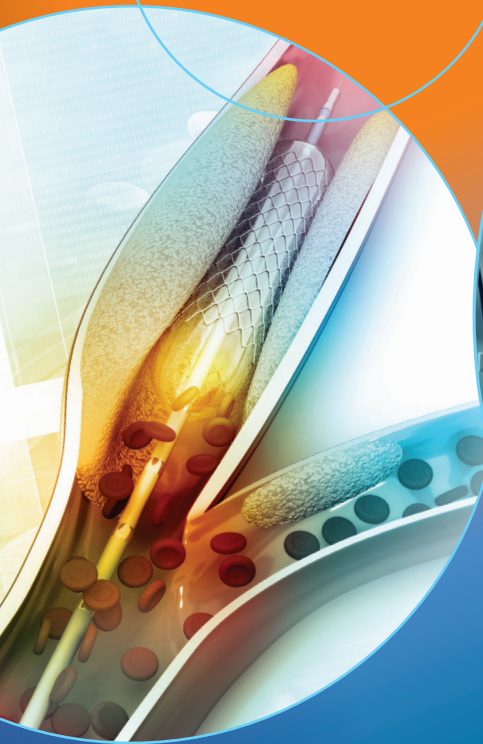


2017 Report on

Code of Ethics Implementation

by APEC Medical Device Industry Associations



Asia-Pacific
Economic Cooperation

Business Ethics for APEC SMEs
Medical Device Sector



Table Of Contents

- 2** INTRODUCTION
- 4** REGIONAL OVERVIEW
- 5** CODE GOVERNANCE
- 6** CODE ALIGNMENT WITH
THE APEC KUALA
LUMPUR PRINCIPLES
- 7** MEMBER ENTERPRISE
IMPLEMENTATION
- 8-9** STATISTICS BY APEC
MEDICAL DEVICE INDUSTRY
ASSOCIATION

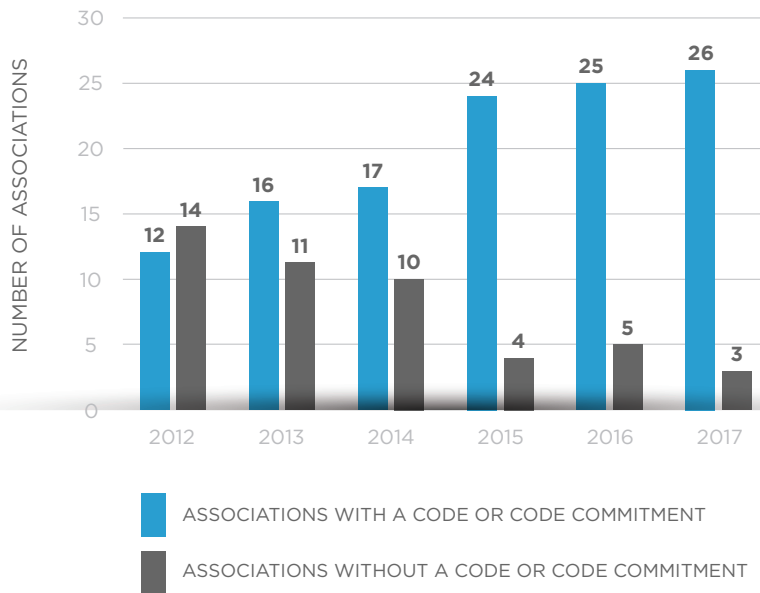
Introduction

The *Business Ethics for APEC SMEs Initiative* monitors code of ethics development and implementation by 29 medical device sector industry associations across the APEC region. These associations collectively represent over 13,000 member enterprises, of which nearly 11,000 are identified as SMEs. These enterprises constitute a significant majority of the firms that develop, manufacture, market, or distribute medical device and diagnostic products in the region.

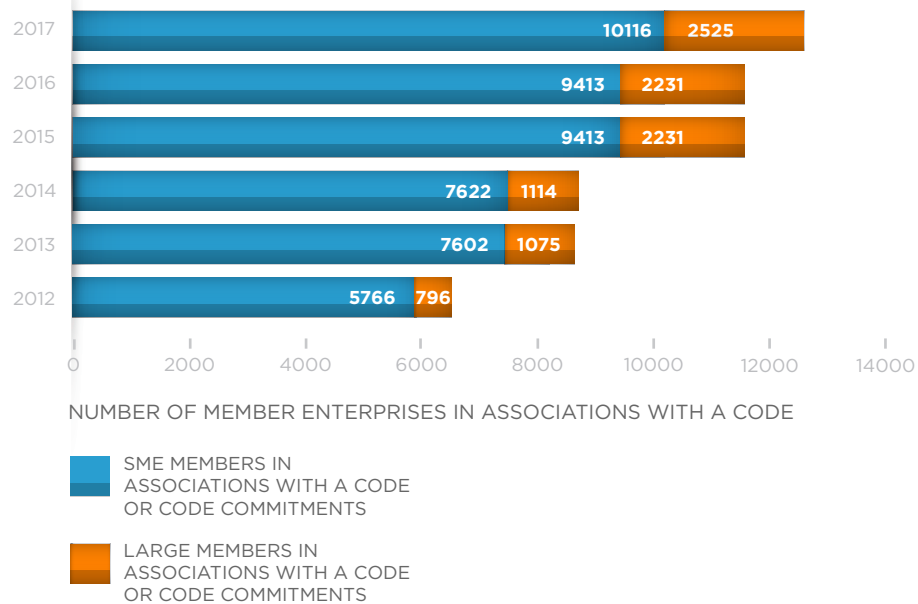
When this initiative's capacity-building program was launched in 2012 to support implementation of the APEC Kuala Lumpur Principles, 12 of these monitored medical device sector industry associations had a code of ethics. In 2017, 26 of these associations have a code of ethics or formalized commitment. 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. To achieve this outcome, the initiative has launched a pilot program in partnership with industry associations to survey member enterprises

that will be expanded across the region in 2018. The initiative also continues to pursue universal code of ethics adoption by medical device sector industry associations by 2020. This report has been prepared for the 2017 APEC Business Ethics for SMEs Forum, the 45th APEC SMEWG Meeting, and 24th APEC SME Ministerial Meeting 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, and (C) member enterprise implementation of the code. The data presented in this report has been provided from the associations and other publicly available sources.

INDUSTRY ASSOCIATIONS WITH A CODE OR CODE COMMITMENT

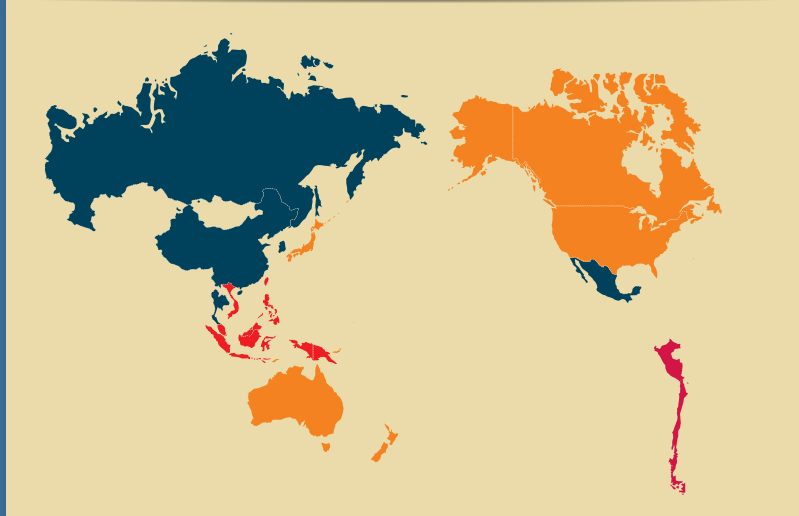


ENTERPRISE MEMBERSHIP OF ASSOCIATIONS WHO HAVE ADOPTED A CODE OR CODE COMMITMENT



Regional Overview

2012



Many economies with limited code coverage in sector

- Codes or commitments with broad coverage of the sector
- Codes undergoing development or alignment
- No codes of ethics for the sector

2017



12 new codes in 7 economies that did not exist in 2012

- Codes or commitments with broad coverage of the sector
- Codes undergoing development or alignment
- No codes of ethics for the sector

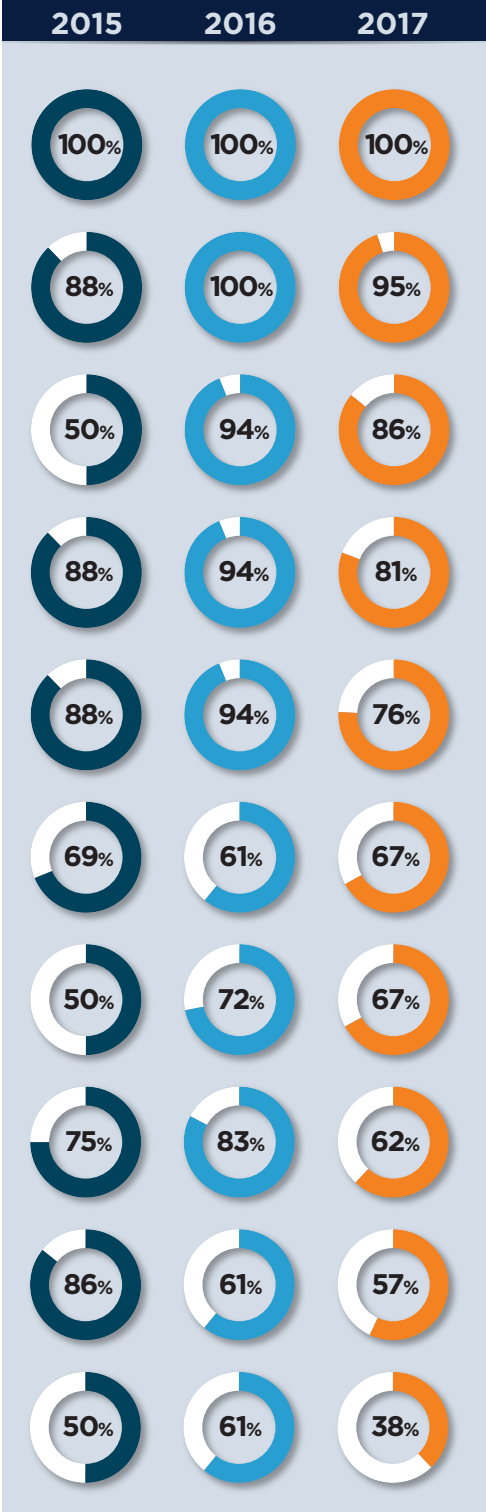
Industry Associations Monitored:	29
Total Member Enterprises:	13,100+
SME Members:	10,500+

STATUS REPORT	2012	2017
Associations with a Code/ Code Commitment:	12	26 (up 14)
Total Member Enterprises:	6,500+	12,600+ (up 6,100+)
SME Members:	5,700+	10,000+ (up 4,300+)

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 2017 survey (21 of the 26 with codes or commitments) indicate that most continue to have a valid governance structure in place. Of note, 100% continue to indicate their current leadership is committed to the code. Most key governance areas assessed in 2017 saw a similar response as 2016, with declines in code distribution to member companies, the designation of a staff member to oversee the code, as well as codes with a regular review and compliant procedure. There remains an opportunity for associations to expand regular code trainings, which remain low due to limited and declining resources.

In fact, **81%** of the medical device sector industry associations surveyed said an online training course designed to help their member companies certify adherence to the APEC Kuala Lumpur Principles would be very helpful or moderately helpful.



Associations with current leadership committed to the code of ethics

Associations that distributed the code to members for input before adoption

Associations that provide one-on-one assistance to members seeking to align their business practices with the code

Associations that distributed the code to all members within the last two years

Associations that have designated staff or a member to oversee code maintenance, promotion, and implementation

Associations who offer one or more code of ethics training to members

Associations that have distributed the code to non-members within the past year, including HCPs, third parties, patients, and governments

Associations with procedures in place to review the code and ensure it is up-to-date

Associations with sufficient resources to support code maintenance, promotion, and implementation

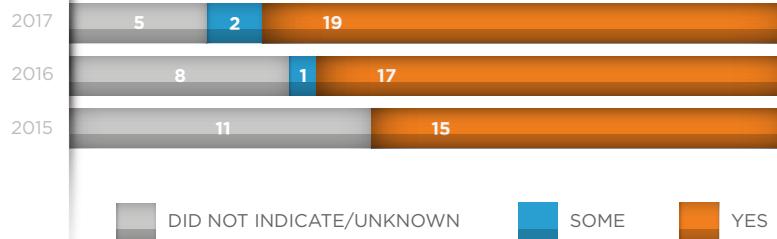
Associations with a code complaint or violation procedure

Code Alignment with the APEC Kuala Lumpur Principles

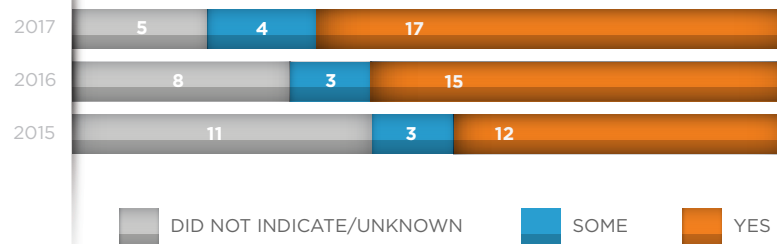
The *Business Ethics for APEC SMEs Initiative* has conducted six medical device sector capacity-building programs since 2012 and has extended support for dozens of local trainings to ensure that new and existing medical device industry association codes of ethics achieve alignment with the APEC Kuala 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 responding to the 2017 survey, **90%** report their code embraces all five fundamental principles of the APEC Kuala Lumpur Principles and **81%** report their code is intently aligned with all the provisions of the Principles. The total number of industry associations reporting their code of ethics embraces the five fundamental principles of the APEC Kuala Lumpur Principles has **increased** each year since 2015. This annual increase is similarly seen in the total number of industry associations reporting alignment with the provisions of the APEC Kuala Lumpur Principles.

REPORTED EMBRACE OF THE FIVE FUNDAMENTAL PRINCIPLES OF THE APEC KUALA LUMPUR PRINCIPLES BY THE 26 ASSOCIATIONS WITH A CODE OR CODE COMMITMENT:



REPORTED ALIGNMENT WITH THE PROVISIONS OF THE APEC KUALA LUMPUR PRINCIPLES BY THE 26 ASSOCIATIONS WITH A CODE OR CODE COMMITMENT:

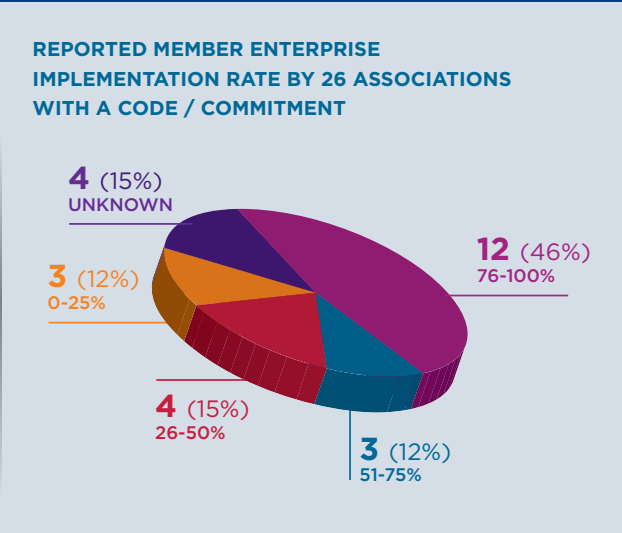
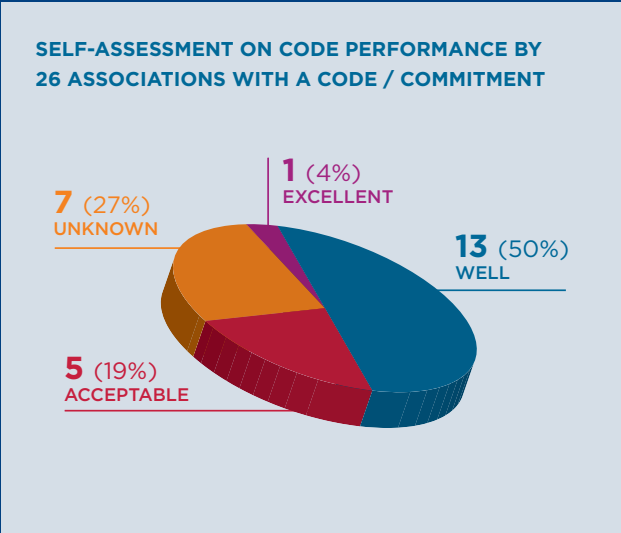


Member Enterprise Implementation

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 largely dependent on estimates provided by each association. To begin to address challenges in obtaining complete and accurate data, the initiative has launched a pilot program in partnership with industry associations to survey member enterprises directly. Initiated in the Philippines, this pilot will be expanded across the region in 2018. Among the associations responding to the 2017 survey (21 of the 26 associations with codes or code commitments), **67%** report their code has performed “excellent” or “well” over the past year. This represents a slight increase from last year. Furthermore, **58%** of those associations completing the 2017 survey report that a majority of their member enterprises adhere to the association’s code in their daily business practices. In examining all 26 associations with codes or commitments, at least **58%** have reported that a majority of their members have implemented the code. This represents a **12%** increase from last year.



ASSOCIATION MONITORING	
Associations who maintain an active list of members who have certified compliance with the code of ethics:	29%
Associations who receive notification when members conduct external validation or audits to measure compliance with the code:	10%



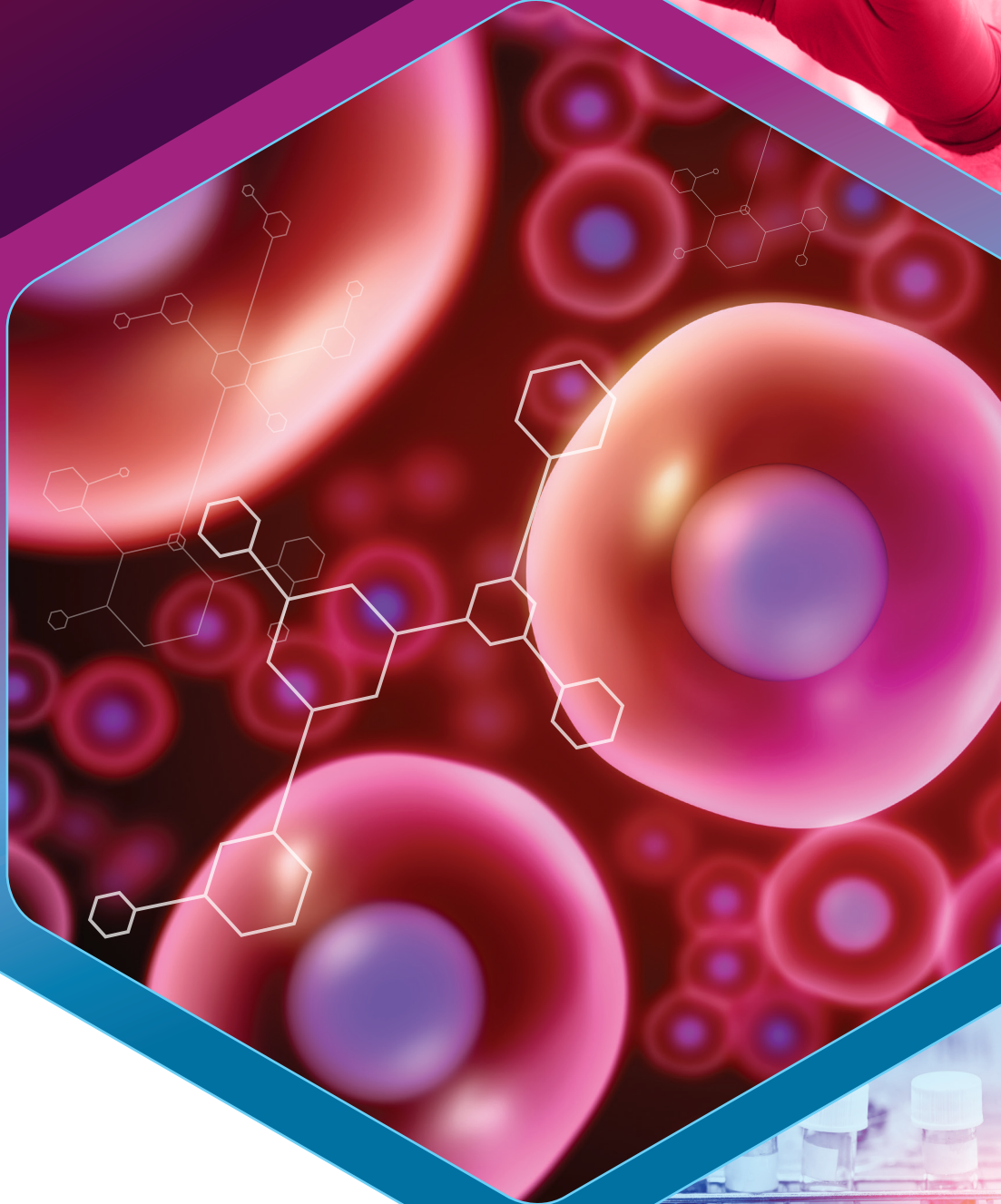
Association	Economy	Member Enterprises		Code Adoption Code Commitment*			Member Implementation	Participation in APEC Business Ethics Forum			
		TOTAL	SMEs	Yes/No	Year Adopt	Last Update		2014	2015	2016	2017
MEDEC	Canada	91	42	Yes	2005	2017	76-100%	Yes	Yes	No	Yes
SCDM	Chile	24	14	Yes	2013	N/A	51-75%	Yes	Yes	Yes	Yes
AMID	Mexico	32	0	Yes	2007	2016	76-100%	Yes	Yes	Yes	Yes
COMSALUD-CCL	Peru	232	198	Yes	2012	N/A	26-50%	Yes	Yes	Yes	Yes
AdvaMed	United States	296	220	Yes	1992	2009	76-100%	Yes	Yes	Yes	Yes
CAMDI	China	2148	1230	Yes	2015	2016	26-50%	Yes	Yes	Yes	Yes
CAME	China	No Data	No Data	No	N/A	N/A	No Data	No	No	No	No
AdvaMed China	China	40	0	Yes	2016	2017	No Data	Yes	Yes	No	Yes
CCCMHPIE	China	1,840	1,688	Yes	2013	2015	51-75%	Yes	Yes	Yes	Yes
HKMHDIA	Hong Kong, China	178	150	Yes	2009	N/A	0-25%	No	No	No	No
JFMDA	Japan	4280	4000	Yes	1993	2017	76-100%	Yes	Yes	Yes	Yes
KMDIA	Korea	876	800	Yes	2011	2012	51-75%	Yes	Yes	Yes	No
TAMTA	Chinese Taipei	22	0	Yes	2015	N/A	76-100%	No	Yes	No	Yes
TMBIA	Chinese Taipei	378	350	No	N/A	N/A	N/A	No	No	No	No
Gakeslab	Indonesia	452	388	Yes	2013	2016	26-50%	Yes	Yes	No	Yes
AMMI	Malaysia	63	17	Yes	2013	N/A	76-100%	No	No	No	No
MMDA	Malaysia	187	100	Yes	2013	N/A	26-50%	No	No	No	No
PAMDRAP	Philippines	104	57	Yes	2015	2017	0-25%	Yes	Yes	Yes	Yes
MEPI	Philippines	88	45	Yes	2015	N/A	N/A	No	No	No	No
APACMed	Multi	55	5	Yes	2015	2017	76-100%	N/A	Yes	No	Yes
AMDI	Singapore	111	81	No	N/A	N/A	N/A	No	No	No	No
SMF-MTIG	Singapore	94	48	Yes	2014	2017	0-25%	Yes	Yes	No	No

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
THAIMED	Thailand	110	110	Yes	2008	2013	76-100%	Yes	No	No	No
MDDSC	Vietnam	11	0	Yes	2017	N/A	No Data	No	No	No	Yes
VIDEMAS	Vietnam	1,000	750	Yes	2017	N/A	No Data	No	No	No	Yes
ADIA	Australia	195	165	Yes	1983	2014	76-100%	No	No	No	No
MTAA	Australia	74	35	Yes	2001	2015	76-100%	Yes	Yes	No	Yes
MTANZ	New Zealand	108	54	Yes	2005	2016	76-100%	Yes	No	Yes	Yes
IMEDA	Russia	41	0	Yes	2008	2013	76-100%	Yes	No	No	No

2017 Report on

Code of Ethics Implementation

by APEC Biopharmaceutical
Industry Associations



Asia-Pacific
Economic Cooperation

Business Ethics for APEC SMEs
Biopharmaceutical Sector



Table Of Contents

- 2** INTRODUCTION
- 4** REGIONAL OVERVIEW
- 5** CODE GOVERNANCE
- 6** CODE ALIGNMENT WITH THE
APEC MEXICO CITY PRINCIPLES
- 7** MEMBER ENTERPRISE
IMPLEMENTATION
- 8-10** STATISTICS BY APEC
BIOPHARMACEUTICAL
INDUSTRY ASSOCIATION

Introduction

The *Business Ethics for APEC SMEs Initiative* monitors code of ethics development and implementation by 66 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 product 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 2017, 51 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. To achieve this outcome, the

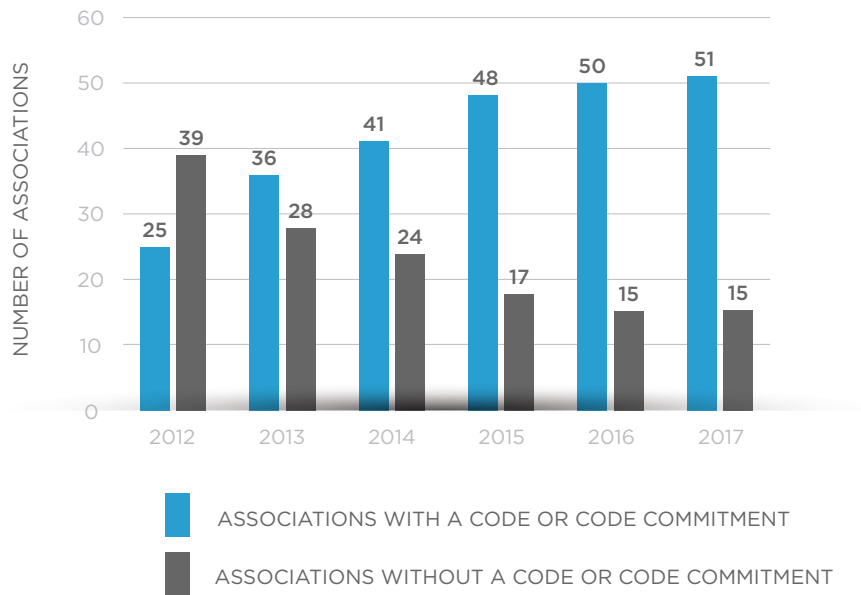
initiative has launched a pilot program in partnership with industry associations to survey member enterprises that will be expanded across the region in 2018.

The initiative also continues to pursue universal code of ethics adoption by APEC biopharmaceutical sector industry associations by 2020.

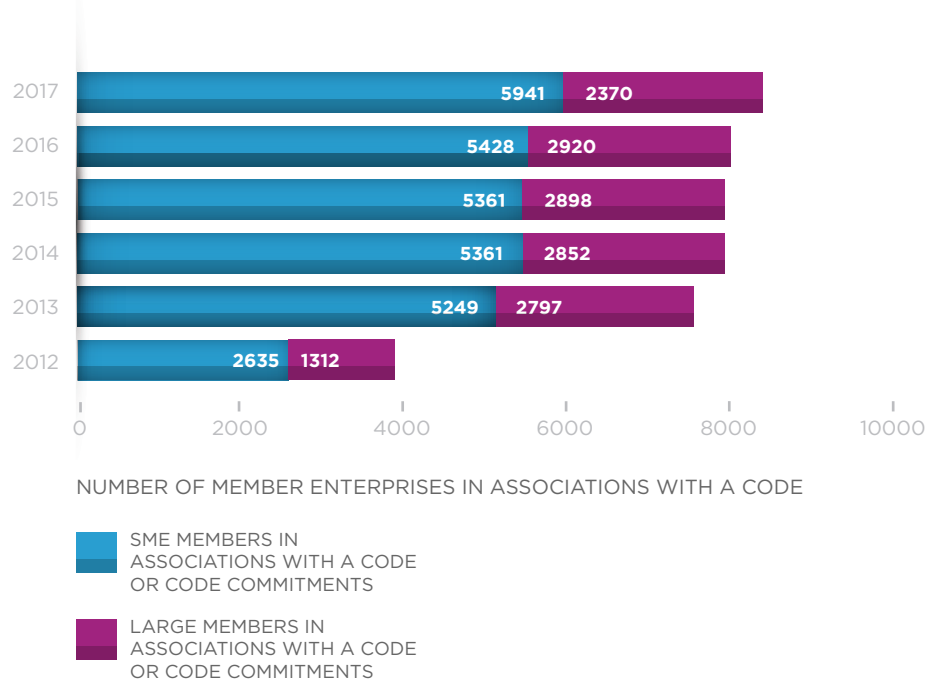
This report has been prepared for the 2017 APEC Business Ethics for SMEs Forum, the 45th APEC SMEWG Meeting, and 24th APEC SME Ministerial Meeting to indicate where progress has been made since 2012, and where challenges remain, for the region's biopharmaceutical sector industry associations in (A) code governance, (B) code alignment with the APEC Principles, and (C) member enterprise implementation of the code. 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

2012



Many economies with limited code coverage in the sector

- Codes with broad coverage of the sector
- Codes but with limited coverage of the sector
- No codes of ethics for the sector

2017



25 new codes in 7 economies that did not exist in 2012

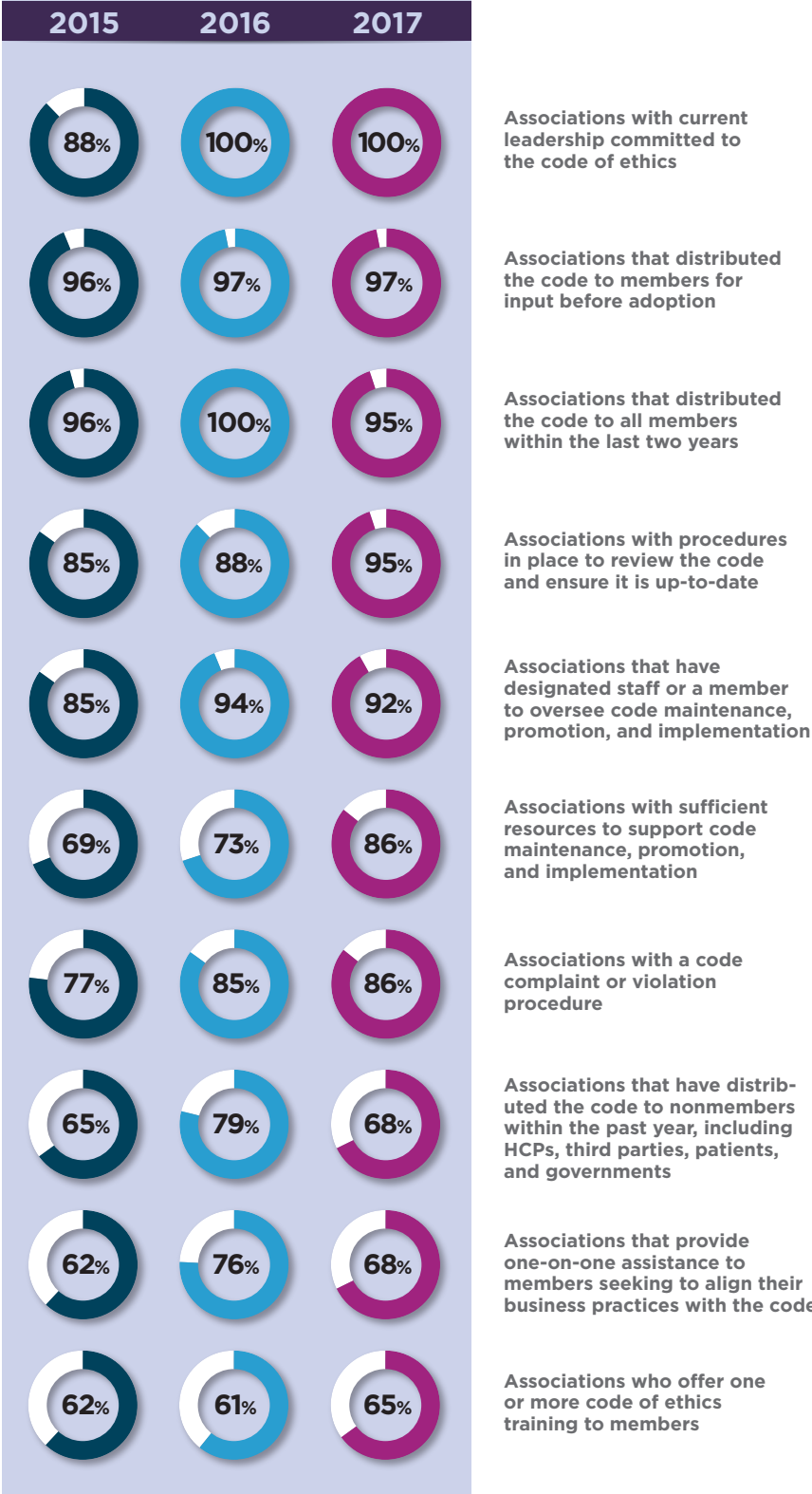
- Codes with broad coverage of the sector
- Codes but with limited coverage of the sector
- No codes of ethics for the sector

Industry Associations Monitored:	66
Total Member Enterprises:	9,600+
SME Members:	6,300+

STATUS REPORT	2012	2017
Associations with a Code/ Code Commitment:	25	51 (up 26)
Total Member Enterprises:	3,900+	8,300+ (up 4,400+)
SME Members:	2,600+	5,900+ (up 3,300+)

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. Responses from those industry associations completing the 2017 survey (37 of the 51 with codes or commitments) indicate that most continue to have a valid governance structure in place. Of note, 100% continue to indicate their current leadership is committed to the code and there is a 13% increase over last year in the number of associations reporting sufficient resources to support code maintenance, promotion, and implementation. Most key governance areas assessed in 2017 saw a similar response as 2016, with declines in the number of associations distributing the code to non-members as well as those providing one-on-one assistance for members. There remains an opportunity for associations to expand regular code trainings, which remain low. Of note, 86% of the biopharmaceutical sector industry associations surveyed said an online training course designed to help their member companies certify adherence to the APEC Mexico City Principles would be very helpful or moderately helpful.



Code Alignment with the APEC Mexico City Principles

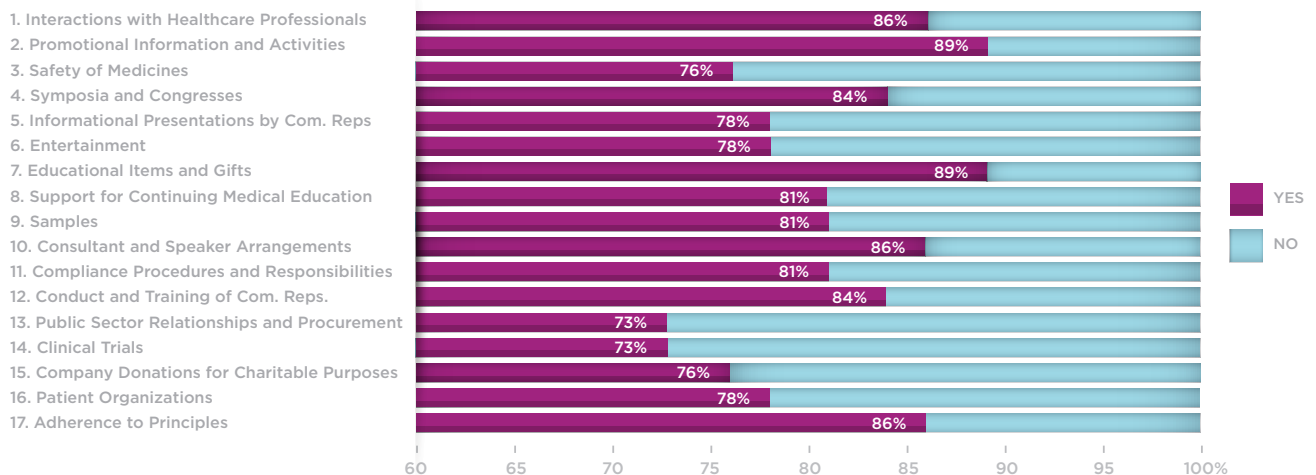
The *Business Ethics for APEC SMEs Initiative* has conducted six biopharmaceutical sector capacity-building programs since 2012 and has extended support for dozens of local trainings to ensure that new and existing biopharmaceutical industry association codes of ethics achieve alignment with the APEC 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 (37 of the 51 with code or commitments), 81% report their code embraces all six fundamental principles of the APEC Mexico City Principles, a 5% increase from the

2016 survey. A significant majority report they contain the Principles' 17 provisions. The two provisions of the APEC Mexico City Principles with the lowest adherence include public sector relationships and procurement as well as clinical trials. These two provisions similarly had the lowest adherence rate in the 2016 survey. While the 2017 survey saw a 10% increase over 2016 in the number of associations that report contributing to and participating in industry capacity-building, along with a 16% increase in those ensuring the code remains relevant and effective to address new business arrangements, the survey also saw an 11% decrease in the number of associations that make training available to health care professionals and other stakeholders.

2017 PERFORMANCE BY INDUSTRY ASSOCIATIONS TO IMPLEMENT APEC MEXICO CITY PRINCIPLES RECOMMENDATIONS:



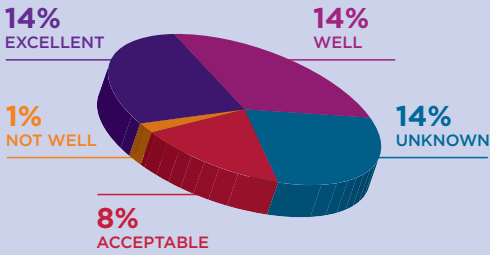
PERCENTAGE OF ASSOCIATION CODES OF ETHICS ALIGNED WITH EACH OF THE PROVISIONS OF THE APEC MEXICO CITY PRINCIPLES (2017):



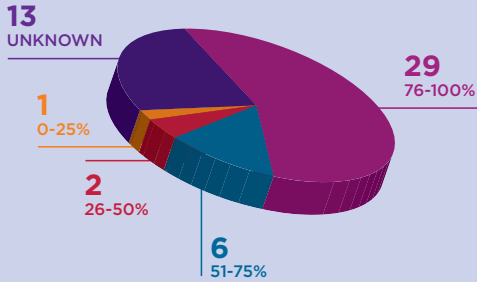
Member Enterprise Implementation

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 largely dependent on estimates provided by each association. To begin to address challenges in obtaining complete and accurate data, the initiative has launched a pilot program in partnership with industry associations to survey member enterprises directly. Initiated in the Philippines, this pilot will be expanded across the region in 2018. Among the associations responding to the 2017 survey (37 of the 51 associations with codes or code commitments), **76%** report their code has performed “excellent” or “well” over the past year. Furthermore, **96%** of these associations report that a majority of their members have implemented the association’s code into daily practices. In examining all 51 associations with codes or commitments, at least **69%** report that a majority of their members have implemented the code.

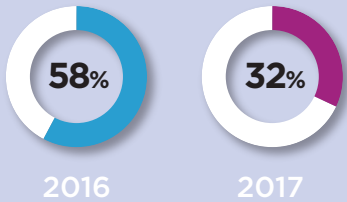
SELF-ASSESSMENT ON CODE PERFORMANCE BY THE 51 ASSOCIATIONS WITH A CODE/COMMITMENT:



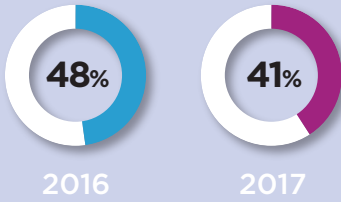
REPORTED MEMBER ENTERPRISE IMPLEMENTATION RATE BY THE 51 ASSOCIATIONS WITH A CODE/COMMITMENT:



Associations who require members to certify compliance with the code:



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



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
Medicines Australia	Australia	35	18	Yes	1960	2015	76-100%	Yes	Yes	No	Yes
GBMA	Australia	7	3	Yes	2010	2016	76-100%	No	No	No	No
IMC	Canada	50	35	Yes	1988	2017	76-100%	Yes	Yes	Yes	Yes
CGPA	Canada	9	4	Yes	1998	2013	No Data	No	No	No	No
ASILFA	Chile	11	7	No	N/A	N/A	N/A	No	No	No	No
CIF	Chile	21	0	Yes	2006	2017	76-100%	No	No	Yes	Yes
CPIA	China	360	110	Yes*	2013*	2015*	26-50%	Yes	Yes	No	Yes
CCCMHPIE	China	1,840	1,688	Yes*	2013*	2015*	51-75%	Yes	Yes	Yes	Yes
PHIRDA	China	83	17	Yes*	2013*	2015*	76-100%	Yes	Yes	Yes	No
RDPAC-CAEFI	China	39	11	Yes	1999	2017	76-100%	Yes	Yes	No	Yes
CATCM	China	700	500	Yes*	2013*	2015*	76-100%	Yes	No	No	No
CAPC	China	384	249	Yes*	2013*	2015*	51-75%	Yes	No	No	No
All-China Federation	China	No Data	No Data	Yes*	2013*	2015*	No Data	No	No	No	No
CMBA	China	No Data	No Data	Yes*	2015*	N/A	No Data	No	No	No	No
CMEA	China	No Data	No Data	Yes*	2015*	N/A	No Data	No	No	No	No
CNMA	China	350	No Data	Yes*	2013*	2015*	No Data	No	No	No	No
CPAPE	China	350	No Data	Yes*	2015*	N/A	No Data	No	No	No	No
CPEMA	China	No Data	No Data	Yes*	2015*	N/A	No Data	No	No	No	No
CPEP	China	No Data	No Data	Yes*	2013*	2015*	No Data	No	No	No	No
CPPA	China	No Data	No Data	Yes*	2015*	N/A	No Data	No	No	No	No
COAP	China	No Data	No Data	Yes*	2015*	N/A	No Data	No	No	No	No
CRAECC	China	No Data	No Data	Yes*	2013*	2015*	No Data	No	No	No	No
HKAPI	Hong Kong, China	47	30	Yes	1971	2017	51-75%	Yes	Yes	Yes	Yes
HKPMA	Hong Kong, China	38	35	No	N/A	N/A	N/A	No	No	No	No

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
PDAHK	Hong Kong, China	44	44	No	N/A	N/A	N/A	No	No	No	No
GP Farmasi	Indonesia	2,900	2,300	Yes	2003	2016	51-75%	Yes	Yes	No	Yes
IPMG	Indonesia	26	0	Yes	2001	2017	76-100%	Yes	Yes	No	Yes
JPMA	Japan	72	5	Yes	1976	2017	76-100%	Yes	Yes	Yes	Yes
JGA	Japan	42	29	Yes	2010	2014	76-100%	No	Yes	No	Yes
KRPIA	Korea	40	5	Yes	2010	N/A	76-100%	No	No	No	No
KPBMA	Korea	183	118	Yes	1994	2014	51-75%	Yes	No	No	No
KoBIA	Korea	107	50	No	N/A	N/A	N/A	No	No	No	No
MOPI	Malaysia	41	32	Yes	2013	2016	No Data	Yes	No	No	No
PhAMA	Malaysia	41	7	Yes	1978	2017	76-100%	No	No	No	No
CANIFARMA	Mexico	95	0	Yes	2005	2013	76-100%	No	No	No	No
CETIFARMA	Mexico	113	63	Yes	2005	2015	76-100%	Yes	Yes	Yes	Yes
AMIIF	Mexico	61	5	Yes	2005	2013	76-100%	No	No	No	No
ANAFAM	Mexico	28	0	Yes	2005	2013	51-75%	Yes	Yes	Yes	No
Medicines New Zealand	New Zealand	26	9	Yes	1962	2015	76-100%	No	No	No	No
ADIFAN	Peru	13	13	Yes	2014	N/A	76-100%	Yes	Yes	Yes	Yes
ALAFARPE	Peru	17	0	Yes	2016	N/A	76-100%	No	Yes	Yes	Yes
ALAFAL	Peru	11	5	Yes	2016	N/A	76-100%	No	No	Yes	No
PCPI	Philippines	115	100	Yes	2014	N/A	76-100%	Yes	Yes	No	No
PHAP	Philippines	40	10	Yes	1993	2016	76-100%	Yes	Yes	Yes	Yes
MEPI	Philippines	46	0	Yes	2015	N/A	No Data	No	No	No	No
AIPM	Russia	44	14	Yes	1998	2016	76-100%	No	No	No	No
ARPM	Russia	20	0	No	N/A	N/A	N/A	No	No	No	No
SAPI	Singapore	40	0	Yes	<2010	2016	76-100%	No	No	No	No

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
SMF-LSIG	Singapore	48	30	No	N/A	N/A	N/A	No	No	No	No
IRPMA	Chinese Taipei	47	37	Yes	1994	2016	76-100%	No	No	No	Yes
TRPMA	Chinese Taipei	28	28	No	N/A	N/A	N/A	No	No	No	No
TPMA	Chinese Taipei	210	160	No	N/A	N/A	N/A	No	No	No	No
TGPA	Chinese Taipei	65	10	No	N/A	N/A	N/A	No	No	No	No
CAPA	Chinese Taipei	125	115	No	N/A	N/A	N/A	No	No	No	No
CPMDA	Chinese Taipei	50	16	No	N/A	N/A	N/A	No	No	No	No
NPCA	Chinese Taipei	No Data	No Data	No	N/A	N/A	N/A	No	No	No	No
TPADA	Chinese Taipei	175	165	No	N/A	N/A	N/A	No	No	No	No
TPMMA	Chinese Taipei	55	55	No	N/A	N/A	N/A	No	No	No	No
PReMA	Thailand	38	14	Yes	1986	2016	76-100%	Yes	Yes	Yes	Yes
TPMA	Thailand	70	60	Yes	2016	N/A	26-50%	No	Yes	Yes	Yes
GPO	Thailand	1	0	Yes	2015	N/A	76-100%	No	Yes	No	No
PhRMA	United States	30	0	Yes	2002	2009	76-100%	Yes	Yes	Yes	Yes
VNPCA	Viet Nam	168	100	Yes	2014	2016	0-25%	Yes	Yes	Yes	Yes
Pharma Group	Viet Nam	26	0	Yes	2014	2016	76-100%	No	Yes	Yes	Yes
FIFARMA	Regional	13	0	Yes	2014	N/A	76-100%	No	No	No	No
ALIFAR	Regional	N/A	N/A	No	N/A	N/A	N/A	No	No	No	No



Asia-Pacific
Economic Cooperation

Business Ethics for APEC SMEs Biopharmaceutical Sector