

2020 Report on

Code of Ethics Implementation

by Biopharmaceutical Industry Associations in the APEC Region

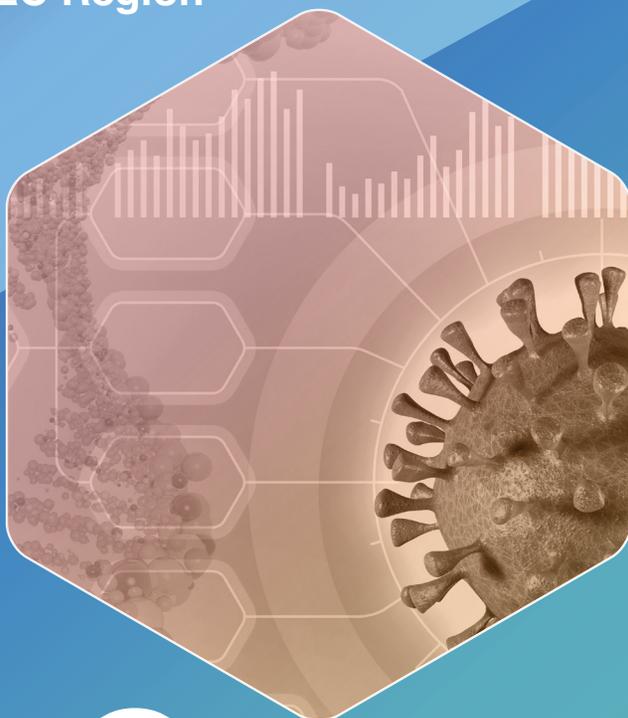


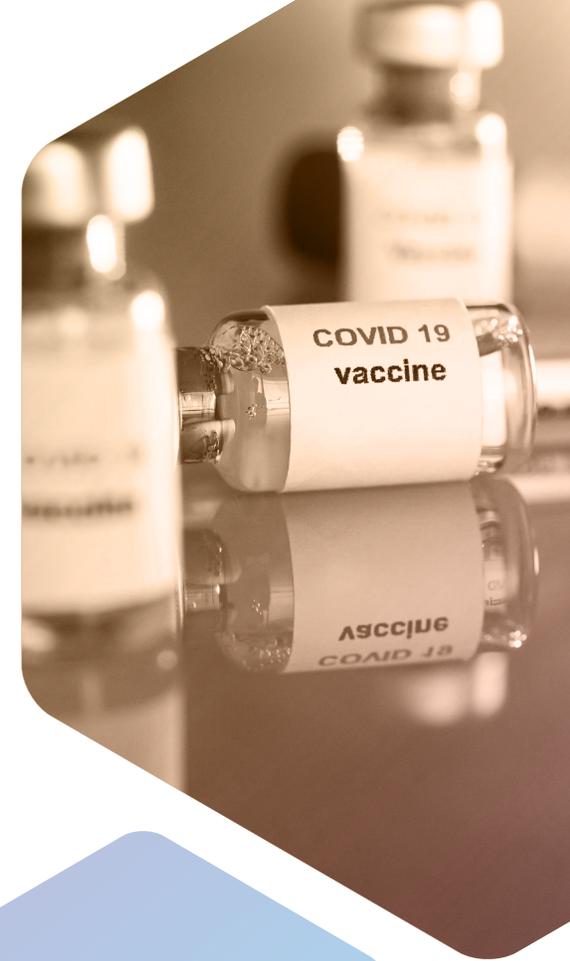
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Introduction

As APEC economies address the COVID-19 pandemic and resulting economic crisis, biopharmaceutical industry associations across the region are responding by reinforcing ethics and integrity. The *Business Ethics for APEC SMEs Initiative* biopharmaceutical sector program supports this response. Launched in 2011, the Initiative is the world's largest public-private partnership to strengthen ethical business practices. Endorsed by APEC Economic Leaders and Ministers, this initiative - comprised of industry associations representing thousands of small and medium-sized enterprises in the biopharmaceutical sector - sets best practices through the APEC Mexico City Principles.

Code implementation efforts are one of the initiative's core activities. This is monitored through an annual survey of 71 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) multi-stakeholder and non-member engagement.



Key Findings

CODE ADOPTION:

Over the past decade, code of ethics adoption by biopharmaceutical industry associations has transitioned from minimal to near universal. Biopharmaceutical industry associations in the APEC region have shifted focus from code adoption to code implementation.

When the initiative began implementing the APEC Mexico City Principles in 2012, there were only 25 associations with a code or code commitment. In 2020, there are 56 associations with a code or code commitment, signaling a massive shift in the sector. The Initiative aims to achieve universal code of ethics adoption by every biopharmaceutical industry association in the APEC region by 2021.

CODE IMPLEMENTATION:

Code of ethics training decreased in 2020. As a result of the COVID-19 pandemic, associations report a decline in ethics training among members (a drop of nine percent since a new high in 2018).

Most associations are considering updates to their codes. 87 percent of associations are considering updating their codes of ethics in the next five years to account for new changes in technology.

MULTI-STAKEHOLDER AND NON-MEMBER ENGAGEMENT:

Interest in collaborating with diverse stakeholders to strengthen ethical business conduct has never been higher. Associations report record levels of interest in working with other organizations to promote ethical business conduct (87 percent). The highest external stakeholder category with which associations seek to collaborate on ethical business conduct is government (62 percent). Every association in the region indicated that governments play an important role in encouraging ethical business conduct.

The time has come to update the APEC Mexico City Principles. A majority of associations (55 percent) believe the APEC Principles should be updated in 2021 to account for changes in the sector and wider healthcare system. Key themes of interest include artificial intelligence, drug promotion, healthcare professional education, and international collaboration.

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

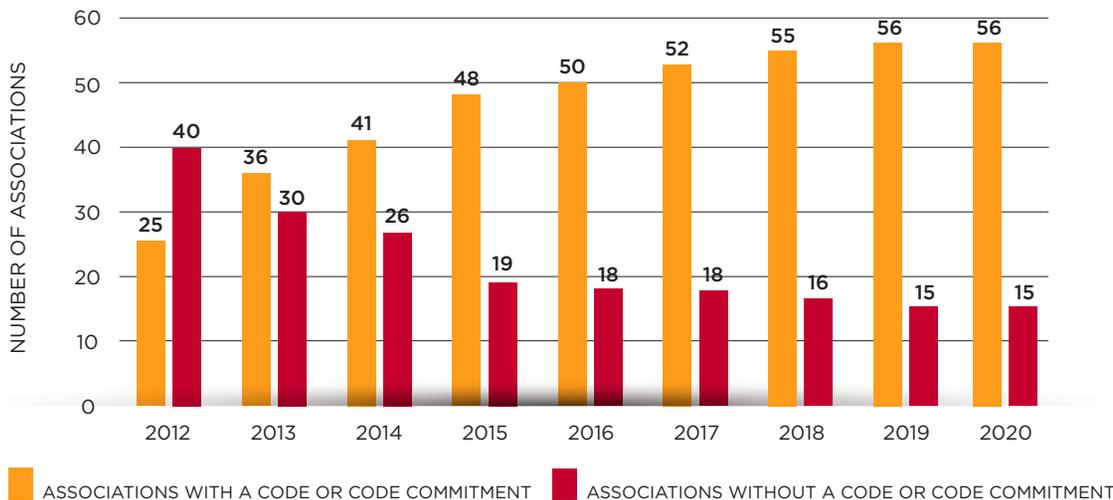
Since the *Business Ethics for APEC SMEs Initiative* began supporting industry code adoption in 2012, a large majority of associations have embraced the APEC Mexico City Principles. As of 2020, at least 56 biopharmaceutical industry associations in the APEC region have established a code or code commitment. These associations represent nearly 10,000 companies, of which more than 5,000 are SMEs.

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). Collectively, these represent nearly 600 SME member companies.

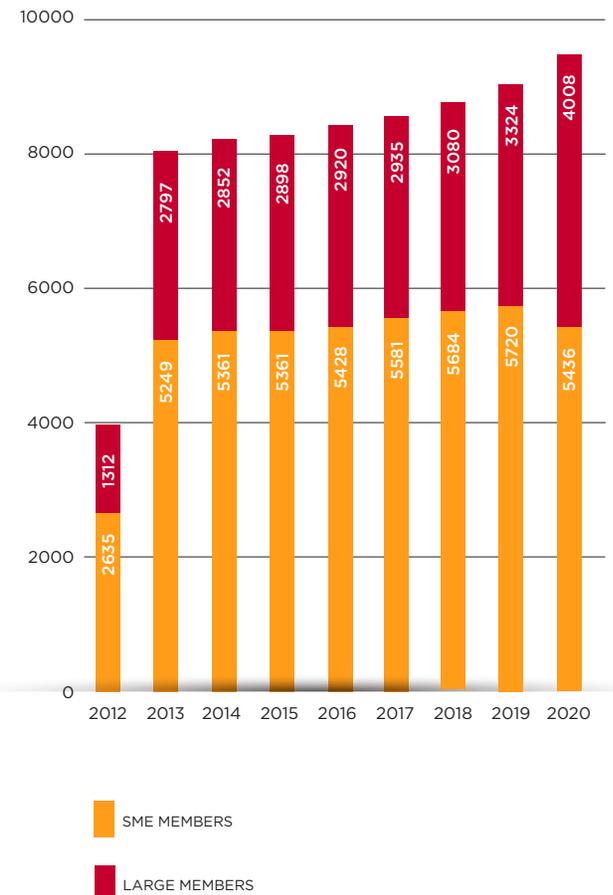
With significant uptake of codes of ethics among biopharmaceutical industry associations in the APEC region over the last decade, the initiative has shifted efforts from code adoption to code implementation. A strategy is in place to support the remaining associations with the opportunity to adopt a code of ethics.

As code adoption has expanded to the majority of biopharmaceutical industry associations in the APEC region, thousands of businesses, including SMEs, have been provided training and resources to adopt an enterprise-level code of ethics. Industry association adoption of codes of ethics translates to 9,444 enterprises – of which 5,436 are SMEs – being covered by a code.

CODE OF ETHICS ADOPTION BY BIOPHARMACEUTICAL INDUSTRY ASSOCIATIONS HAS TRANSITIONED FROM MINIMAL TO NEAR UNIVERSAL OVER THE PAST DECADE



MORE THAN 5000 SMEs COVERED BY A CODE OR CODE COMMITMENT IN APEC REGION



PART 2

Code of Ethics Implementation

KEY TAKEAWAYS: CODE GOVERNANCE

- **Code of ethics training decreased in 2020.** As a result of the COVID-19 pandemic, associations report a decline in ethics training among members (a drop of six percent from 2019).
- **Most associations are considering updates to their codes.** 87 percent of associations are considering updating their codes of ethics in the next five years to account for new changes in technology.

Once a code has been adopted, it is implemented in three areas: code governance, code alignment, and member adherence.

Code Governance - Once an industry association has adopted a code of ethics, ensuring sound code governance can safeguard the operating environment for all relevant code implementation activities. Since 2015, more than 70 percent of the industry associations responding to the survey have offered code of ethics training to members. More than half of associations offer a code complaint or violation procedure. This mechanism has been used by 44 percent of industry associations in the last two years. In light of the COVID-19 pandemic, associations report a best practice of assigning a focal point on ethics and integrity to any internal taskforce, committee, or coordinating body to ensure the issue is included as a core component of response activities.

Code Alignment - Many industry associations with a code or code commitment have chosen to incorporate the entire text of the APEC Mexico City Principles, while others have adapted certain provisions to align with local requirements. 82 percent indicated they are aligned with the APEC Mexico City Principles, while 16 percent indicate they adhere to some of the Principles. Updates to the Code of Practice by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) may account for why 85 percent of survey respondents ban gift giving to healthcare professionals in their code or code



commitment. While there are fewer industry associations (a decrease of 12 percent from 2019) planning on amendments to their code of ethics within the next year, 40 percent of associations are planning to make amendments. 87 percent of biopharmaceutical industry associations are considering updating their codes of ethics in the next five years to account for new changes in technology.

Only 15 percent of industry associations face challenges aligning to the APEC Mexico City Principles. These challenges include misalignment among member companies on certain best practices advised by the APEC Principles and with external stakeholders such as healthcare professionals (HCPs) and government stakeholders.

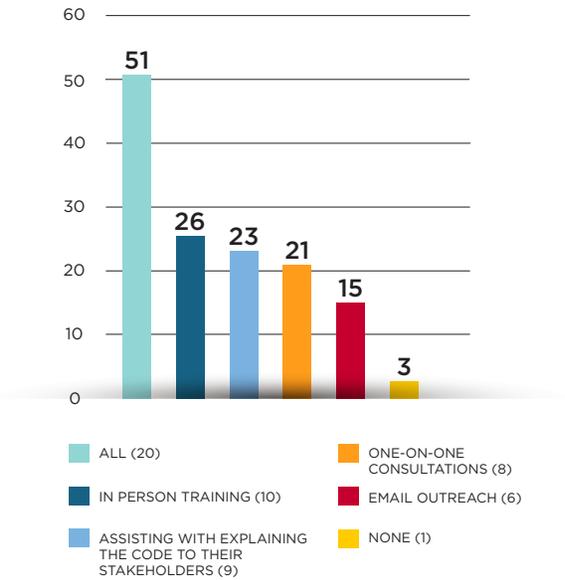
**KEY TAKEAWAYS:
MEMBER ADHERENCE**

- **Member adherence to association codes of ethics has slightly increased in 2020.** The Initiative has set a goal of full membership adherence to associations’ codes of ethics by 2025. This year, 44 associations report member implementation of a code or code commitment, up from 41 last year.
- **A combination of activities is essential to help drive member adherence.** The majority of associations engage in a mix of activities to boost member adherence. The most effective activity is in-person training.
- **Tone from the top is considered a meaningful intervention.** All industry associations that count SMEs as a majority of their membership are interested in hosting an APEC Leaders in Ethics and Integrity Program (LEIP).

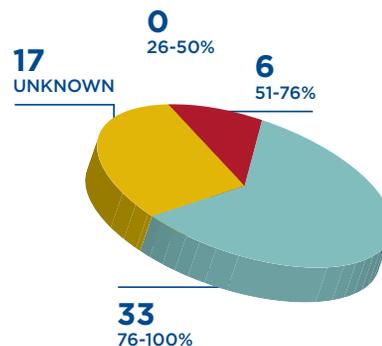
Member Adherence - There are diverse strategies to bolster member adherence among bio-pharmaceutical industry associations in the APEC region. COVID-19 has placed an additional urgency on the importance of building ethics and integrity capacity within member companies, particularly among SME members.

The most effective association activities to reach members include in-person training, targeted communications and outreach about the code with stakeholders, one-on-one consultations, and email outreach. Of the survey respondents, 72 percent reported that member companies are convened by the association on a routine basis (at least twice a year), providing an opportunity for code training. Reinforcing “tone at the top” and convening leadership is of interest to associations as a strategy to implement the code.

MOST EFFECTIVE ASSOCIATION ACTIVITIES



REPORTED MEMBER IMPLEMENTATION BY THE 56 ASSOCIATIONS WITH A CODE/COMMITMENT



CREATE A CULTURE OF ETHICS AND INTEGRITY BY ESTABLISHING THE “TONE AT THE TOP.”



All industry associations that count SMEs as a majority of their membership are interested in hosting an APEC Leaders in Ethics and Integrity Program (LEIP)



82 percent of industry associations interact with the CEOs of member companies on a yearly basis, providing an opportunity to reinforce ethics and integrity “tone at the top.”

Insights on COVID-19

Recommendations from biopharmaceutical associations in the APEC region from the May 2020 *Special Webinar Session: COVID-19 & Business Ethics for APEC SMEs Initiative* include:

- **Integrate ethics and integrity into communications with member companies, the media, and relevant stakeholders.** This may include the assignment of a focal point on ethics and integrity into internal taskforces, committees, or coordinating mechanisms on COVID-19 to ensure the issue is included as a core component of response activities. Associations may also consider establishing an ethics committee comprised of member companies to deliberate on ethics issues and oversee the code.
- **Avoid short-term changes to codes and best practices.** While agility is essential to respond to a crisis, ethics and integrity standards should not be lowered during or after COVID-19.
- **APEC Mexico City Principles remain foundational.** Associations should continue to convey the importance of a values-based approach, enshrined in the APEC Mexico City Principles, and not revert to operationalized compliance, such as do and do not lists.
- **Lean into collective action and multi-stakeholder engagement.** Associations should leverage collective action and multi-stakeholder collaboration to reinforce ethics and integrity wherever possible, such as through consensus frameworks. These platforms should consider virtual tools, including capacity-building resources, in order to succeed.
- **Expand capacity-building.** Associations can play an important role in virtual capacity-building. Association platforms can be used to share effective virtual training strategies among member companies, particularly SMEs.

Opportunities and challenges for industry associations in 2020

Industry associations are experiencing unexpected opportunities and challenges amidst COVID-19. Some industry associations see the pandemic as a unique opportunity to promote business integrity while others believe the pandemic has made such efforts even more difficult. This variance is best understood through conditions on the ground as well as the existing structure put into place by the association to support its code of ethics. In general, associations that view the pandemic as an opportunity had a code of ethics in place for a longer period of time than those who view the pandemic as a challenge to these efforts.

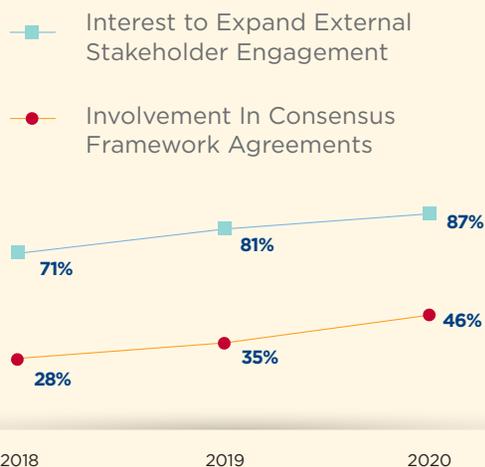
OPPORTUNITIES	CHALLENGES
<ul style="list-style-type: none">• Promoting business integrity• Promoting code of ethics awareness• Establishing consensus frameworks• Strengthening relationships between industry and healthcare professionals• Expanding membership• Supporting current members amidst COVID-19• Collaborating with other biopharmaceutical associations• Expand public-private partnership to promote ethics• Expanding use of code by non-members• Developing guidelines for virtual engagement• Disclosure / transfer of value• Increasing collaboration among industry, government, and academic institutions• Engaging patient group	<ul style="list-style-type: none">• Reinforcing ethics and integrity amidst COVID-19• Maintaining ongoing projects amidst COVID-19• Changing activities and behaviors due to COVID-19• Monitoring information provision to medical professionals• Managing continuity of medicine supply

PART 3

Multi-Stakeholder and Non-Member Engagement

As associations continue to prioritize external stakeholder engagement on business ethics and integrity, the below insights provide an expanded perspective on ethical collaboration with government, guidance for third parties and patient groups, and engagement with healthcare professionals (HCPs).

EXTERNAL STAKEHOLDER ENGAGEMENT



Multi-stakeholder collaboration is understood by biopharmaceutical industry associations in the APEC region as an essential element to achieving an ethical business environment and healthcare system. As a strategic recommendation from the May 2020 *Special Webinar Session: COVID-19 & Business Ethics for APEC SMEs Initiative*, industry association leaders should lean into collective action and multi-stakeholder collaboration to reinforce integrity whenever possible, including as consensus frameworks. Consensus frameworks agreements for ethical collaboration are emerging as a significant mechanism in the APEC region for biopharmaceutical industry associations to collaborate with external stakeholders on code of ethics implementation. 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 71 biopharmaceutical associations, **46 percent** are already

party to a consensus framework agreement. And those associations not currently part of a framework who are interested in joining one are located in Hong Kong, China; Indonesia; Korea; Malaysia; Mexico; New Zealand; Chinese Taipei; Thailand; and the United States.

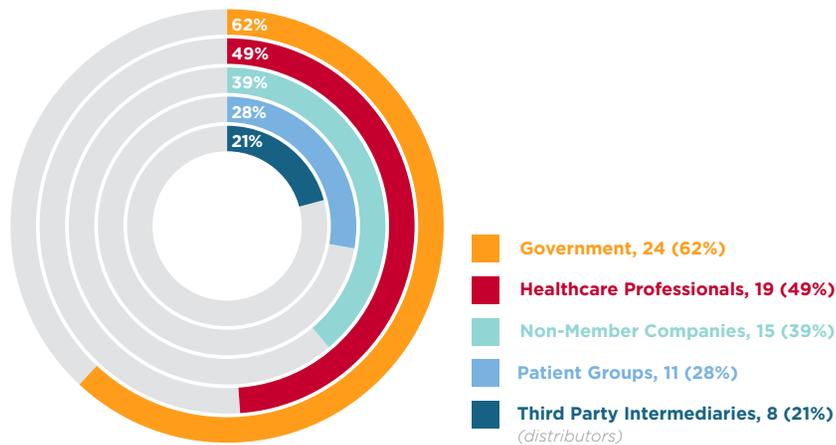
When analyzing industry interactions between specific stakeholder groups to promote integrity and codes of ethics, the highest percentage of engagement is with government and has remained so since this initiative started tracking this figure in 2018. Notably, comparing insights from 2018-2020, the activity of government involvement in the development and implementation of consensus frameworks has continued to increase. Box 2 provides further information on the initiative's Guide for Government Strategies to Encourage Ethical Business Conduct (the Guide).

The second highest level of engagement for industry is with healthcare professional interactions, with **49 percent** (a decrease of ten percent compared to 2019).

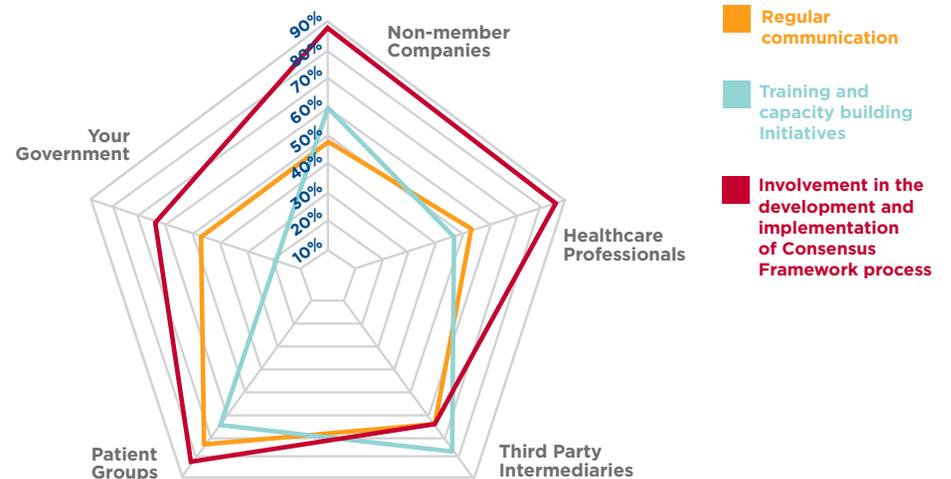
KEY TAKEAWAYS: MULTI-STAKEHOLDER AND NON-MEMBER ENGAGEMENT

- **Associations are keen to expand external stakeholder engagement.** This trend has increased by 16 percent since 2018.
- **Nearly half of associations are part of a consensus framework agreement.** This trend has nearly doubled since 2018. There are a number of additional associations in discussions to develop a consensus framework, which would encompass a clear majority of associations.
- **Industry associations now view government engagement as significant.** All associations indicate that governments play an important role in encouraging an environment of ethical business conduct. **Government remains the most engaged stakeholder for associations on ethical business conduct (62 percent).** This is followed by coordination with healthcare professionals, non-member companies, patient organizations, and third party intermediaries, including distributors. While **23 percent** of associations report they have introduced the Resource Guide for Government Strategies to Encourage Ethical Business Conduct to their governments, **87 percent** of associations view their government as still needing to implement programs and policies to encourage ethical business conduct.
- **Partnerships with Healthcare Professionals.** 72 percent indicate interest in partnerships with healthcare professionals to implement medical school coursework and training on the code. In addition, **59 percent** of associations indicate that healthcare professionals have aligned to the Mexico City Principles within their economies.

COORDINATION WITH NON-MEMBER STAKEHOLDERS ON ETHICAL PRACTICES AND/OR CODE OF ETHICS



IF THERE IS COORDINATION, ACTIVITIES INCLUDE:



PART 3 continued

GOVERNMENT STRATEGIES TO ENCOURAGE ETHICAL BUSINESS CONDUCT

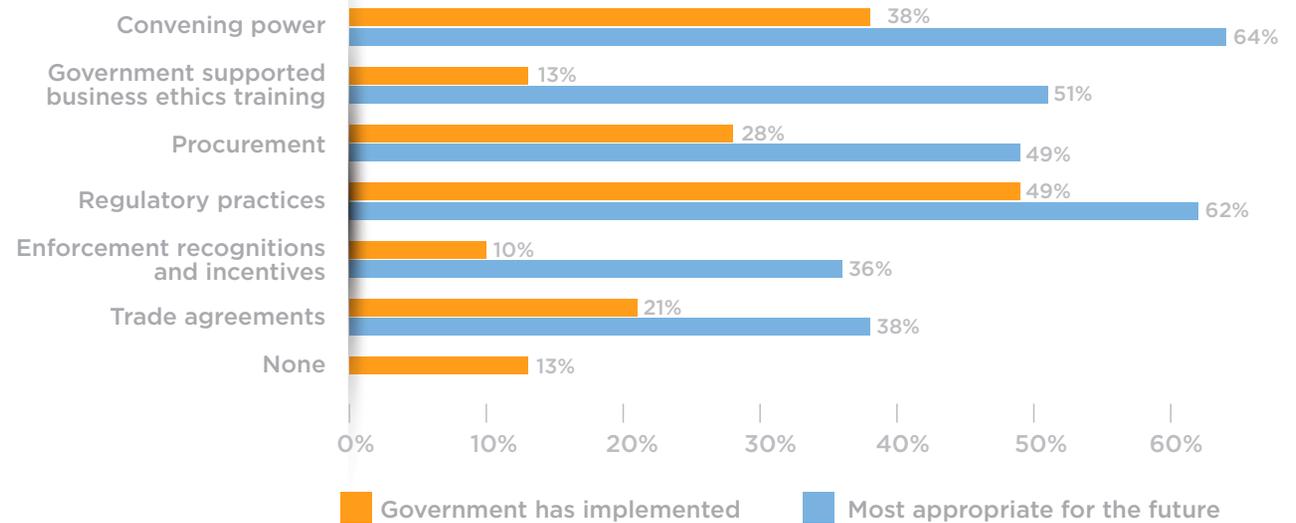
All associations with a code of ethics or a code commitment that responded to this survey believe that governments play an important role in encouraging an environment of ethical business conduct. **23 percent of these** associations have introduced the APEC Resource Guide of Government Strategies to Encourage Ethical Business Conduct to their governments. The guide outlines govern-

ment best practices and case studies to encourage ethical business conduct through six strategies: (1) Convening Power; (2) Procurement; (3) Regulatory Practices; (4) Enforcement Recognitions and Incentives; (5) Government Supported Business Ethics Training; and (6) Trade Agreements. Regulatory practices are reported to be the strategy with the highest current implementation (49 per-

cent), while the lowest is enforcement recognitions and incentives (10 percent). Looking to the future, associations are most interested in governments taking on an expanded role in convening power, regulatory practices, and government supported business ethics training.



87% of APEC biopharmaceutical associations believe governments should implement strategies to encourage ethical business conduct

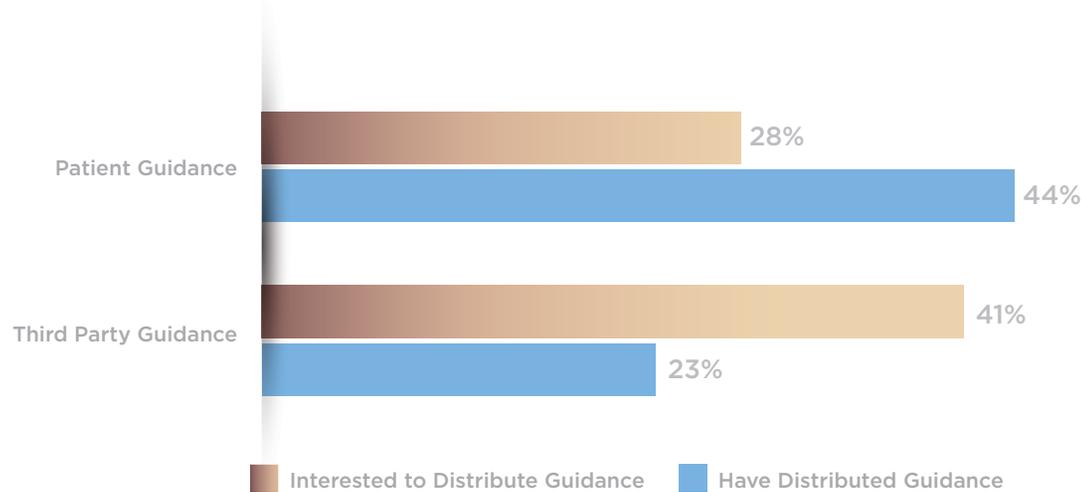


PART 3 continued

INDUSTRY GUIDANCE FOR ETHICAL THIRD PARTY INTERMEDIARY RELATIONSHIPS AND ETHICAL INTERACTIONS WITH PATIENTS AND PATIENTS ORGANIZATIONS

The Business Ethics for APEC SMEs Initiative calls for the development of guidance on ethical third party intermediary relationships in the biopharmaceutical sector and guidance on industry interaction with patients and patient organizations. 44 percent of associations have already implemented patient guidance, with another 28 percent interested in doing so. Only 23 percent of associations have implemented third party guidance, but 41 percent are interested in doing so. Lower interest in issuing patient group guidance may be a result of the recently released IFPMA Note for Guidance on Patient and Patient Organization Interactions. Many association codes of ethics already include expectations for third party relationships, which may explain the lower reported rate of third party guidance.

PERCENTAGE OF INDUSTRY ASSOCIATIONS INTERESTED TO CIRCULATE NEW GUIDANCE



HCP ENGAGEMENT

59%

of APEC biopharmaceutical associations report healthcare professionals in their economies are aligned with the APEC Mexico City Principles

72%

of APEC biopharmaceutical associations are interested in partnering with healthcare professionals to implement medical school coursework and code of ethics training

PART 4

Code of Ethics Compendium of APEC Biopharmaceutical Industry Associations

Association	Economy	Member Enterprises		Code Adoption Commitment*		Code		Member Implementation	Participation in Consensus Framework Agreement
		TOTAL	SMEs	Yes/No	Year Adopt	Last Update			
Medicines Australia ▲	Australia	31	1	Yes	1960	2019	76-100%	Yes	
GBMA ▲	Australia	7	4	Yes	2010	2015	76-100%	No	
IMC ▲	Canada	29	20	Yes	1988	2019	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	2006	2019	76-100%	Yes	
Cámara Nacional de Laboratorios ▲	Chile	13	13	Yes	1999	2019	76-100%	Yes	
PROLMED ▲	Chile	3	0	Yes	2018	2020	76-100%	Yes	
CPIA ▲	China	500	135	Yes*	2013*	2018*	51-75%	Yes	
CCCMHPIE ▲	China	1700	1530	Yes*	2013*	2019*	76-100%	Yes	
PhIRDA ▲	China	93	14	Yes	2018	2018	76-100%	Yes	
RDPAC-CAEFI ▲	China	42	0	Yes	1999	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	

▲ UPDATED WITH 2020 SURVEY RESULTS

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	24	24	Yes	2001	2019	76-100%	No	
JPMA ▲	Japan	72	5	Yes	1976	2019	76-100%	Yes	
JGA ▲	Japan	40	24	Yes	2010	2019	76-100%	Yes	
KRPIA ▲	Korea	45	33	Yes	2009	2017	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	47	15	Yes	2013	2016	Unknown	No	
PhAMA	Malaysia	46	0	Yes	1978	2019	76-100%	No	
CANIFARMA ▲	Mexico	98	20	Yes	2005	2013	76-100%	No	
CETIFARMA ▲	Mexico	102	75	Yes	2005	2020	76-100%	Yes	
AMIIF ▲	Mexico	40	10	Yes	2007	2013	76-100%	No	
ANAFAM ▲	Mexico	6	0	Yes	2005	2013	51-75%	No	
ANADIM	Mexico	No Data	No Data	No	N/A	N/A	No Data	No	
Medicines New Zealand ▲	New Zealand	27	8	Yes	1962	2019	76-100%	No	
ADIFAN	Peru	13	13	Yes	2014	N/A	76-100%	Yes	
ALAFARPE ▲	Peru	21	2	Yes	2016	2019	76-100%	Yes	
ALAFAL	Peru	10	5	Yes	2016	N/A	76-100%	Yes	
PCPI ▲	Philippines	100	50	Yes	2014	2014	51-75%	No	
PHAP ▲	Philippines	35	8	Yes	2000	2019	76-100%	Yes	

▲ UPDATED WITH 2020 SURVEY RESULTS

Association	Economy	Member Enterprises		Code Adoption Commitment*		Code		Member Implementation	Participation in Consensus Framework Agreement
		TOTAL	SMEs	Yes/No	Year Adopt	Last Update			
MEPI	Philippines	46	0	Yes	2015	N/A	No Data	No	
AIPM	▲ Russia	61	0	Yes	1998	2019	76-100%	No	
ARPM	Russia	20	0	No	N/A	N/A	N/A	No	
SAPI	▲ Singapore	40	0	Yes	<2010	2020	76-100%	No	
SMF-LSIG	Singapore	48	30	No	N/A	N/A	N/A	No	
IRPMA	▲ Chinese Taipei	44	0	Yes	2003	2019	76-100%	No	
TRPMA	▲ Chinese Taipei	26	26	Yes	2020	2020	N/A	No	
TPMA	Chinese Taipei	210	160	No	N/A	N/A	N/A	No	
TGPA	▲ Chinese Taipei	68	41	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	33	12	Yes	1986	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	34	0	Yes	2002	2019	76-100%	No	
AAM	United States	24	No Data	Yes	2018	2018	Unknown	No	
VNPCA	▲ Viet Nam	180	130	Yes	2014	2017	51-75%	Yes	
Pharma Group	▲ Viet Nam	22	0	Yes	2014	2019	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	

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