

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





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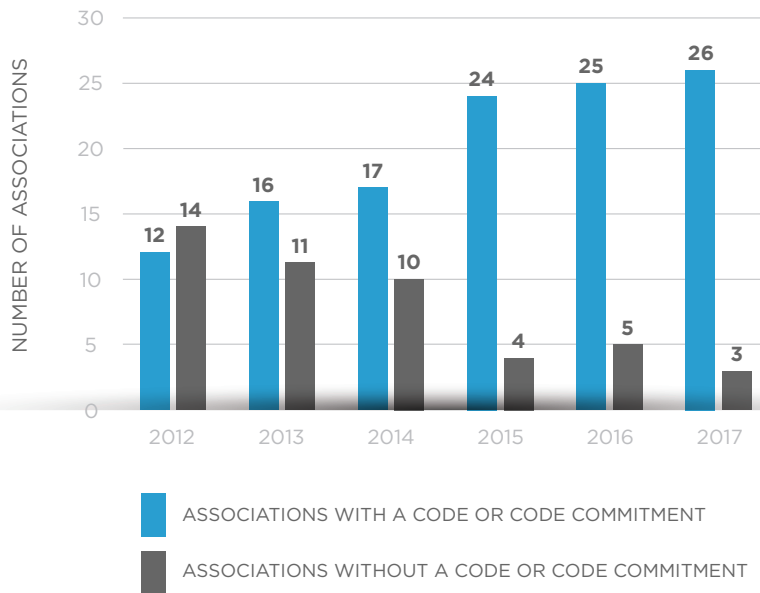
Introduction

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.

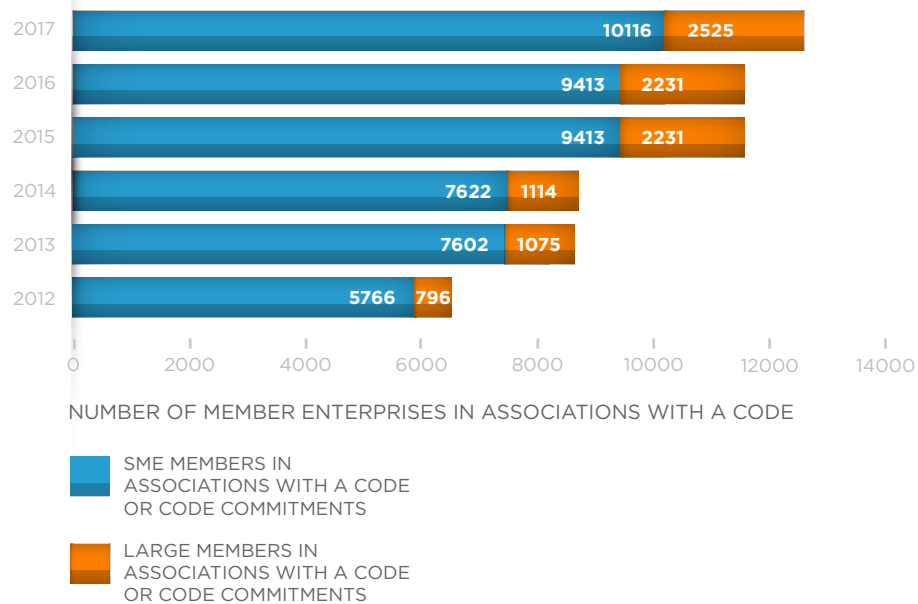
When this initiative's capacity-building program was launched in 2012 to support implementation of the APEC Kuala Lumpur Principles, 12 of these monitored medical device sector industry associations had a code of ethics. In 2017, 26 of these associations have a code of ethics or formalized commitment.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

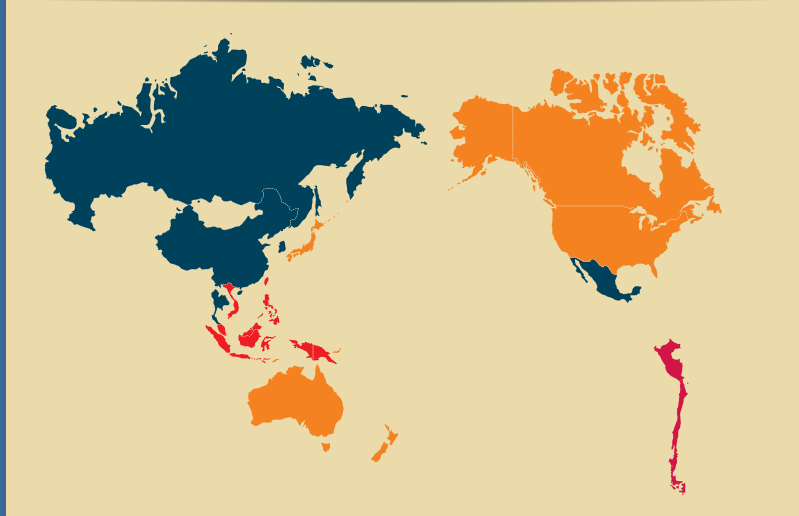


ENTERPRISE MEMBERSHIP OF ASSOCIATIONS WHO HAVE ADOPTED A CODE OR CODE COMMITMENT



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

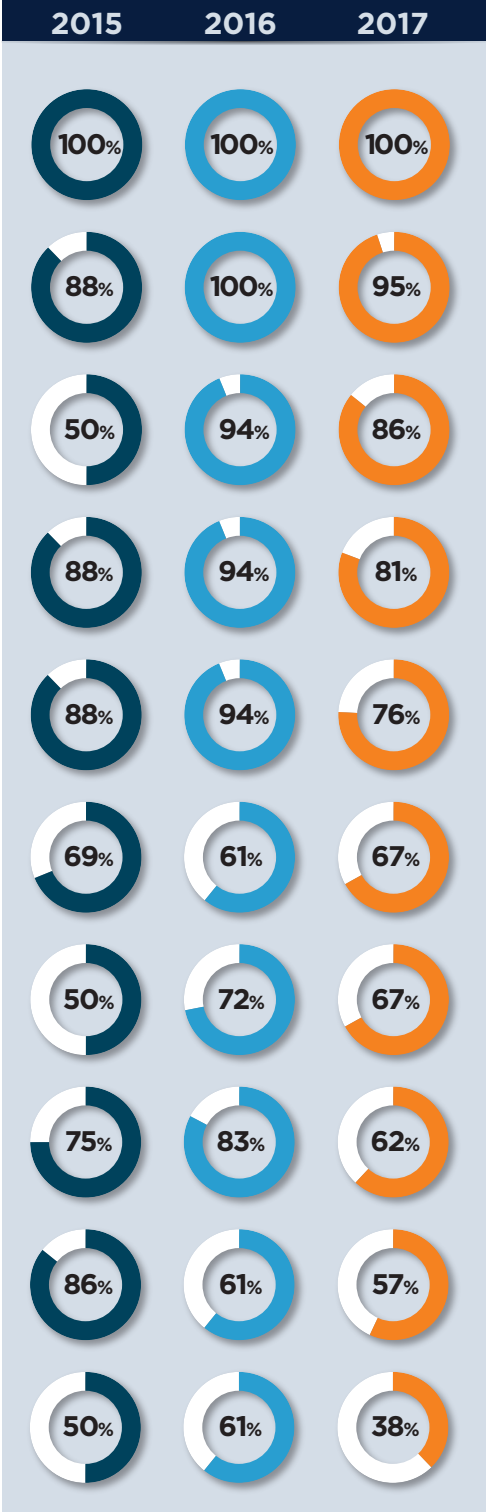
Industry Associations Monitored:	29
Total Member Enterprises:	13,100+
SME Members:	10,500+

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

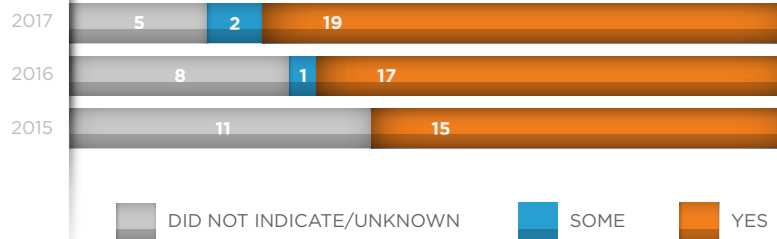
Associations with a code complaint or violation procedure

Code Alignment with the APEC Kuala Lumpur Principles

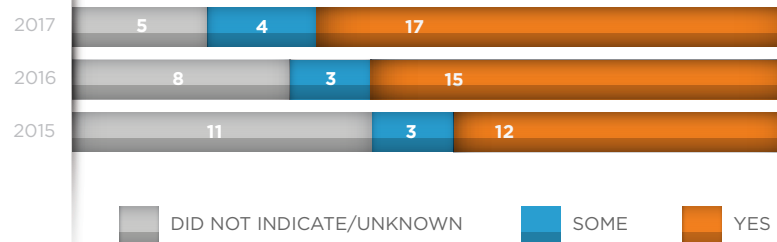
The *Business Ethics for APEC SMEs Initiative* has conducted six medical device sector capacity-building programs since 2012 and has extended support for dozens of local trainings to ensure that new and existing medical device industry association codes of ethics achieve alignment with the APEC Kuala 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:

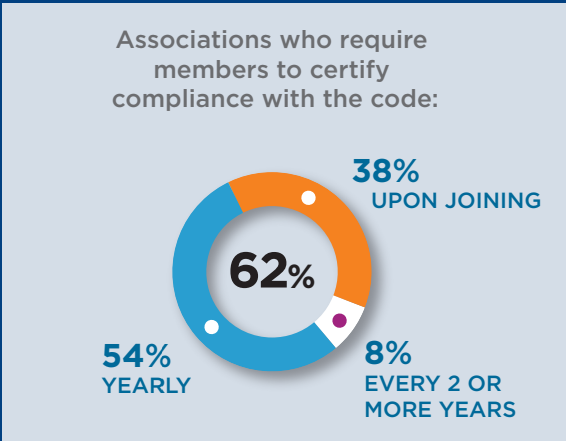


REPORTED ALIGNMENT WITH THE PROVISIONS OF THE APEC KUALA LUMPUR PRINCIPLES BY THE 26 ASSOCIATIONS WITH A CODE OR CODE COMMITMENT:

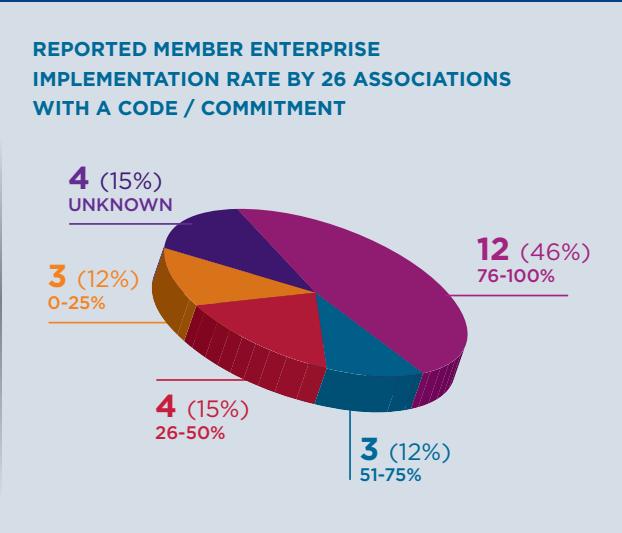
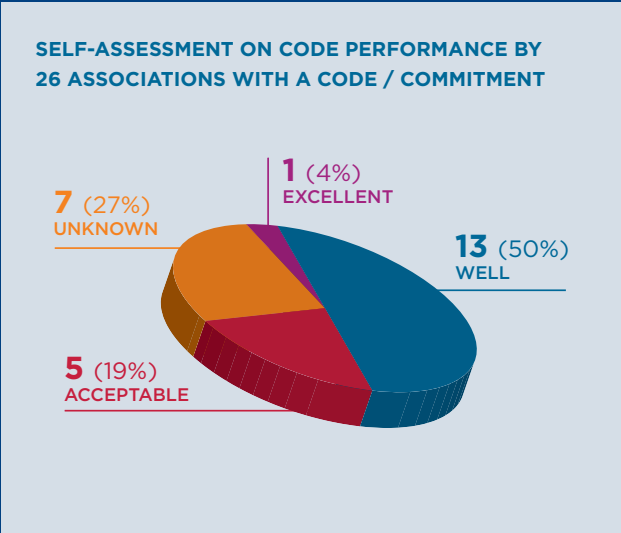


Member Enterprise Implementation

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



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