> <p>Key themes:</p> <ul style="list-style-type: none">• Convening power and the value of bringing together diverse partners to engage with local companies• Case studies on CEO implementation• Peer to peer insights (e.g. opportunity for local CEOs to hear from others on how they assess risks, help employees and support one another).	<p>Host: Life Sciences Ontario, Medtech Canada, Innovative Medicines Canada, BIOTECanada, and Health Charities Coalition Canada</p> <p>Partners included: Industry (including medical technology association and multi-national companies), government, academia, other industry supporters, patient organizations.</p> <p>Key themes:</p> <ul style="list-style-type: none">• Helping companies strengthen export readiness for international partnerships• Responsible business conduct as an essential element of international trade• Role of multi-national companies to advance ethical business practices for small businesses that they may seek to partner with in the future• Importance of engaging early, often, and meaningfully with patients

PART 3

Multi-Stakeholder and Non-Member Engagement

Multi-stakeholder collaboration in the biopharmaceutical sector is an essential element to achieving an ethically robust business environment and healthcare system. Attaining high ethical standards across APEC economies requires commitment and engagement by every key stakeholder in the region, including governments, patient organizations, industry associations and their members (as well as non-member companies), healthcare professionals, and third-party intermediaries.

When this initiative began tracking these figures in 2018, only about 40% of associations reported that they engage with patient organizations regarding codes of ethics. In 2021, however, industry interactions with patient organizations, specifically regular communication and development & implementation of consensus framework, increased to more than 60%.

Across time, government interactions have consistently centered around regular communication, with little engagement on training & capacity building. In 2020 and 2021, there has been greater industry engagement with healthcare professionals across the board, with efforts centered most heavily around development & implementation of Consensus Framework.

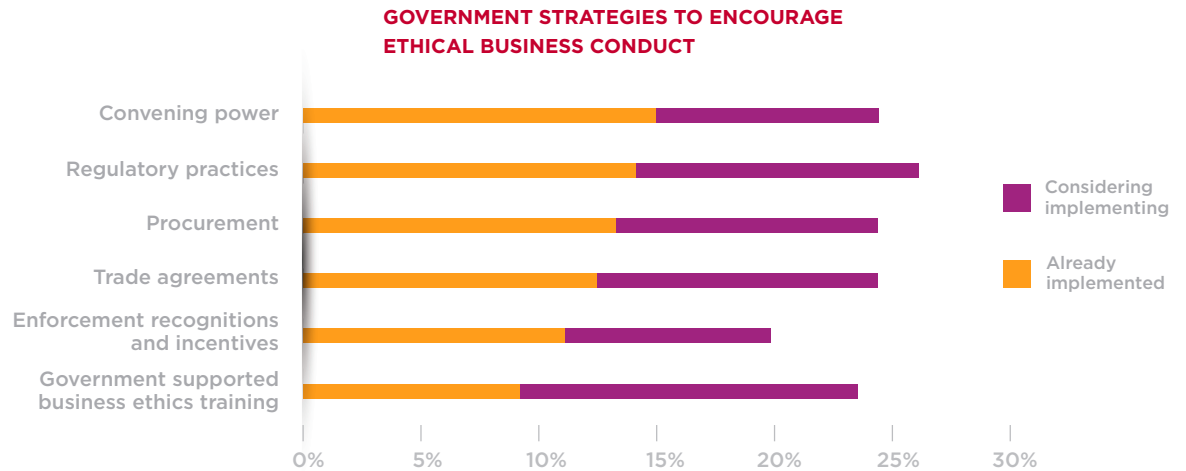
Perhaps the most dramatic change we see is that reported industry association engagement with third-party intermediaries rose from only 20% in 2020 to 60% in 2021.



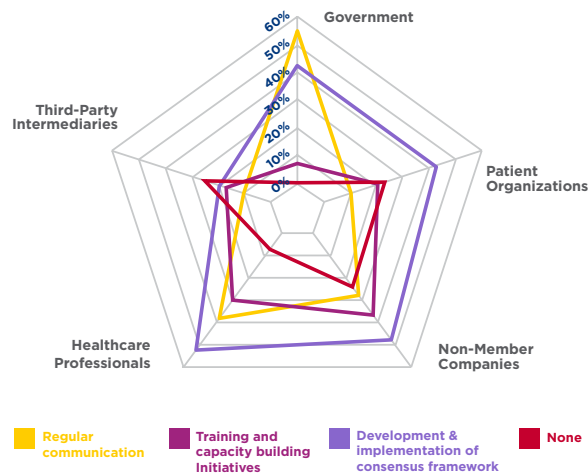
Multi-Stakeholder and Non-Member Engagement continued

Government Strategies to Encourage Ethical Business Conduct

Governments are uniquely positioned to strategically promote an environment of ethical business conduct. The APEC Resource Guide of Government Strategies to Encourage Ethical Business Conduct outlines government best practices and case studies to encourage ethical business conduct through the six strategies seen in the graphic. The greatest number of associations report that convening power, governments promoting ethical business conduct by bringing stakeholders together, is most implemented across the APEC region, while government supported business ethics training is under consideration by the most survey respondents.



PERCENT OF INDUSTRY ASSOCIATIONS ENGAGING WITH SPECIFIC STAKEHOLDERS IN 2021



CONSENSUS FRAMEWORKS FOR ETHICAL COLLABORATION

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 health system to convene on a routine basis and facilitate discussions and action items

that support ethical business conduct. The Business Ethics for APEC SMEs Initiative calls for consensus frameworks in each APEC economy by 2023 and implementation by 2025. Of the region's 70 biopharmaceutical associations, nearly half are already party to a consensus framework agreement. Those associations not currently part of a framework who are interested in joining one are located in nine economies: Hong Kong, China; Indonesia; Korea; Malaysia; Mexico; Chinese Taipei; Thailand; and the United States. New Zealand is anticipated to launch a new framework agreement by October 2021.

Code of Ethics Compendium of Biopharmaceutical Industry Associations in the APEC Region

Association	Economy	Member Enterprises		Code Adoption Commitment*			Member Implementation	Participation in Consensus Framework Agreement
		TOTAL	SMEs	Yes/No	Year Adopt	Last Update		
Medicines Australia	▲ Australia	29	0	Yes	1960	2020	76-100%	Yes
GBMA	▲ Australia	7	4	Yes	2010	2015	76-100%	No
IMC	▲ Canada	36	20	Yes	1988	2020	Unknown	Yes
CGPA	Canada	11	0	Yes	1998	2013	No Data	No
ASILFA	Chile	9	0	No	N/A	N/A	N/A	Yes
CIF	▲ Chile	23	0	Yes	2007	2020	76-100%	Yes
Cámara Nacional de Laboratorios	▲ Chile	13	10	Yes	1999	2019	76-100%	Yes
CPIA	▲ China	510	145	Yes*	2013*	2018*	51-75%	Yes
CCCMHPIE	▲ China	1500	1350	Yes*	2011*	2013*	76-100%	Yes
PhIRDA	▲ China	96	30	Yes	2018	2018	76-100%	Yes
RDPAC-CAEFI	▲ China	43	0	Yes	2007	2019	76-100%	Yes
CATCM	China	700	500	Yes*	2013*	2015*	76-100%	Yes
CAPC	China	384	249	Yes*	2013*	2015*	51-75%	Yes
All-China Federation	China	No Data	No Data	Yes*	2013*	2015*	No Data	Yes
CMBA	China	300	250	Yes*	2015*	N/A	No Data	Yes
CMEA	China	No Data	No Data	Yes*	2015*	N/A	No Data	Yes
CNMA	China	350	No Data	Yes*	2013*	2015*	No Data	Yes
CPAPE	China	350	No Data	Yes*	2015*	N/A	No Data	Yes
CPEMA	China	No Data	No Data	Yes*	2015*	N/A	No Data	Yes
CPEP	China	150	No Data	Yes*	2013*	2015*	No Data	Yes
CPPA	China	No Data	No Data	Yes*	2015*	N/A	No Data	Yes

Association	Economy	Member Enterprises		Code Adoption Commitment*	Code		Member Implementation	Participation in Consensus Framework Agreement
		TOTAL	SMEs	Yes/No	Year Adopt	Last Update		
COAP	China	No Data	No Data	Yes*	2015*	N/A	No Data	Yes
CRAECC	China	No Data	No Data	Yes*	2013*	2015*	No Data	Yes
HKAPI	▲ Hong Kong, China	45	4	Yes	1970	2019	76-100%	No
HKPMA	Hong Kong, China	38	35	No	N/A	N/A	N/A	No
PDAHK	Hong Kong, China	44	44	No	N/A	N/A	N/A	No
GP Farmasi	▲ Indonesia	2400	1500	Yes	2003	2016	51-75%	No
IPMG	▲ Indonesia	23	23	Yes	2001	2019	76-100%	No
JPMA	▲ Japan	73	5	Yes	1976	2019	76-100%	Yes
JGA	▲ Japan	39	24	Yes	2010	2019	76-100%	Yes
KRPIA	▲ Korea	44	28	Yes	2009	2019	76-100%	No
KPBMA	▲ Korea	200	150	Yes	1994	2017	76-100%	No
KoBIA	Korea	107	50	No	N/A	N/A	N/A	No
MOPI	▲ Malaysia	49	45	Yes	2013	2016	Unknown	No
PhAMA	Malaysia	35	1	Yes	1978	2020	76-100%	No
CANIFARMA	▲ Mexico	98	10	Yes	2005	2021	76-100%	Yes
CETIFARMA	▲ Mexico	162	140	Yes	2006	2021	76-100%	Yes
AMIIF	▲ Mexico	39	10	Yes	2006	2020	76-100%	No
ANAFAM	▲ Mexico	6	0	Yes	2005	2013	Unknown	No
ANADIM	Mexico	No Data	No Data	No	N/A	N/A	No Data	No
Medicines New Zealand	▲ New Zealand	25	7	Yes	1962	2019	76-100%	No
ADIFAN	Peru	13	13	Yes	2014	N/A	76-100%	Yes
ALAFARPE	▲ Peru	23	2	Yes	2000	2020	76-100%	Yes
ALAFAL	Peru	10	5	Yes	2016	N/A	76-100%	Yes
PCPI	▲ Philippines	100	90	Yes	2014	2014	51-75%	No

▲ UPDATED WITH 2021 SURVEY RESULTS

Association	Economy	Member Enterprises		Code Adoption	Code		Member Implementation	Participation in Consensus Framework Agreement	
		TOTAL	SMEs	Commitment*	Year Adopt	Last Update			
				Yes/No					
PHAP	▲	Philippines	38	15	Yes	1993	2020	76-100%	Yes
MEPI		Philippines	46	0	Yes	2015	N/A	No Data	No
AIPM	▲	Russia	32	19	Yes	1998	2020	76-100%	No
ARPM		Russia	20	0	No	N/A	N/A	N/A	No
SAPI	▲	Singapore	34	0	Yes	<1980	2021	76-100%	No
SMF-LSIG		Singapore	48	30	No	N/A	N/A	N/A	No
IRPMA	▲	Chinese Taipei	47	0	Yes	2003	2019	76-100%	No
TRPMA	▲	Chinese Taipei	52	52	Yes	2020	2020	N/A	No
TPMA		Chinese Taipei	210	160	No	N/A	N/A	N/A	No
TGPA	▲	Chinese Taipei	66	36	No	N/A	N/A	N/A	No
CAPA		Chinese Taipei	125	115	No	N/A	N/A	N/A	No
CPMDA		Chinese Taipei	50	16	No	N/A	N/A	N/A	No
NPCA		Chinese Taipei	No Data	No Data	No	N/A	N/A	N/A	No
TPADA		Chinese Taipei	8	0	No	N/A	N/A	N/A	No
TPMMA		Chinese Taipei	55	55	No	N/A	N/A	N/A	No
PReMA	▲	Thailand	32	14	Yes	1987	2019	76-100%	No
TPMA	▲	Thailand	70	60	Yes	2015	2019	Unknown	No
GPO		Thailand	1	0	Yes	2015	N/A	76-100%	No
PhRMA	▲	United States	33	0	Yes	2002	2019	76-100%	No
AAM		United States	24	No Data	Yes	2018	2018	Unknown	No
VNPCA	▲	Viet Nam	180	130	Yes	2015	2017	51-75%	Yes
Pharma Group	▲	Viet Nam	23	0	Yes	2014	2020	76-100%	Yes
IQGx	▲	Viet Nam	11	0	Yes*	2016	2019	76 -100%	Yes
FIFARMA	▲	Regional	13	0	Yes	2014	2020	76-100%	No
ALIFAR		Regional	N/A	N/A	No	N/A	N/A	N/A	No

APEC Project: SME 01 2020 A
Produced by Business Ethics
for APEC SMEs Initiative

For Asia Pacific Economic Cooperation Secretariat
35 Heng Mui Keng Terrace Singapore 119616
Tel: +65 6891 9600 Fax: +65 6891 9690

Email: info@apec.org
Website: www.apec.org

©2021 APEC Secretariat