



**Asia-Pacific
Economic Cooperation**

**Business Ethics for APEC SMEs
Biopharmaceutical Sector**

Report on Code of Ethics Implementation by APEC Biopharmaceutical Industry Associations, 2012-2016

Prepared for the:

2016 APEC Business Ethics for SMEs Forum | Lima, Peru | 5-6 September 2016

43rd APEC Small & Medium Enterprise Working Group | Lima, Peru | 7-8 September 2016

23rd APEC Small & Medium Enterprise Ministerial Meeting | Lima, Peru | 9 September 2016

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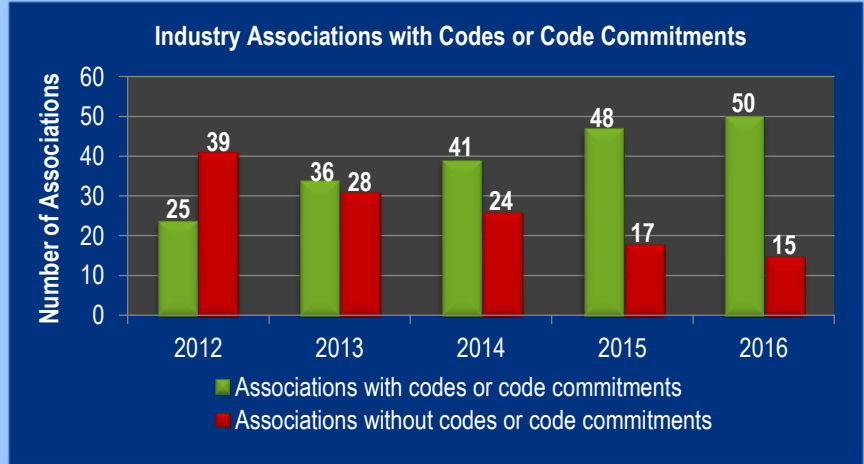
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INTRODUCTION

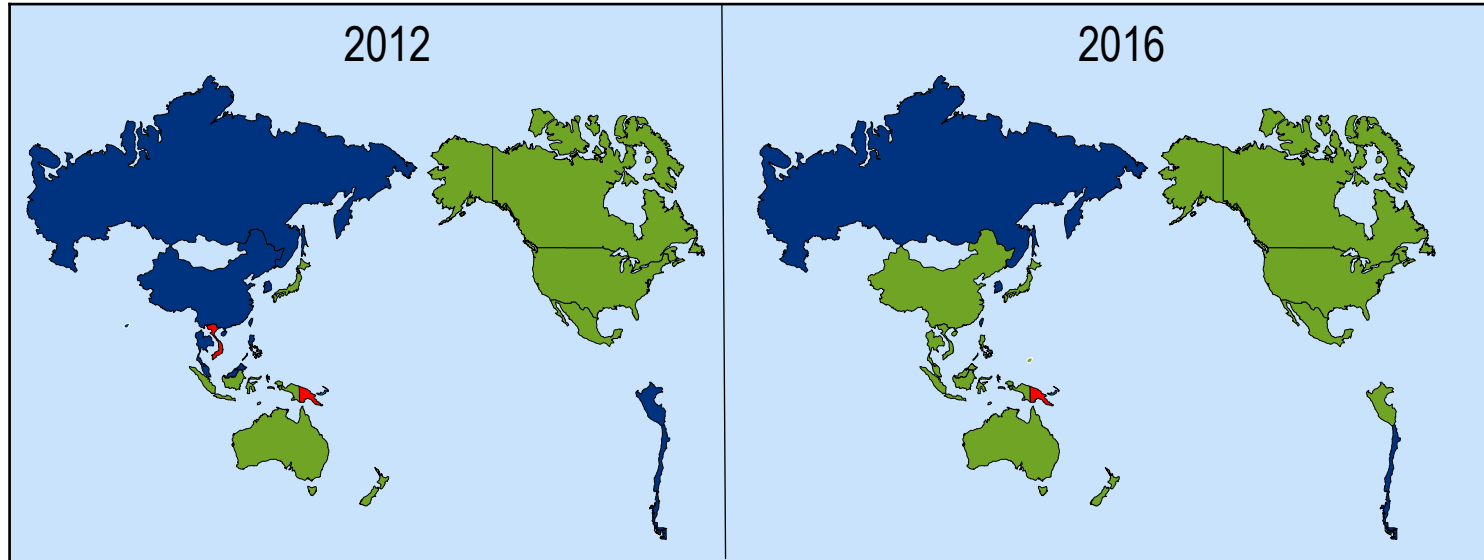
The *Business Ethics for APEC SMEs Initiative* monitors code of ethics development and implementation by 65 biopharmaceutical industry associations across the APEC region. These associations collectively represent over 9,000 member enterprises, of which over 6,000 are identified as SMEs. These enterprises constitute a significant majority of the firms that develop, manufacture, market, or distribute pharmaceutical and/or biologic 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 associations had a code of ethics. In 2016, 50 of these associations have a code of ethics or formalized commitment. As a result, the Initiative met the goal endorsed by SME Ministers to double the number of industry association codes (the Nanjing Declaration). The Initiative remains focused on all associations achieving implementation of these codes by a majority of their member enterprises by 2017. The Initiative is also pursuing universal code of ethics adoption by industry association by 2020.

This report has been prepared for the 2016 APEC Business Ethics for SMEs Forum, the 43rd APEC SMEWG Meeting, and 23rd APEC SME Ministerial Meeting to indicate where progress has been made since 2012, and where challenges remain, for these biopharmaceutical industry associations in (A) code governance, (B) code alignment with the APEC Principles, and (C) member implementation of the code. The data provided in this report has been provided from the associations and other publicly available sources.



REGIONAL OVERVIEW



Many economies with limited code coverage in sector

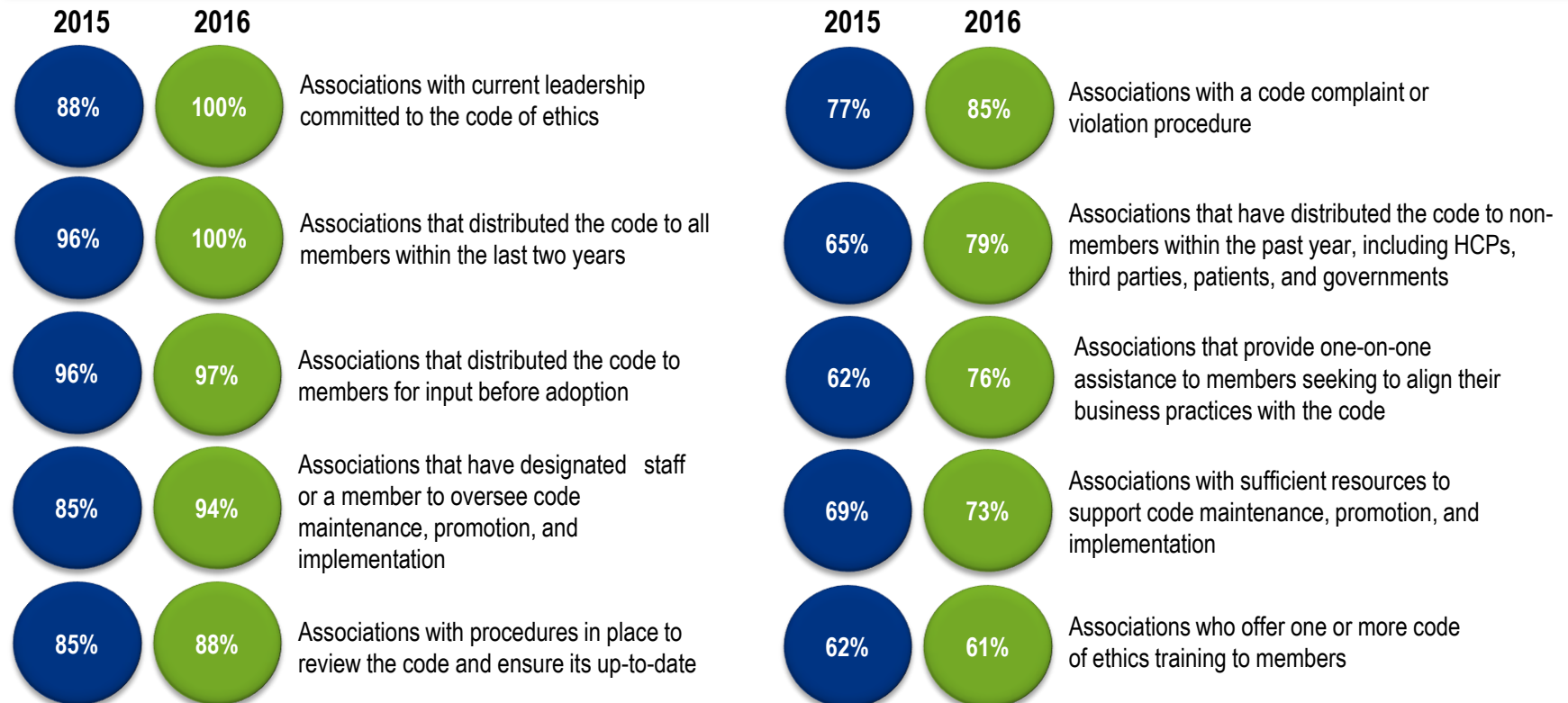
25 new codes in 7 economies that did not exist in 2012

- Codes with broad coverage of the sector
- Codes but with limited coverage of the sector

Industry Associations Monitored	65	
Member Companies	9,200+	
SME Member Companies	6,100+	
STATUS REPORT	2012	2016
Associations with Code / Commitment	25	50 (↑25)
Member Companies	3,900+	8,300+ (↑4,400+)
SME Member Companies	2,600+	5,400+ (↑2,800+)

CODE GOVERNANCE

Biopharmaceutical industry association codes of ethics are strong tools to disseminate and harmonize ethical 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 associations completing the 2016 APEC ethics survey (33 of the 50 with codes or commitments) indicate that most have a valid governance structure and have been undertaking improvements over the past year. Of note, **100%** indicate their current leadership is committed to the code. There was also a **14%** increase over the past year in the number of associations distributing their codes to non-member stakeholders as well as those providing one-on-one code implementation assistance to members. However, there is opportunity for associations to expand regular code trainings, which may be currently limited due to finite resources.

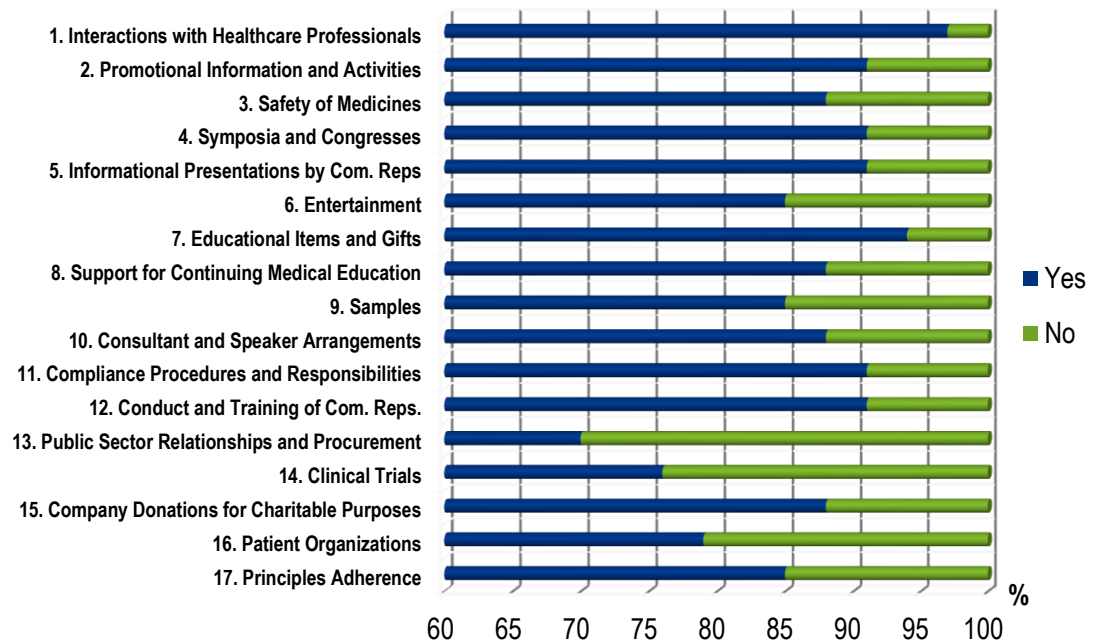


ALIGNMENT WITH THE APEC MEXICO CITY PRINCIPLES

The *Business Ethics for APEC SMEs Initiative* has conducted five 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. There has been notable success in this effort. Among recently adopted codes or code commitments, many industry associations chose to incorporate the entire text of the APEC Principles while others adapted certain provisions to ensure alignment with local requirements. Among the associations responding to the 2016 APEC ethics survey (33 of the 50 with codes or commitments), **76%** report their code embraces all six fundamental principles of the APEC Mexico City Principles. A significant majority report they contain the Principles' 17 provisions. The three provisions of the APEC Mexico City Principles with the lowest adherence include public sector relationships and procurement, clinical trials, and patient organizations.



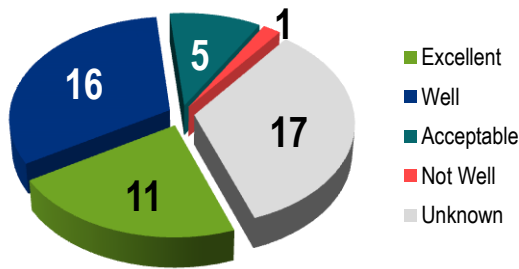
Percentage of Association Codes of Ethics Aligned with Each the 17 Provisions of the APEC Mexico City Principles (2016)



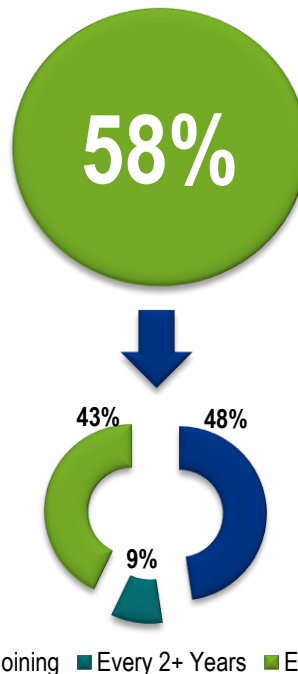
MEMBER IMPLEMENTATION

Assessing member implementation of an association's code of ethics is the most difficult component of the Initiative's monitoring activities. Data is dependent on estimates provided by each association. Without comprehensive surveys conducted by associations among their entire membership, the Initiative will have challenges obtaining complete and accurate data. Examining available information, there are several positive trends. Among the associations responding to the 2016 APEC ethics survey (33 of 50 with codes or commitments), **82%** report their code has performed "excellent" or "well" over the past year. Furthermore, **88%** of these associations report that a majority of their members have implemented the association's code into daily practices. In examining all 50 associations with codes or commitments, at least **58%** report that a majority of their members have implemented the code.

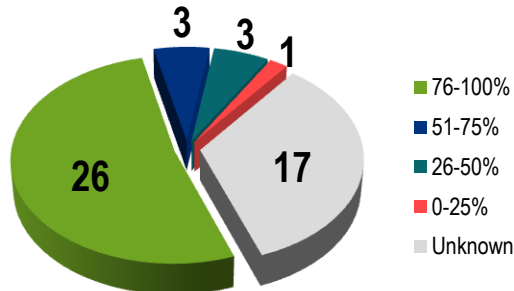
Self-Assessment on Code Performance by the 50 Associations with a Code / Commitment



Associations who require members to certify compliance with the code



Reported Member Implementation Rate by the 50 Associations with a Code / Commitment



ASSOCIATION MONITORING

Associations who maintain an active list of members who have certified compliance with the code of ethics	48%
Associations who receive notification when members conduct external validation or audits to measure compliance with the code	21%
Associations who receive notification, and also make a list readily available of their members who conduct external validation or audits	11%

SUB REGION	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

THE AMERICAS

ASILFA	Chile	11	7	No	N/A	N/A	N/A	No	No	No
CIF Chile	Chile	18	0	Yes	2006	2012	76-100%	No	No	Yes
CGPA	Canada	9	4	Yes	1998	2013	No Data	No	No	No
Innovative Medicines Can.	Canada	51	32	Yes	1988	2016	76-100%	Yes	Yes	Yes
CANIFARMA	Mexico	95	No Data	Yes	2005	2013	No Data	No	No	No
ANAFAM	Mexico	28	0	Yes	2005	2013	51-75%	Yes	Yes	Yes
AMIIF	Mexico	41	0	Yes	2005	2013	76-100%	No	No	No
ADIFAN	Peru	12	12	Yes	2014	N/A	No Data	Yes	Yes	Yes
ALAFARPE	Peru	19	7	Yes	2016	N/A	76-100%	No	Yes	Yes
ALAFAL	Peru	11	5	Yes	2006	2016	76-100%	No	No	Yes
PhRMA	United States	52	13	Yes	2002	2009	76-100%	Yes	Yes	Yes
ALIFAR	Multi	N/A	N/A	No	N/A	N/A	N/A	No	No	No
FIFARMA	Multi	11	0	Yes	2014	N/A	76-100%	No	No	Yes

OCEANIA

Medicines Aust.	Australia	37	10	Yes	1960	2015	76-100%	Yes	Yes	No
GBMA	Australia	8	4	Yes	2010	2015	76-100%	No	No	No
Medicines N.Z.	New Zealand	26	9	Yes	1962	2015	76-100%	No	No	No

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NORTH & EAST ASIA

All-China Fed.	China	No Data	No Data	Yes*	2013*	2015*	No Data	No	No	No
CAPC	China	384	249	Yes*	2013*	2015*	51-75%	Yes	No	No
CATCM	China	600	400	Yes*	2013*	2015*	No Data	Yes	No	No
CCCMHPIE	China	1,840	1,688	Yes*	2013*	2015*	51-75%	Yes	Yes	Yes
CMBA	China	No Data	No Data	Yes*	2015*	N/A*	No Data	No	No	No
CMEA	China	No Data	No Data	Yes*	2015*	N/A*	No Data	No	No	No
CNMA	China	350	No Data	Yes*	2013*	2015*	No Data	No	No	No
CPAPE	China	350	No Data	Yes*	2015*	N/A*	No Data	No	No	No
CPEMA	China	No Data	No Data	Yes*	2015*	N/A*	No Data	No	No	No
CPEP	China	No Data	No Data	Yes*	2013*	2015*	No Data	No	No	No
CPIA	China	308	90	Yes*	2013*	2015*	26-50%	Yes	Yes	No
CPPA	China	No Data	No Data	Yes*	2015*	N/A*	No Data	No	No	No
COAP	China	No Data	No Data	Yes*	2015*	N/A*	No Data	No	No	No
CRAECC	China	No Data	No Data	Yes*	2013*	2015*	No Data	No	No	No
PhIRDA	China	70	35	Yes*	2013*	2015*	76-100%	Yes	Yes	Yes
RDPAC	China	38	0	Yes	2006	2015	76-100%	Yes	Yes	No
HKPMA	Hong Kong, China	38	35	No	N/A	N/A	N/A	No	No	No

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NORTH & EAST ASIA

PDAHK	Hong Kong, China	44	44	No	N/A	N/A	N/A	No	No	No
HKAPI	Hong Kong, China	42	30	Yes	1970	2016	76-100%	Yes	Yes	Yes
JGA	Japan	41	30	Yes	2010	N/A	76-100%	No	Yes	No
JPMA	Japan	73	7	Yes	1993	2013	76-100%	Yes	Yes	Yes
KoBIA	Korea	107	50	No	N/A	N/A	N/A	No	No	No
KPMA	Korea	183	118	Yes	1994	2014	51-75%	Yes	No	No
KRPIA	Korea	41	0	Yes	2009	2014	76-100%	No	No	No
CAPA	Chinese Taipei	125	115	No	N/A	N/A	N/A	No	No	No
CPMDA	Chinese Taipei	50	16	No	N/A	N/A	N/A	No	No	No
IRPMA	Chinese Taipei	46	36	Yes	1994	2016	76-100%	No	No	No
NPCA	Chinese Taipei	No Data	No Data	No	N/A	N/A	N/A	No	No	No
TRPMA	Chinese Taipei	28	28	No	N/A	N/A	N/A	No	No	No
TGPA	Chinese Taipei	50	10	No	N/A	N/A	N/A	No	No	No
TPADA	Chinese Taipei	175	165	No	N/A	N/A	N/A	No	No	No
TPMA	Chinese Taipei	163	122	No	N/A	N/A	N/A	No	No	No
TPMMA	Chinese Taipei	55	55	No	N/A	N/A	N/A	No	No	No

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SOUTHEAST ASIA	G.P. Farmasi	Indonesia	2,900	2,300	Yes	2003	2016	26-50%	Yes	Yes	No
	IPMG	Indonesia	25	0	Yes	2001	2015	76-100%	Yes	Yes	No
	MOPI	Malaysia	42	32	Yes	2013	N/A	No Data	Yes	No	No
	PhAMA	Malaysia	41	13	Yes	1978	2015	76-100%	No	No	No
	MEPI	Philippines	46	0	Yes*	2015*	N/A*	No Data	No	No	No
	PHAP	Philippines	38	10	Yes	1993	2016	76-100%	Yes	Yes	Yes
	PCPI	Philippines	120	100	Yes	2014	N/A	26-50%	Yes	Yes	Yes
	SMF-LSIG	Singapore	48	30	No	N/A	N/A	N/A	No	No	No
	SAPI	Singapore	35	0	Yes	<2010	2016	76-100%	No	No	No
	PReMA	Thailand	37	14	Yes	1986	2016	76-100%	Yes	Yes	Yes
	GPO	Thailand	1	0	Yes*	2014*	N/A*	No Data	No	Yes	No
	TPMA	Thailand	70	60	Yes	2016	N/A	26-50%	No	Yes	Yes
	VNPCA	Viet Nam	155	120	Yes	2013	2015	0-25%	Yes	Yes	Yes
	Pharma Group	Viet Nam	23	0	Yes	2014	2016	76-100%	No	Yes	Yes

EUROPE	AIPM	Russia	31	0	Yes	1998	2015	76-100%	No	No	No
	ARPM	Russia	20	0	No	N/A	N/A	N/A	No	No	No