



**Asia-Pacific
Economic Cooperation**

**Business Ethics for APEC SMEs
Medical Device Sector**



Report on Code of Ethics Implementation by APEC Medical Device 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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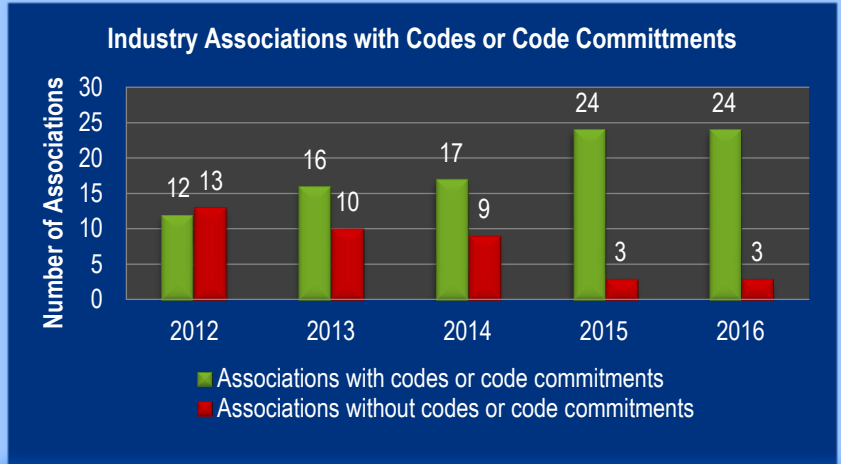
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INTRODUCTION

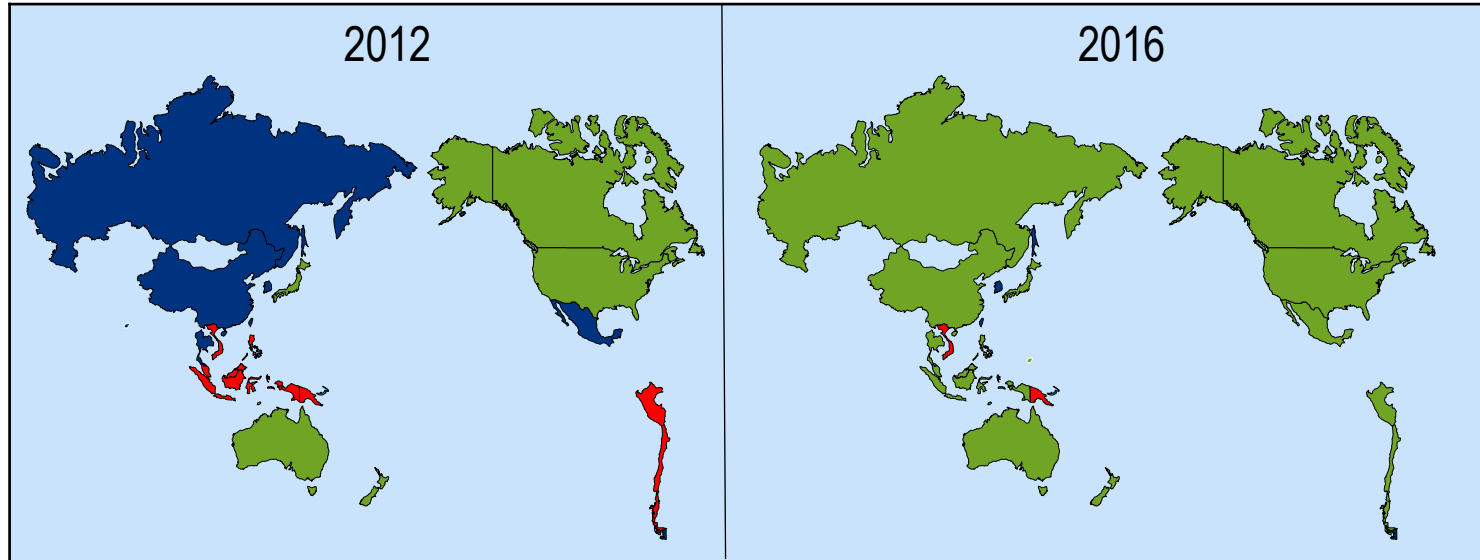
The *Business Ethics for APEC SMEs Initiative* monitors code of ethics development and implementation by 27 medical device industry associations across the APEC region. These associations collectively represent over 12,000 member enterprises, of which nearly 10,000 are identified as SMEs. These enterprises 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 associations had a code of ethics. In 2016, 24 of these associations have a code of ethics or formalized commitment. As a result, the Initiative met the goal endorsed by the 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 medical device 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

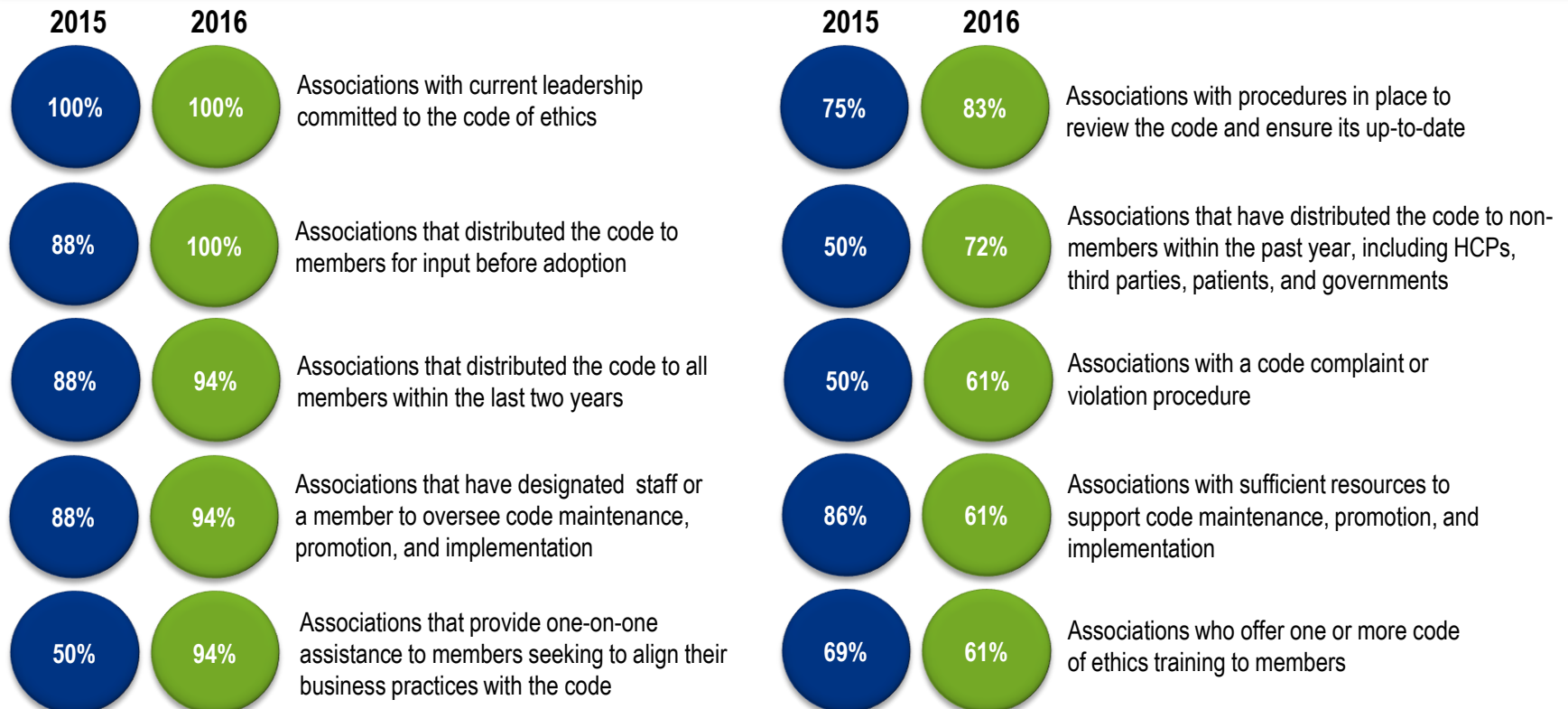
12 new codes in 7 economies that did not exist in 2012

- Codes or commitments with broad coverage of the sector
- Codes undergoing development or alignment

Industry Associations Monitored	27	
Member Companies	12,100+	
SME Member Companies	9,800+	
STATUS REPORT	2012	2016
Associations with Code / Commitment	12	24 (↑12)
Member Companies	6,500+	11,600+ (↑5,100+)
SME Member Companies	5,700+	9,400+ (↑3,700+)

CODE GOVERNANCE

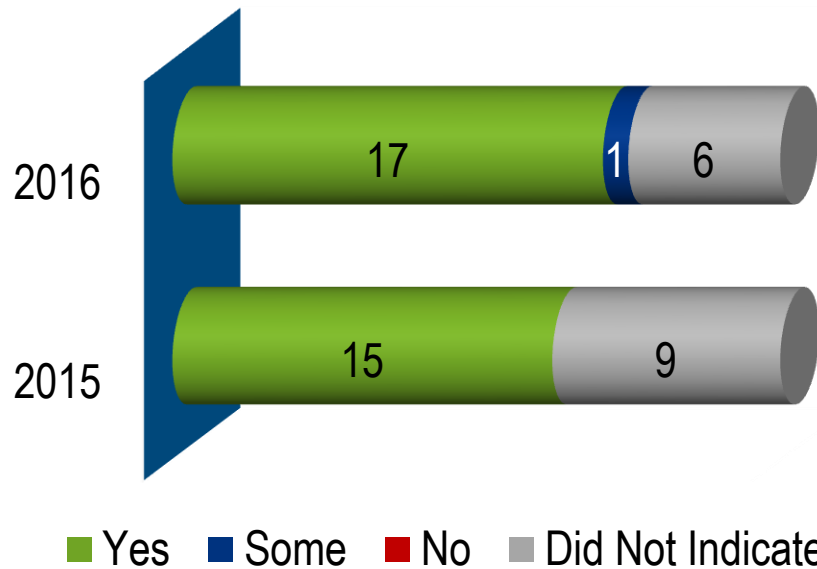
Medical device industry association codes of ethics are strong tools to disseminate and harmonize ethical practices among many enterprises. However, they only serve as effective tools if robust code governance is in place. The Initiative monitors several crucial areas to identify whether such governance exists. Responses from those associations completing the 2016 APEC ethics survey (18 of the 24 with codes or commitments) indicate that most have a valid governance structure in place and have been working to improve them over the past year. Of note, **100%** continue to indicate their current leadership is committed to the code. There was also a **44%** increase in the number of associations that provide one-on-one code implementation assistance to members as well as a **22%** increase in the number of associations distributing their codes to non-member stakeholders. However, there is opportunity for associations to expand regular code trainings, which appear to be decreasing from reduced resources.



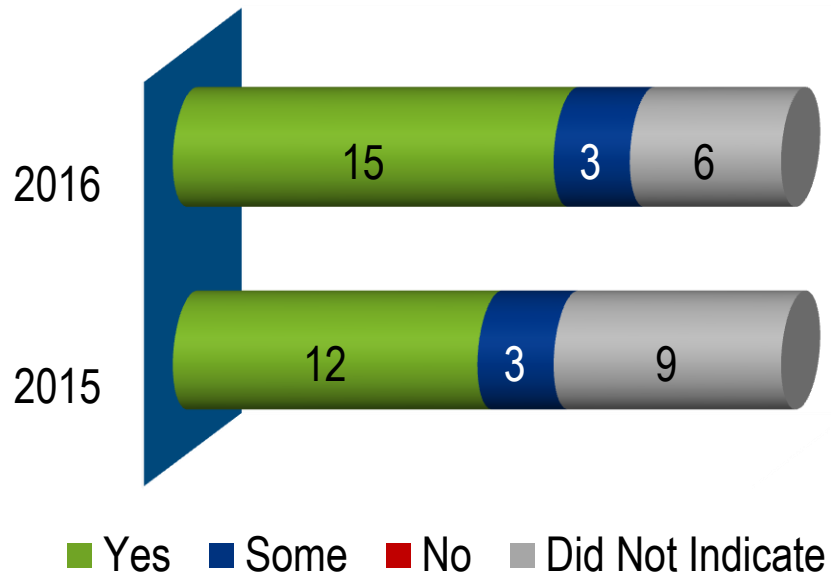
ALIGNMENT WITH THE APEC KUALA LUMPUR PRINCIPLES

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 medical device industry association codes of ethics achieve alignment with the APEC Kuala Lumpur Principles and the APEC model industry association code. There has been notable success in this effort. 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 2016 APEC ethics survey (18 of the 24 with codes or commitments), **94%** report their code embraces all five fundamental principles of the APEC Kuala Lumpur Principles and **83%** report their code incorporates the Principles' provisions.

Reported embrace of the five fundamental principles of the APEC Kuala Lumpur Principles by the 24 associations with a code or code commitment



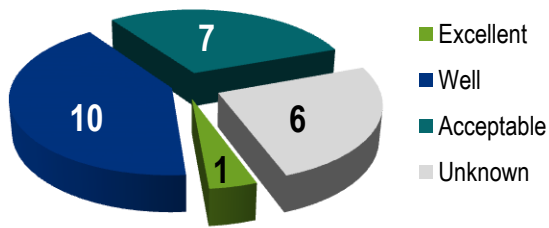
Reported alignment with the provisions of the APEC Kuala Lumpur Principles by the 24 associations with a code or code commitment



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. Among the associations responding to the 2016 APEC ethics survey (18 of the 24 with codes or commitments), **61%** report their code has performed “excellent” or “well” over the past year. Furthermore, the same percentage (**61%**) of these associations report that a majority of their members have implemented the association’s code into their daily business practices. In examining all 24 associations with codes or commitments, at least **46%** report that a majority of their members have implemented the code.

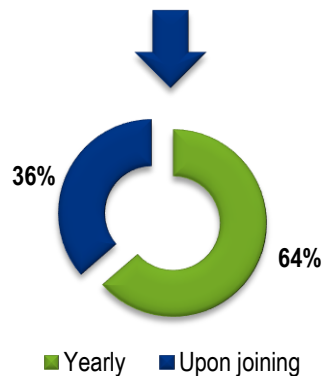
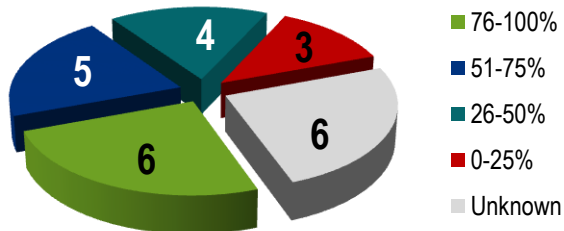
Self-Assessment on Code Performance by the 24 Associations with a Code / Commitment



Associations who require members to certify compliance with the code



Reported Member Implementation Rate by the 24 Associations with a Code / Commitment



ASSOCIATION MONITORING

Associations who maintain an active list of members who have certified compliance with the code of ethics	44%
Associations who receive notification when members conduct external validation or audits to measure compliance with the code	0

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	MEDEC	Canada	96	46	Yes	2006	2015	26-50%	Yes	Yes	No
	SCDM	Chile	21	13	Yes	2013	N/A	26-50%	Yes	Yes	Yes
	AMID	Mexico	28	0	Yes	2009	2013	76-100%	Yes	Yes	Yes
	COMSALUD-CCL	Peru	300	240	Yes	2012	N/A	25-50%	Yes	Yes	Yes
	AdvaMed	United States	280	204	Yes	1993	2009	51-75%	Yes	Yes	Yes

NORTH & EAST ASIA	CAMDI	China	1,950	1,100	Yes*	2015*	N/A*	No Data	Yes	Yes	Yes
	CAME	China	No Data	No Data	No	N/A	N/A	N/A	No	No	No
	AdvaMed China	China	N/A	N/A	Yes	2015	N/A	N/A	Yes	Yes	No
	CCCMHPIE	China	1,840	1,688	Yes*	2013*	2015*	51-75%	Yes	Yes	Yes
	HKMHDIA	Hong Kong, China	178	150	Yes	2009	N/A	0-25%	No	No	No
	JFMDA	Japan	4,280	4,000	Yes	1993	2010	51-75%	Yes	Yes	Yes
	KMDIA	Korea	876	800	Yes	2011	2012	51-75%	Yes	Yes	Yes
	TAMTA	Chinese Taipei	22	0	Yes	2015	N/A	76-100%	No	Yes	No
	TMBIA	Chinese Taipei	378	350	No	N/A	N/A	N/A	No	No	No

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
SOUTHEAST ASIA	Gakeslab	Indonesia	762	641	Yes	2015	2016	0-25%	Yes	Yes	No
	AMMI	Malaysia	59	20	Yes	2014	N/A	76-100%	No	No	No
	MMDA	Malaysia	167	100	Yes	2013	N/A	26-50%	No	No	No
	PAMDRAP	Philippines	88	45	Yes	2015	N/A	0-25%	Yes	Yes	Yes
	MEPI	Philippines	46	0	Yes*	2015*	N/A*	No Data	No	No	No
	APACMed	Multi	40	5	Yes	2015	N/A	76-100%	N/A	Yes	No
	AMDI	Singapore	111	81	No	N/A	N/A	N/A	No	No	No
	SMF-MTIG	Singapore	87	35	Yes	2013	N/A	0-25%	Yes	Yes	No
	THAIMED	Thailand	107	57	Yes	2008	2013	76-100%	Yes	No	No
OCEANIA	ADIA	Australia	185	184	Yes	1983	2014	51-75%	No	No	No
	MTAA	Australia	82	33	Yes	2006	2015	76-100%	Yes	Yes	No
	MTANZ	New Zealand	110	52	Yes	2005	2016	76-100%	Yes	No	Yes
EUROPE	IMEDA	Russia	40	0	Yes	<2012	2013	76-100%	Yes	No	No