

2018 Report on

Code of Ethics Implementation

by APEC Medical Device Industry Associations



Asia-Pacific
Economic Cooperation

Business Ethics for APEC SMEs
Medical Device Sector

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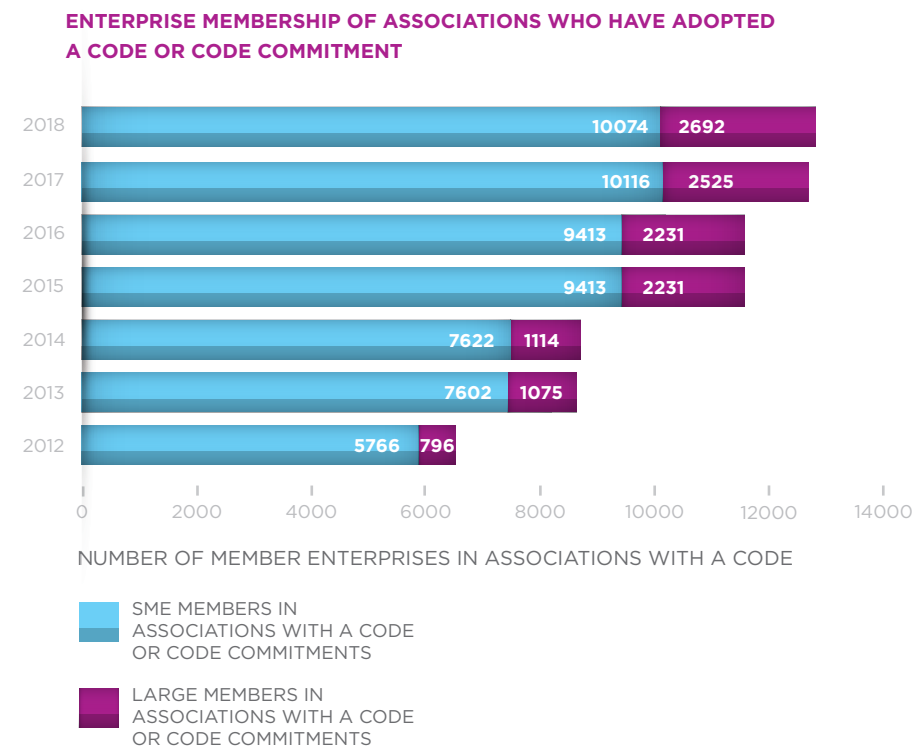
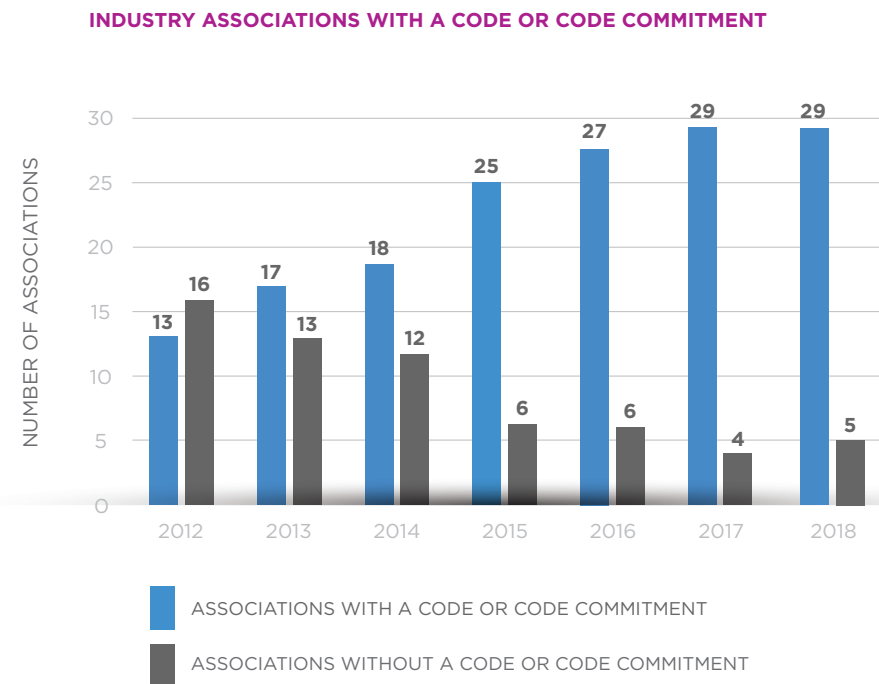
Introduction

The *Business Ethics for APEC SMEs Initiative* monitors code of ethics development and implementation by 34 medical device sector industry associations across the APEC region. These enterprises constitute a significant majority of the firms that develop, manufacture, market, or distribute medical device and diagnostic products in the region.

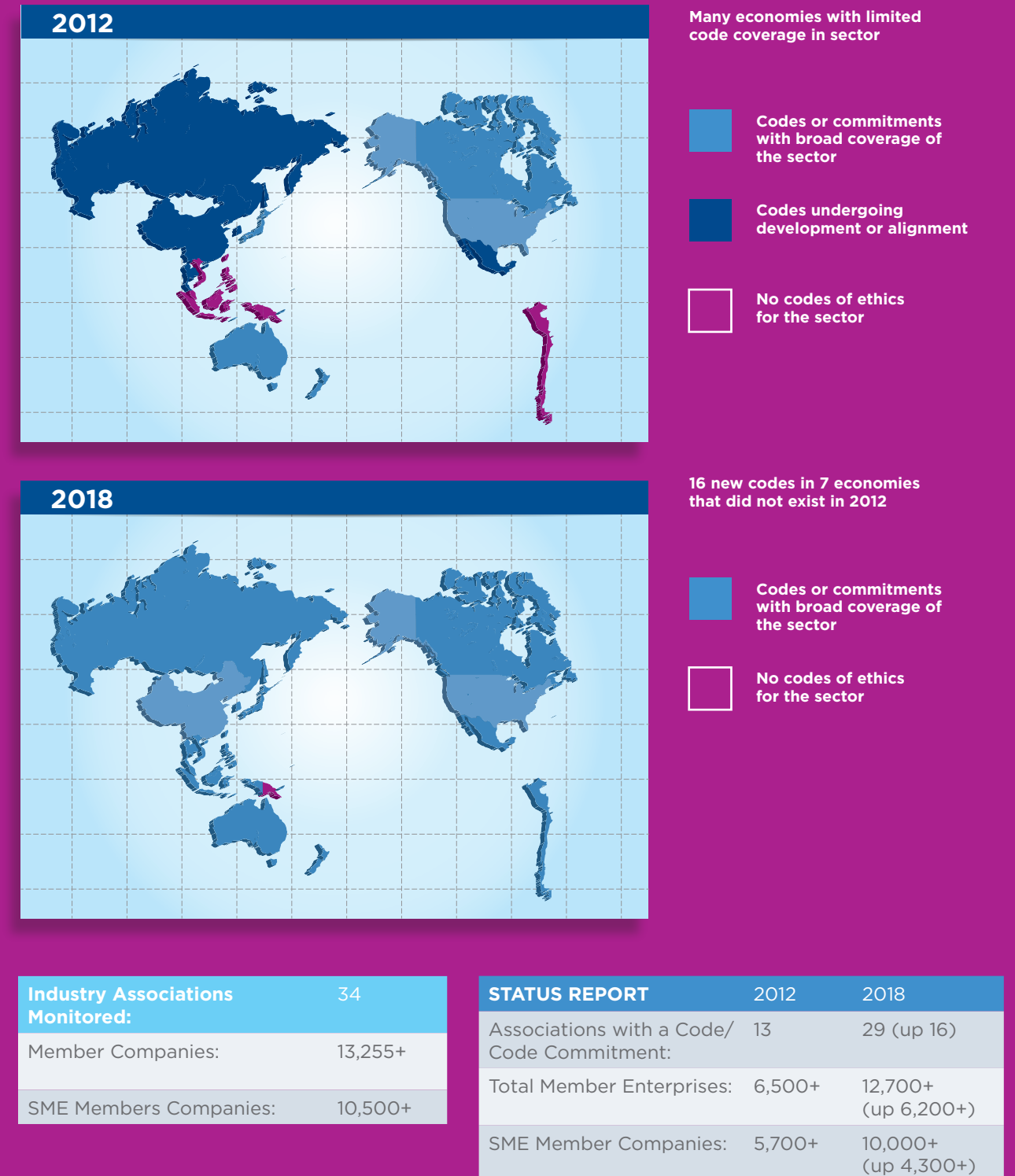
When this initiative's capacity-building program was launched in 2012 to support implementation of the APEC Kuala Lumpur Principles, 13 of these monitored medical device sector industry associations had a code of ethics. In 2018, 29 of these associations have a code of ethics or formalized commitment. The initiative remains dedicated to realizing all medical device sector industry associations that have adopted a code also achieve implementation of the code's provisions by a majority of their member enterprises. The initiative continues

to pursue universal code of ethics adoption by medical device sector industry associations by 2020 with the remaining five associations without a code or code commitment located in Chile, China, Mexico, Singapore, and Chinese Taipei.

This report has been prepared for the 2018 APEC Business Ethics for SMEs Forum, to indicate where progress has been made since 2012, and where challenges remain, for the region's medical device sector industry associations in (A) code governance, (B) code alignment with the APEC Principles, (C) member enterprise implementation of the code, and (D) external stakeholder engagement on the code, a new monitoring area. The data provided in this report has been provided from the associations and other publicly available sources.

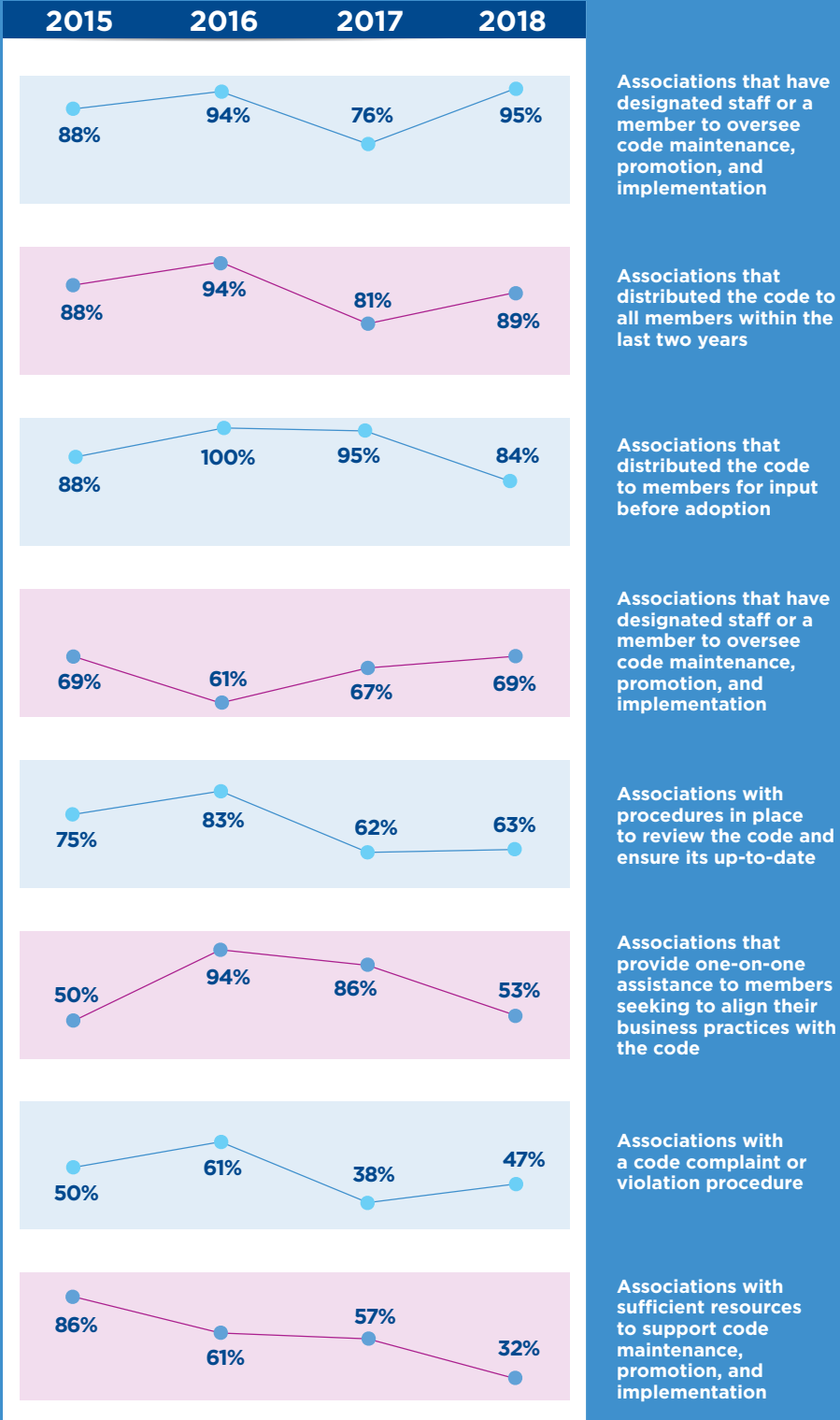


Regional Overview



Code Governance

Medical device sector industry association codes of ethics are strong tools to disseminate and harmonize ethical business practices among many enterprises. However, they only serve as effective tools if robust code governance is in place. The initiative monitors several crucial areas to identify whether such governance exists. Responses from those industry associations completing the 2018 survey (19 of the 29 with codes or commitments) indicate that most continue to have a valid governance structure in place. 2018 data highlights a notable increase in associations with a staff member to oversee the code, and associations with a code complaint or violation procedure. Areas of challenge include a continued decline in resources and one-on-one assistance to members seeking to align their business practices with the code.

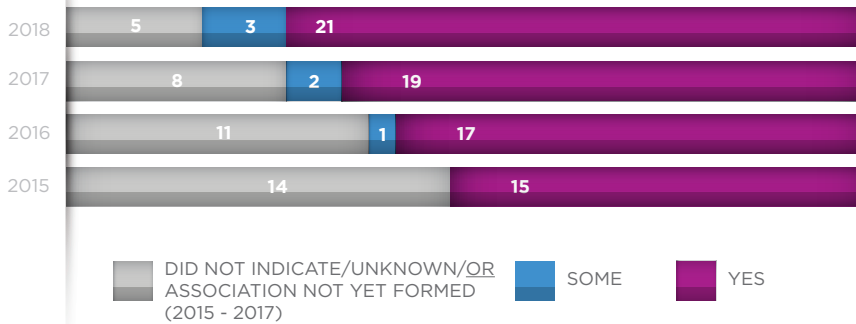


Alignment with the APEC Kuala Lumpur Principles

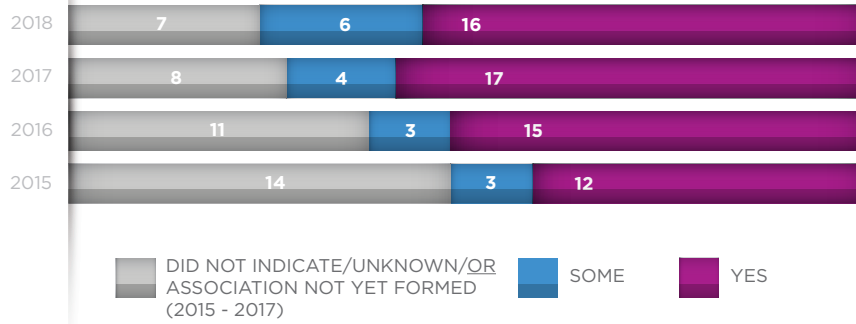
The *Business Ethics for APEC SMEs Initiative* has conducted seven medical device sector capacity-building programs since 2012 and has extended support for dozens of local trainings to ensure that new and existing medical device industry association codes of ethics achieve alignment with the APEC Kuala Lumpur Principles and the APEC model industry association code. Among adopted codes or code commitments,

many industry associations chose to incorporate the entire text of the APEC Principles while others adapted certain provisions to align with local requirements. Among the associations with a code of ethics, at least **73%** report their code embraces all five fundamental principles of the APEC Kuala Lumpur Principles and at least **55%** report their code is intently aligned with all the provisions of the Principles.

REPORTED EMBRACE OF THE FIVE FUNDAMENTAL PRINCIPLES OF THE APEC KUALA LUMPUR PRINCIPLES BY THE 29 ASSOCIATIONS WITH A CODE OR CODE COMMITMENT:



REPORTED ALIGNMENT WITH THE PROVISIONS OF THE APEC KUALA LUMPUR PRINCIPLES BY THE 29 ASSOCIATIONS WITH A CODE OR CODE COMMITMENT:

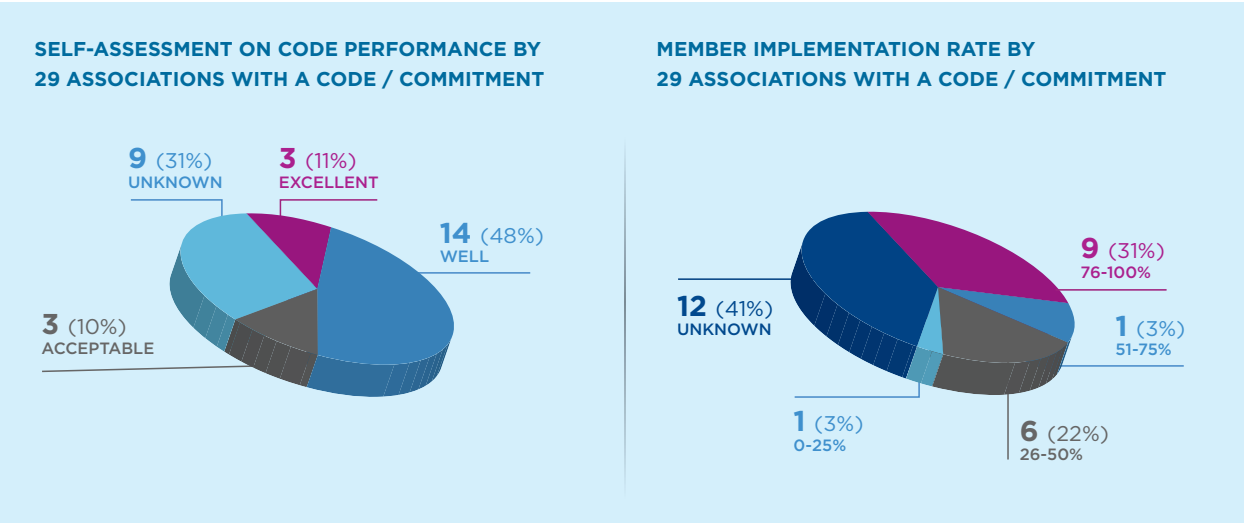


Member Implementation

Assessing member enterprise implementation of a medical device sector industry association’s code of ethics remains the most difficult component of the initiative’s monitoring activities. To-date, data is dependent on estimates provided by each association. Among the associations responding to the 2018 survey (19 of the 29 associations with codes or code commitments), **59%** report their code has performed “excellent” or “well” over the past year.



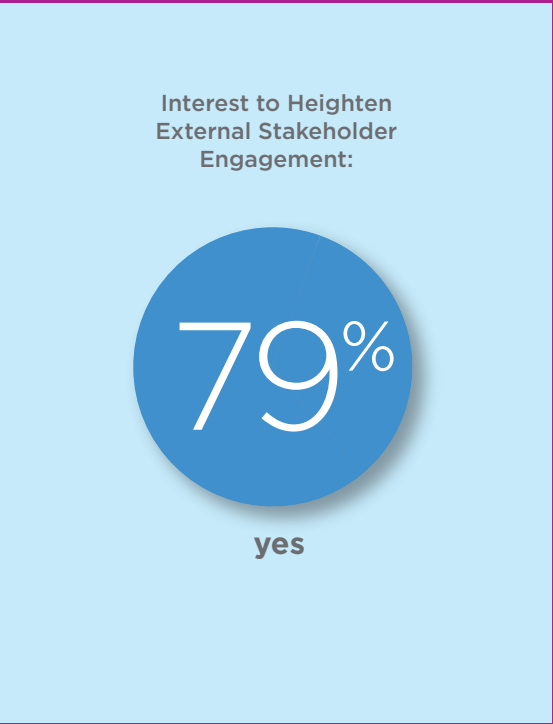
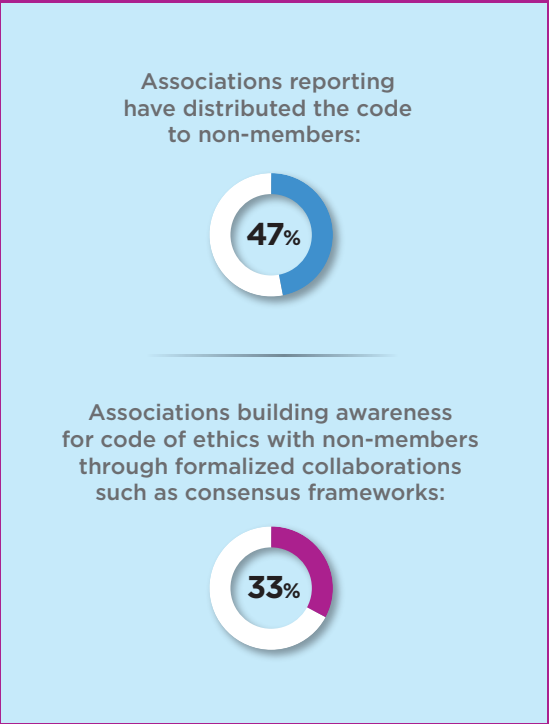
Association Monitoring	
Associations who maintain an active list of members who have certified compliance with the code of ethics:	28%
Associations who receive notification when members conduct external validation or audits to measure compliance with the code:	0%



External Engagement

How medical device industry associations engage with external stakeholders (non-members) on their codes of ethics has emerged as fourth area of assessment in code implementation. While important for association members to adhere and implement their code, many encounter a “non-member dilemma” of how to operate in the same market with those who do not subscribe to the code of ethics. This data highlights associations who engage with external stakeholders such as

non-member companies, healthcare professionals, third party intermediaries, patient groups, governments, and other stakeholders. Among the associations responding to the 2018 survey (19 of the 29 associations with codes or code commitments), 47% report they have distributed their code to non-member stakeholders. 79% of associations report they are interested to heighten external stakeholder engagement on their code of ethics.



Association	Economy	Member Enterprises		Code Adoption <i>Code Commitment*</i>			Member Implementation	Participation in APEC Business Ethics Forum				
		TOTAL	SMEs	Yes/ No	Year Adopt	Last Update		2014	2015	2016	2017	2018
ADIA	Australia	205	197	Yes	1974	2017	76-100%	No	No	No	No	No
MTAA	Australia	74	35	Yes	2001	2015	76-100%	Yes	Yes	Yes	Yes	Yes
IDV Australia	Australia	37	No Data	Yes	2010	2013	No Data	No	No	No	No	No
MEDEC	Canada	78	21	Yes	2005	2017	26-50%	Yes	Yes	No	Yes	No
ADIMECH	Chile	No Data	No Data	No	N/A	N/A	No Data	No	No	No	No	No
APIS	Chile	30	No Data	Yes	2018	2018	No Data	No	No	No	No	Yes
SCDM	Chile	27	16	Yes	2013	2018	No Data	Yes	Yes	Yes	Yes	Yes
AdvaMed China	China	40	0	Yes	2016	2017	No Data	Yes	Yes	No	Yes	Yes
CAMDI	China	2,148	1,230	Yes	2015	2016	26-50%	Yes	Yes	Yes	Yes	Yes
CAME	China	No Data	No Data	No	N/A	N/A	No Data	No	No	No	No	No
CCCMHPIE	China	1,840	1,688	Yes	2013	2017	76-100%	Yes	Yes	Yes	Yes	Yes
HKMH DIA	Hong Kong, China	178	150	Yes	2009	N/A	0-25%	No	No	No	No	No
TAMTA	Chinese Taipei	22	0	Yes	2015	2015	76-100%	No	Yes	No	Yes	Yes
TMBIA	Chinese Taipei	378	350	No	N/A	N/A	N/A	No	No	No	No	No
Gakeslab	Indonesia	452	388	Yes	2013	2016	26-50%	Yes	Yes	No	Yes	No
AMDD	Japan	63	<10	Yes	2016	N/A	No Data	No	No	No	No	Yes
JFMDA	Japan	4280	4000	Yes	1993	2017	76-100%	Yes	Yes	Yes	Yes	Yes
KMDIA	Korea	825	788	Yes	2011	2017	No Data	Yes	Yes	Yes	No	Yes
AMMI	Malaysia	67	21	Yes	2013	2017	No Data	No	No	No	No	No
MMDA	Malaysia	176	100	Yes	2013	N/A	26-50%	No	No	No	No	No
AMID	Mexico	32	0	Yes	2013	2017	76-100%	Yes	Yes	Yes	Yes	Yes
ASEMED	Mexico	No Data	No Data	No	No Data	No Data	No Data	No	No	No	No	No

Association	Economy	Member Enterprises		Code Adoption <i>Code Commitment*</i>			Member Implementation	Participation in APEC Business Ethics Forum				
		TOTAL	SMEs	Yes/ No	Year Adopt	Last Update		2014	2015	2016	2017	2018
APACMed	Multi	92	20	Yes	2016	2018	76-100%	N/A	Yes	No	Yes	Yes
MTANZ	New Zealand	105	52	Yes	2005	2016	26-50%	Yes	No	Yes	Yes	Yes
COMSALUD-CCL	Peru	188	138	Yes	2012	N/A	26-50%	Yes	Yes	Yes	Yes	No
MEPI	Philippines	88	45	Yes	2015	N/A	N/A	No	No	No	No	No
PAMDRAP	Philippines	117	57	Yes	2015	2017	No Data	Yes	Yes	Yes	Yes	Yes
IMEDA	Russia	48	0	Yes	2008	2013	Unknown	Yes	No	No	No	No
AMD I	Singapore	111	81	No	N/A	N/A	N/A	No	No	No	No	No
SMF-MTIG	Singapore	94	48	Yes	2014	2017	0-25%	Yes	Yes	No	No	No
THAIMED	Thailand	110	110	Yes	2008	2013	76-100%	Yes	No	No	No	No
AdvaMed	United States	330	220	Yes	1992	2009	76-100%	Yes	Yes	Yes	Yes	Yes
MDDSC	Viet Nam	20	0	Yes	2017	N/A	No Data	No	No	No	Yes	No
VIMEDAS	Viet Nam	1,000	750	Yes	2015	2016	No Data	No	No	No	Yes	No



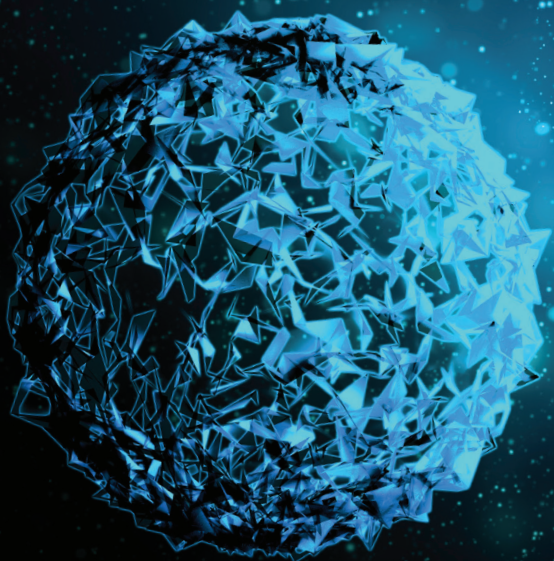
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Industry Associations



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Introduction

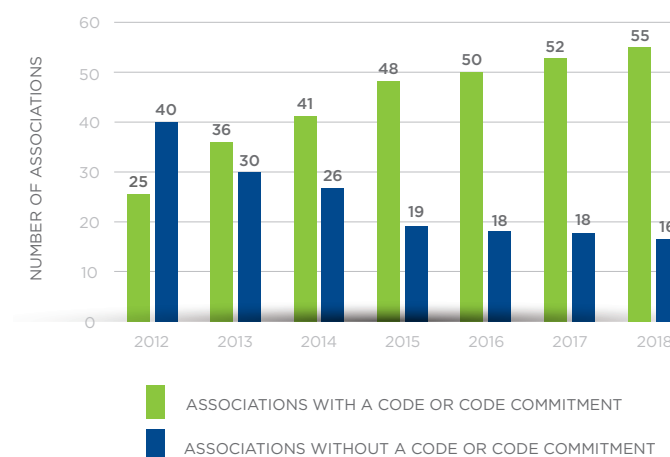
The *Business Ethics for APEC SMEs Initiative* monitors code of ethics development and implementation by 71 biopharmaceutical sector industry associations across the APEC region. These associations collectively represent nearly 10,000 member enterprises, of which over 6,000 are identified as SMEs. These enterprises constitute a significant majority of the firms that develop, manufacture, market, or distribute pharmaceutical and/or biological products in the region.

When this initiative's capacity building program was launched in 2012 to support implementation of the APEC Mexico City Principles, 25 of these monitored biopharmaceutical sector industry associations had a code of ethics. In 2018, 55 of these associations have a code of ethics or formalized commitment. The initiative remains dedicated to realizing all biopharmaceutical sector industry associations that have adopted a code also achieve implementation of the code's

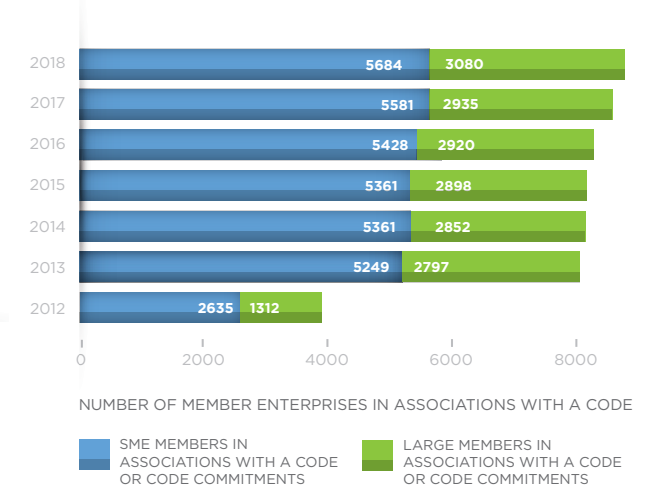
provisions by a majority of their member enterprises. The initiative also continues to pursue universal code of ethics adoption by APEC biopharmaceutical sector industry associations by 2020. The remaining 16 biopharmaceutical associations without a code or commitment are located in Chile; Hong Kong, China; Korea; Mexico; Singapore; Russia; and Chinese Taipei.

This report has been prepared for the 2018 APEC Business Ethics for SMEs Forum to indicate where progress has been made since 2012, and where challenges remain, for the region's biopharmaceutical sector industry associations in (A) code governance, (B) code alignment with the APEC Principles, (C) member enterprise implementation of the code, and (D) external stakeholder engagement on the code, a new monitoring area. The data provided in this report has been provided from the associations and other publicly available sources.

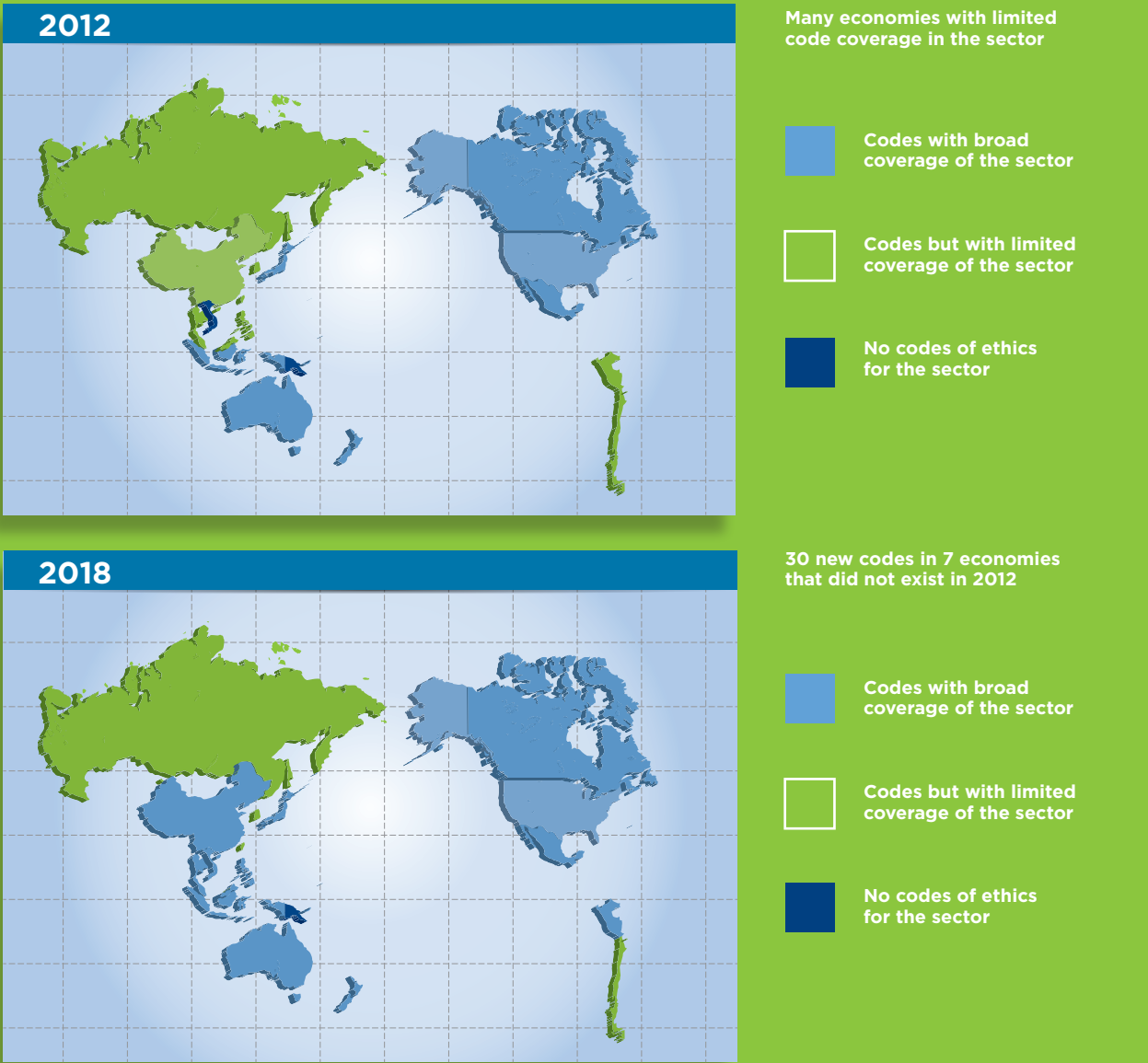
INDUSTRY ASSOCIATIONS WITH A CODE OR CODE COMMITMENT



ENTERPRISE MEMBERSHIP OF ASSOCIATIONS WHO HAVE ADOPTED A CODE OR CODE COMMITMENTS



Regional Overview

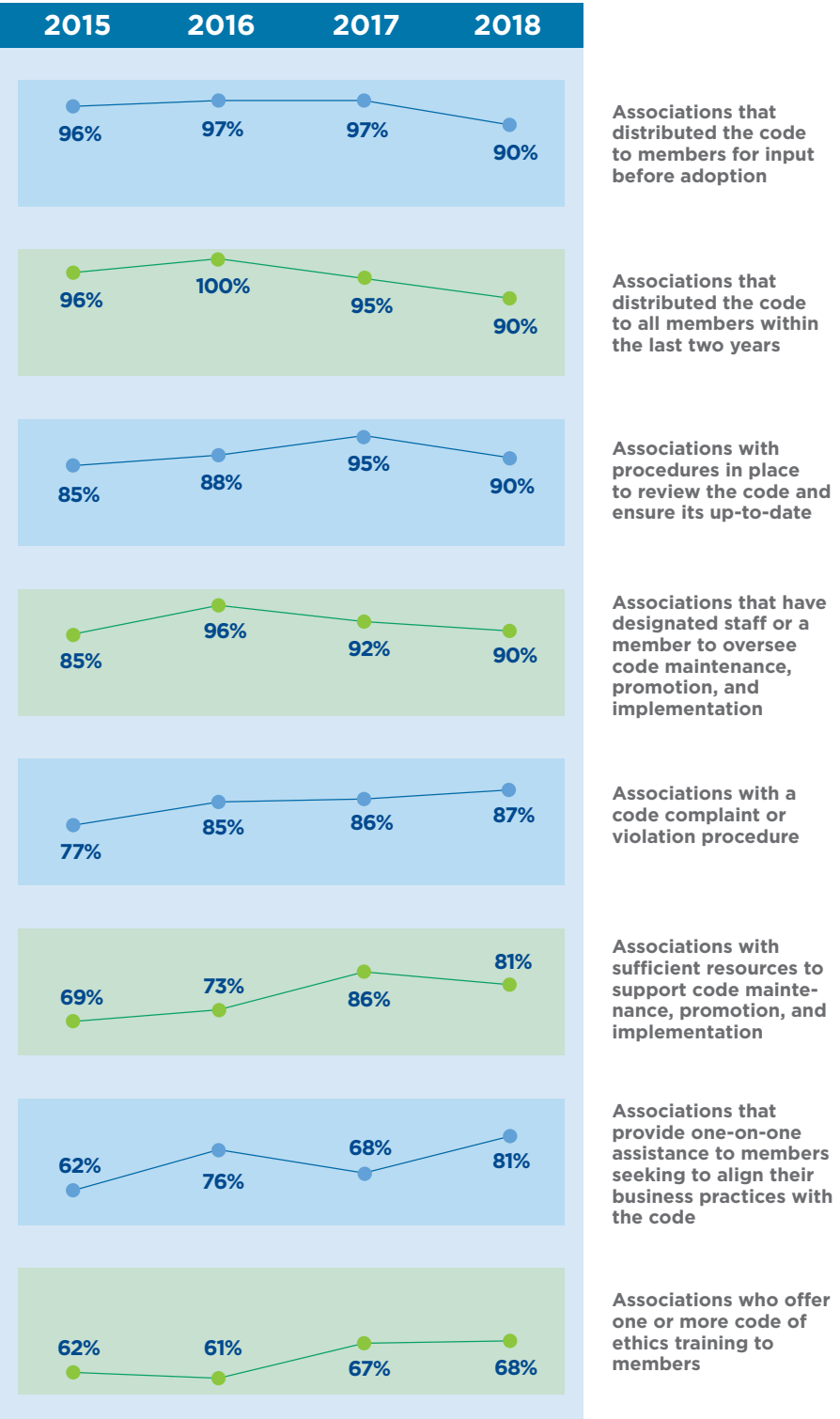


Industry Associations Monitored:	71
Total Member Enterprises:	9,740+
SME Members:	6,390+

STATUS REPORT	2012	2018
Associations with a Code/Code Commitment:	25	55 (up 30)
Total Member Enterprises:	3,900+	8,760+ (up 4,860)
SME Members:	2,600+	5,680+ (up 3,080)

Code Governance

Biopharmaceutical sector industry association codes of ethics are strong tools to disseminate and harmonize ethical business practices among many enterprises. However, they only serve as effective tools if robust code governance is in place. The initiative monitors several crucial areas to identify whether such governance exists. Most key governance areas assessed in 2018 saw a similar response as 2017, with a 13% increase in associations that provide one-on-one assistance to members seeking to align their business practices with the code. There remains an opportunity for associations to expand regular code trainings, which remain low.

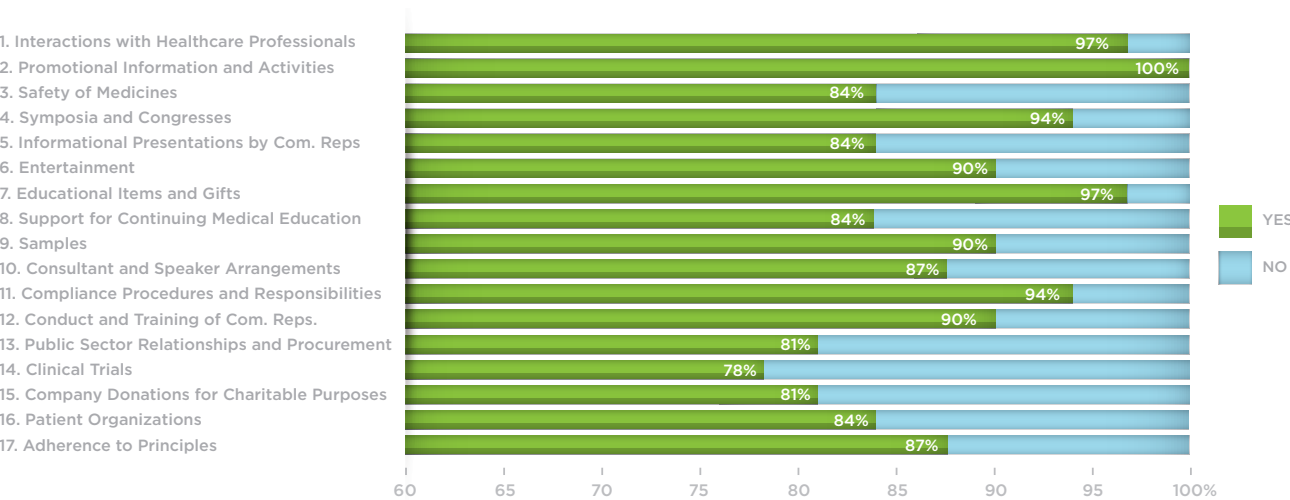


Code Alignment with the APEC Mexico City Principles

The *Business Ethics for APEC SMEs Initiative* has conducted seven biopharmaceutical sector capacity-building programs since 2012 and has extended support for dozens of local trainings to ensure that new and existing biopharmaceutical industry association codes of ethics achieve alignment with the APEC Mexico City Principles. Among adopted codes or code commitments, many industry associations chose to incorporate the entire text of the APEC Principles while others adapted certain provisions to align with local requirements. Among the associations responding to the 2017 survey (31 of the 55 with code or commitments),

90% report their code embraces all six fundamental principles of the APEC Mexico City Principles. A significant majority report they contain the Principles' 17 provisions (see below). The three provisions of the APEC Mexico City Principles with the lowest adherence include public sector relationships and procurement, clinical trials, and company donations for charitable purposes. These three provisions similarly had the lowest adherence rate in the 2017 survey. This report contains information based on self-reporting.

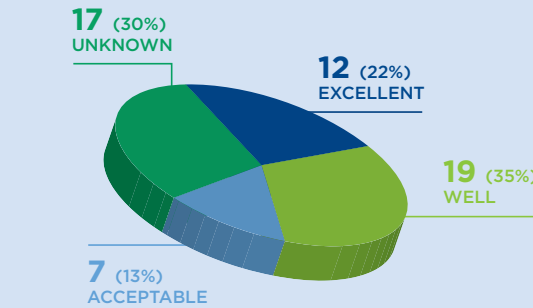
PERCENTAGE OF ASSOCIATION CODES OF ETHICS ALIGNED WITH EACH OF THE PROVISIONS OF THE APEC MEXICO CITY PRINCIPLES (2018):



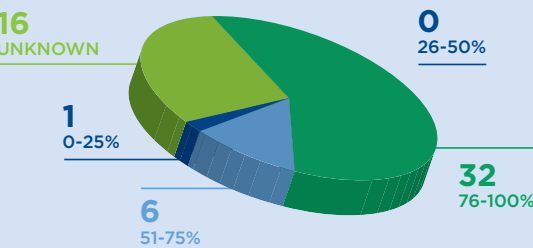
Member Enterprise Implementation

Assessing member enterprise implementation of a biopharmaceutical sector industry association's code of ethics remains the most difficult component of the initiative's monitoring activities. To-date, data is dependent on estimates provided by each association. Among the associations responding to the 2018 survey (31 of the 55 associations with codes or code commitments), **73%** report their code has performed "excellent" or "well" over the past year. Furthermore, **100%** of these associations report that a majority of their members have implemented the association's code into daily practices. In examining all 55 associations with codes or commitments, at least **69%** report that a majority of their members have implemented the code. **97%** of associations reported their interest in a virtual ethics compliance training and certification program and **90%** have interest to support dissemination. To support this demand, the *Business Ethics for APEC SMEs Initiative* will initiate a "Virtual Ethics for SMEs Compliance Program" for the biopharmaceutical sector. Testing on this program will begin in 2018.

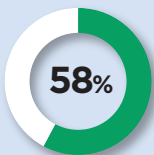
SELF-ASSESSMENT ON CODE PERFORMANCE BY THE 55 ASSOCIATIONS WITH A CODE/COMMITMENT:



REPORTED MEMBER IMPLEMENTATION RATE BY THE 55 ASSOCIATIONS WITH A CODE/COMMITMENT:

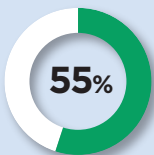


Associations who report requiring members to certify compliance with the code:



2018

Associations who report maintaining an active list of members who have certified compliance with the code of ethics:



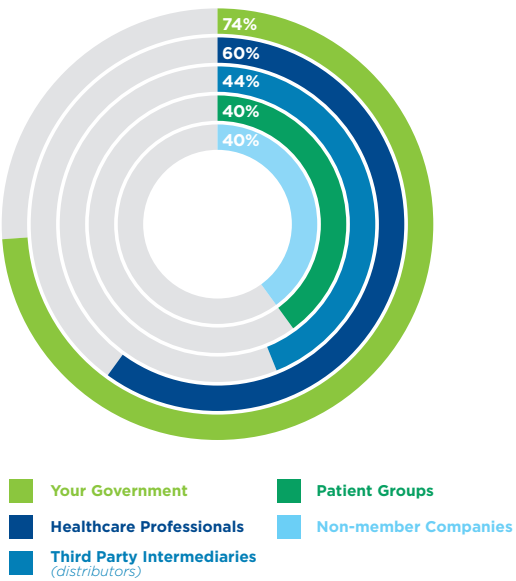
2018

External Engagement

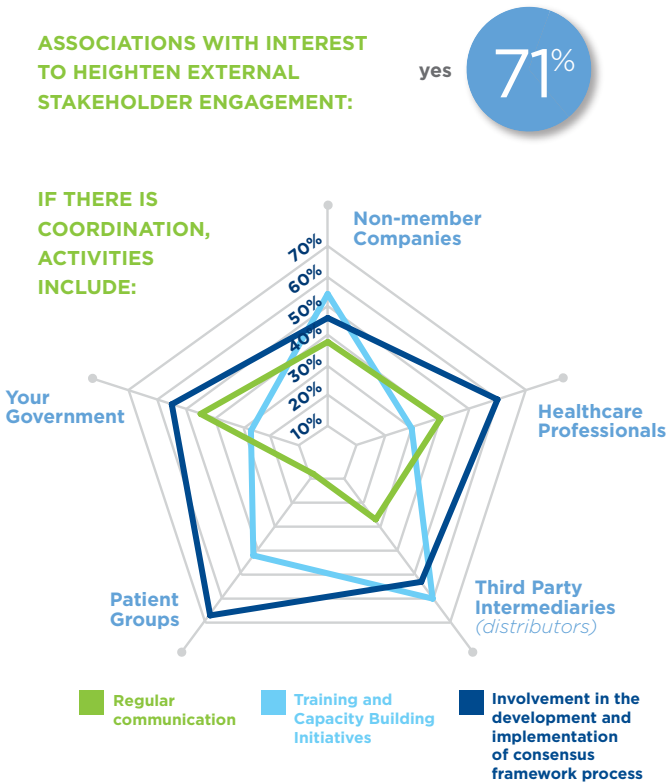
How biopharmaceutical industry associations engage with external stakeholders (non-members) on their codes of ethics has emerged as a fourth area of assessment in code implementation. While important for association members to adhere and implement their code, many encounter a “non-member dilemma” of how to operate in the same market with those who do not subscribe to the code of ethics. This data

highlights associations who engage with external stakeholders on their code, such as non-member companies, healthcare professionals, third party intermediaries, patient groups, governments, and other stakeholders. Among the associations responding to the 2018 survey (31 of the 55 associations with codes or code commitments), **71%** have an interest to heighten their external engagement in the future.

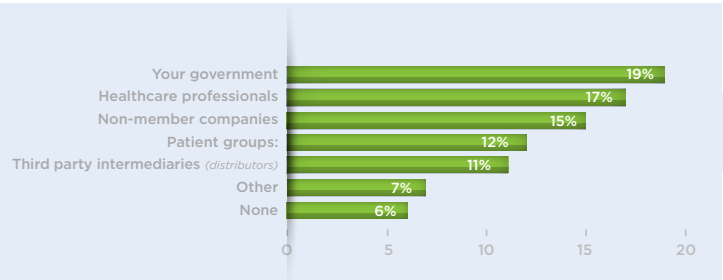
COORDINATION WITH NON-MEMBER STAKEHOLDERS ON ETHICAL PRACTICES AND/OR YOUR CODE OF ETHICS



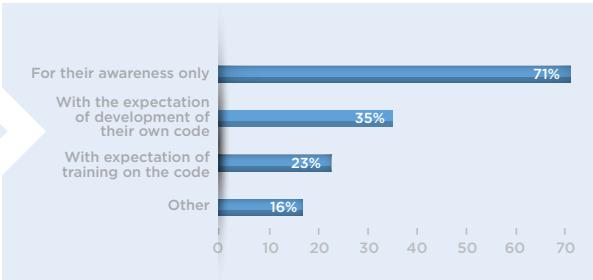
ASSOCIATIONS WITH INTEREST TO HEIGHTEN EXTERNAL STAKEHOLDER ENGAGEMENT:



STAKEHOLDERS WHO HAVE RECEIVED THE CODE WITHIN THE PAST YEAR...



...AND FOR THE FOLLOWING PURPOSE



Association	Economy	Member Enterprises		Code Adoption Code Commitment*			Member Implementation	Participation in APEC Business Ethics Forum				
		TOTAL	SMEs	Yes/No	Year Adopt	Last Update		2014	2015	2016	2017	2018
Medicines Australia	Australia	35	5	Yes	1960	2015	76-100%	Yes	Yes	No	Yes	Yes
GBMA	Australia	7	3	Yes	2010	2016	76-100%	No	No	No	No	No
IMC	Canada	50	35	Yes	1988	2017	76-100%	Yes	Yes	Yes	Yes	Yes
CGPA	Canada	9	4	Yes	1998	2013	No Data	No	No	No	No	No
ASILFA	Chile	11	7	No	N/A	N/A	N/A	No	No	No	No	No
CIF	Chile	22	0	Yes	2006	2017	76-100%	No	No	Yes	Yes	Yes
CANALAB	Chile	9	10	Yes	2018	N/A	76-100%	No	No	No	No	Yes
PROLMED	Chile	No Data	No Data	Yes	2018	2018	No Data	No	No	No	No	Yes
CPIA	China	405	100	Yes	2013	2015	51-75%	Yes	Yes	No	Yes	Yes
CCCMHPIE	China	1,840	1,688	Yes	2013	2017	76-100%	Yes	Yes	Yes	Yes	Yes
PhIRDA	China	90	23	Yes	2015	N/A	76-100%	Yes	Yes	Yes	No	Yes
RDPAC-CAEFI	China	40	0	Yes	1999	2017	76-100%	Yes	Yes	No	Yes	Yes
CATCM	China	700	500	Yes	2013	2015	76-100%	Yes	No	No	No	No
CAPC	China	384	249	Yes	2013	2015	51-75%	Yes	No	No	No	No
All-China Federation	China	No Data	No Data	Yes	2013	2015	No Data	No	No	No	No	No
CMBA	China	No Data	No Data	Yes	2015	N/A	No Data	No	No	No	No	No
CMEA	China	No Data	No Data	Yes	2015	N/A	No Data	No	No	No	No	No
CNMA	China	350	No Data	Yes	2013	2015	No Data	No	No	No	No	No
CPAPE	China	350	No Data	Yes	2015	N/A	No Data	No	No	No	No	No
CPEMA	China	No Data	No Data	Yes	2015	N/A	No Data	No	No	No	No	No
CPEP	China	No Data	No Data	Yes	2013	2015	No Data	No	No	No	No	No
CPPA	China	No Data	No Data	Yes	2015	N/A	No Data	No	No	No	No	No
COAP	China	No Data	No Data	Yes	2015	N/A	No Data	No	No	No	No	No
CRAECC	China	No Data	No Data	Yes	2013	2015	No Data	No	No	No	No	No

Association	Economy	Member Enterprises		Code Adoption <i>Code Commitment*</i>			Member Implementation	Participation in APEC Business Ethics Forum				
		TOTAL	SMEs	Yes/ No	Year Adopt	Last Update		2014	2015	2016	2017	2018
HKAPI	Hong Kong, China	39	0	Yes	1971	2017	76-100%	Yes	Yes	Yes	Yes	Yes
HKPMA	Hong Kong, China	38	35	No	N/A	N/A	N/A	No	No	No	No	No
PDAHK	Hong Kong, China	44	44	No	N/A	N/A	N/A	No	No	No	No	No
GP Farmasi	Indonesia	2900	2300	Yes	2003	2016	51-75%	Yes	Yes	No	Yes	Yes
IPMG	Indonesia	26	16	Yes	2001	2017	76-100%	Yes	Yes	No	Yes	Yes
JPMA	Japan	71	5	Yes	1976	2017	76-100%	Yes	Yes	Yes	Yes	Yes
JGA	Japan	43	25	Yes	2010	2014	76-100%	No	Yes	No	Yes	Yes
KRPIA	Korea	40	5	Yes	2010	N/A	76-100%	No	No	No	No	Yes
KPBMA	Korea	195	195	Yes	1994	2014	76-100%	Yes	No	No	No	No
KoBIA	Korea	107	50	No	N/A	N/A	N/A	No	No	No	No	No
MOPI	Malaysia	41	32	Yes	2013	2016	No Data	Yes	No	No	No	No
PhAMA	Malaysia	45	2	Yes	1978	2017	76-100%	No	No	No	No	No
CANIFARMA	Mexico	95	0	Yes	2005	2013	76-100%	No	No	No	No	No
CETIFARMA	Mexico	107	74	Yes	2005	2018	76-100%	Yes	Yes	Yes	Yes	Yes
AMIIF	Mexico	43	30	Yes	2005	2018	76-100%	No	No	No	No	Yes
ANAFAM	Mexico	25	0	Yes	2005	2013	51-75%	Yes	Yes	Yes	No	No
ANADIM	Mexico	No Data	No Data	No	N/A	N/A	No Data	No	No	No	No	No
Medicines New Zealand	New Zealand	26	9	Yes	1962	2015	76-100%	No	No	No	No	No
ADIFAN	Peru	13	13	Yes	2014	N/A	76-100%	Yes	Yes	Yes	No	No
ALAFARPE	Peru	17	0	Yes	2016	N/A	76-100%	No	Yes	Yes	Yes	No
ALAFAL	Peru	10	5	Yes	2016	N/A	76-100%	No	No	Yes	No	No
PCPI	Philippines	125	100	Yes	2014	N/A	51-75%	Yes	Yes	No	No	No
PHAP	Philippines	40	20	Yes	1993	2016	76-100%	Yes	Yes	Yes	Yes	Yes
MEPI	Philippines	46	0	Yes	2015	N/A	No Data	No	No	No	No	No

Association	Economy	Member Enterprises		Code Adoption <i>Code Commitment*</i>			Member Implementation	Participation in APEC Business Ethics Forum				
		TOTAL	SMEs	Yes/ No	Year Adopt	Last Update		2014	2015	2016	2017	2018
AIPM	Russia	44	14	Yes	1998	2016	76-100%	No	No	No	No	No
ARPM	Russia	20	0	No	N/A	N/A	N/A	No	No	No	No	No
SAPI	Singapore	37	0	Yes	<2010	2018	76-100%	No	No	No	No	No
SMF-LSIG	Singapore	48	30	No	N/A	N/A	N/A	No	No	No	No	No
IRPMA	Chinese Taipei	48	5	Yes	1994	2016	76-100%	No	No	No	No	No
TRPMA	Chinese Taipei	28	28	No	N/A	N/A	N/A	No	No	No	No	No
TPMA	Chinese Taipei	210	160	No	N/A	N/A	N/A	No	No	No	No	No
TGPA	Chinese Taipei	65	10	No	N/A	N/A	N/A	No	No	No	No	No
CAPA	Chinese Taipei	125	115	No	N/A	N/A	N/A	No	No	No	No	No
CPMDA	Chinese Taipei	50	16	No	N/A	N/A	N/A	No	No	No	No	No
NPCA	Chinese Taipei	No Data	No Data	No	N/A	N/A	N/A	No	No	No	No	No
TPADA	Chinese Taipei	175	165	No	N/A	N/A	N/A	No	No	No	No	No
TPMMA	Chinese Taipei	55	55	No	N/A	N/A	N/A	No	No	No	No	No
PReMA	Thailand	36	27	Yes	1986	2018	76-100%	Yes	Yes	Yes	Yes	Yes
TPMA	Thailand	67	60	Yes	2015	2018	0-25%	No	Yes	Yes	Yes	Yes
GPO	Thailand	1	0	Yes	2015	N/A	76-100%	No	Yes	No	No	No
PhRMA	United States	32	0	Yes	2002	2009	76-100%	Yes	Yes	Yes	Yes	Yes
AAM	United States	44	No Data	Yes	2018	2018	No Data	No	No	No	No	No
VNPCA	Viet Nam	172	130	Yes	2014	2017	51-75%	Yes	Yes	Yes	Yes	Yes
Pharma Group	Viet Nam	26	0	Yes	2014	2016	76-100%	No	Yes	Yes	Yes	Yes
IQGx	Viet Nam	6	No Data	Yes	No Data	No Data	No Data	No	No	No	No	No
FIFARMA	Regional	13	0	Yes	2014	N/A	76-100%	No	No	Yes	No	No
ALIFAR	Regional	N/A	N/A	No	N/A	N/A	N/A	No	No	No	No	No



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