

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

Table of Contents

- 1-2 INTRODUCTION
- 3 REGIONAL OVERVIEW
- 4 CODE GOVERNANCE
- 5 ALIGNMENT WITH THE APEC KUALA LUMPUR PRINCIPLES
- 6 MEMBER IMPLEMENTATION
- 7 EXTERNAL ENGAGEMENT
- 8-9 STATISTICS BY APEC MEDICAL DEVICE INDUSTRY ASSOCIATION

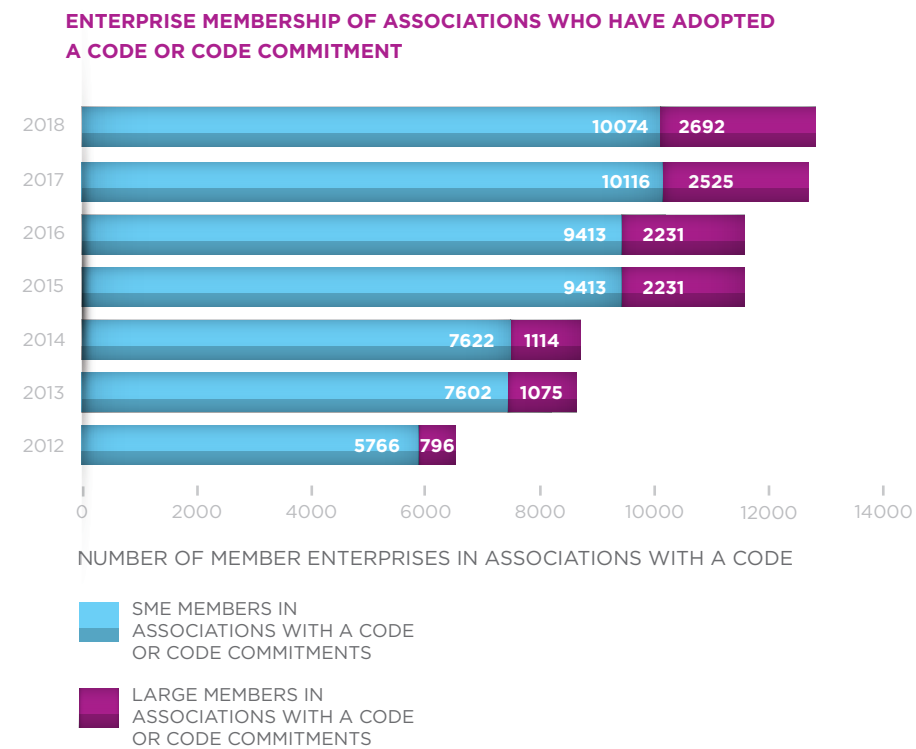
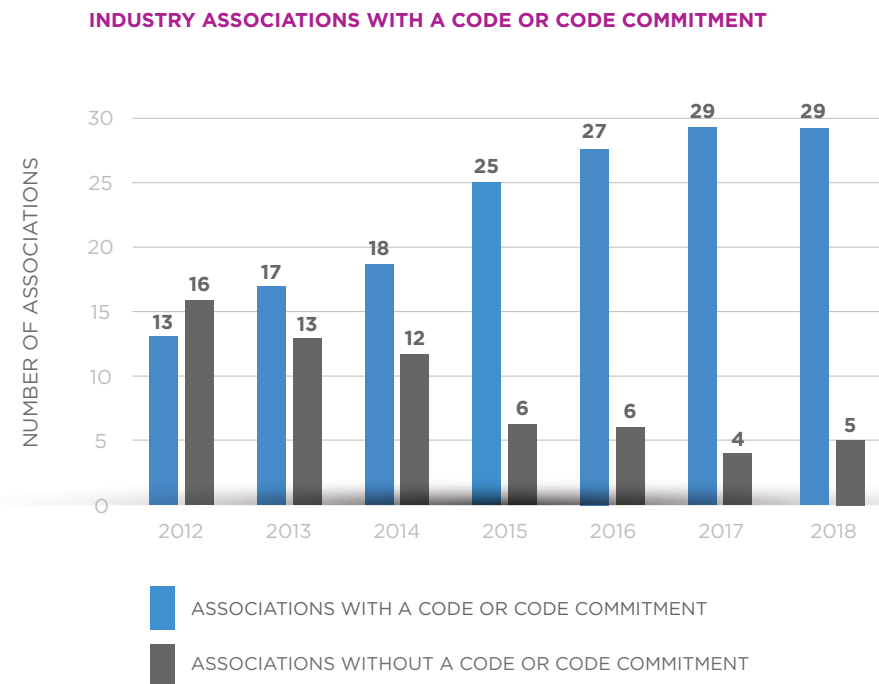
Introduction

The *Business Ethics for APEC SMEs Initiative* monitors code of ethics development and implementation by 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.

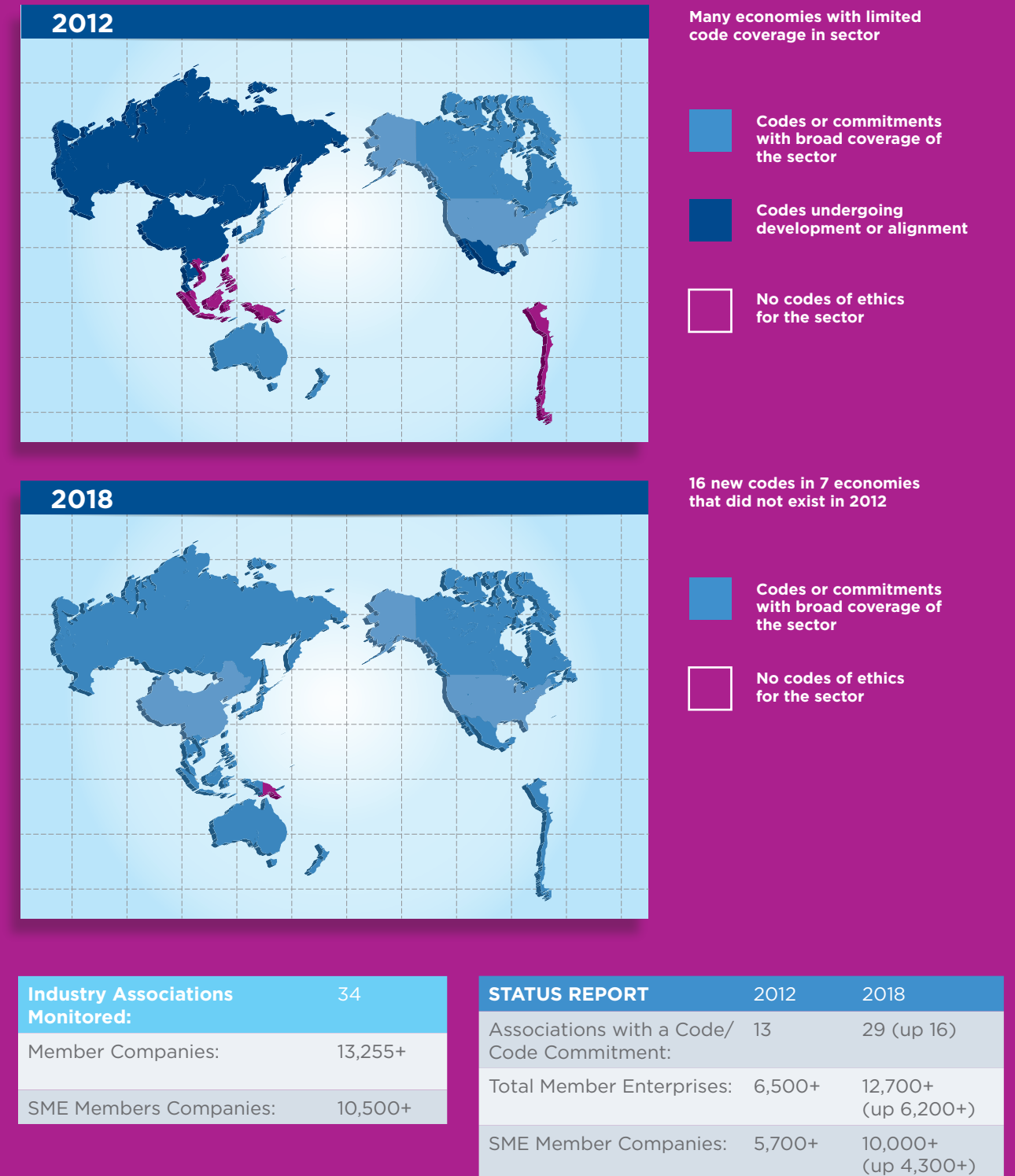
When this initiative's capacity-building program was launched in 2012 to support implementation of the APEC Kuala Lumpur Principles, 13 of these monitored medical device sector industry associations had a code of ethics. In 2018, 29 of these associations have a code of ethics or formalized commitment. 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.

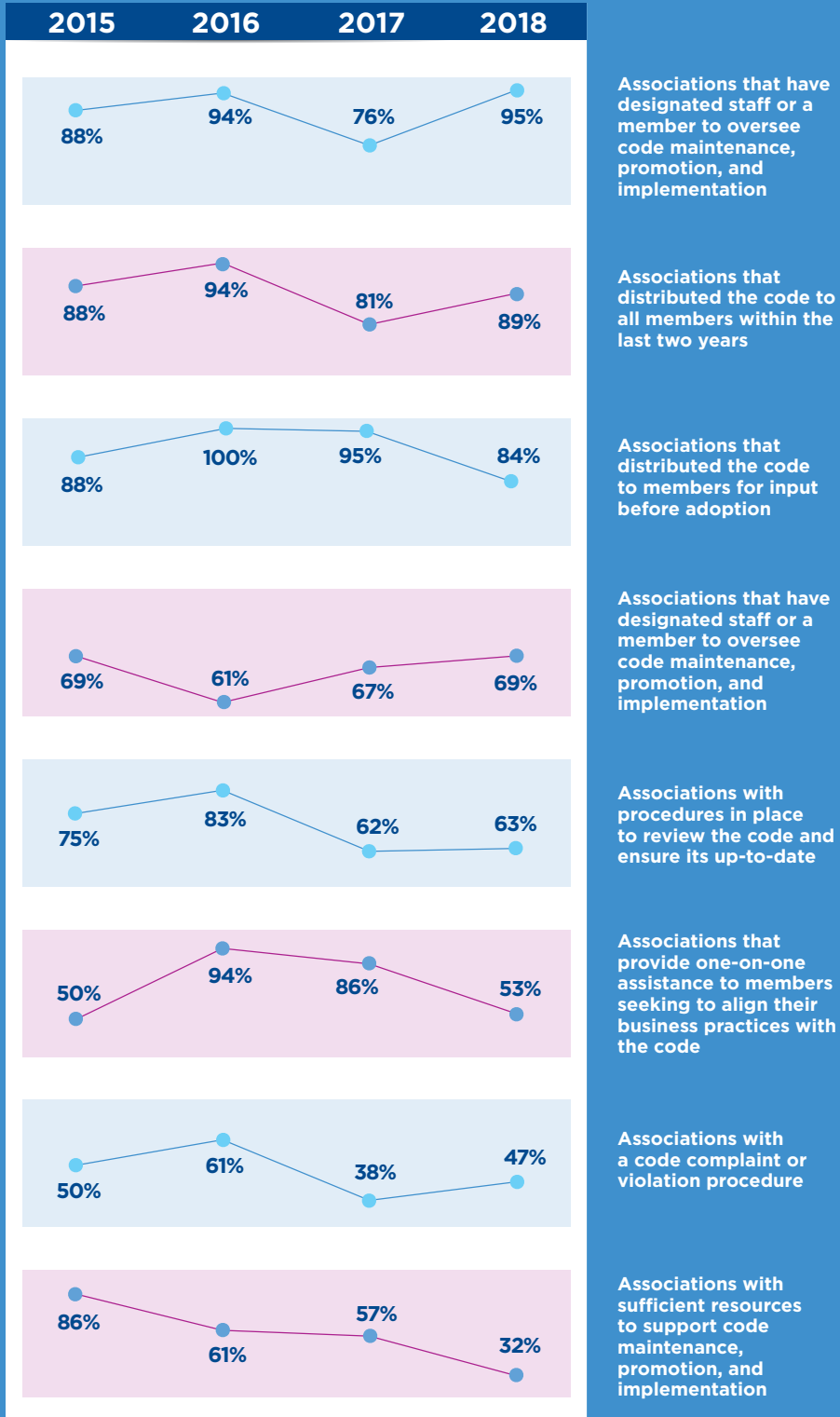


Regional Overview



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.

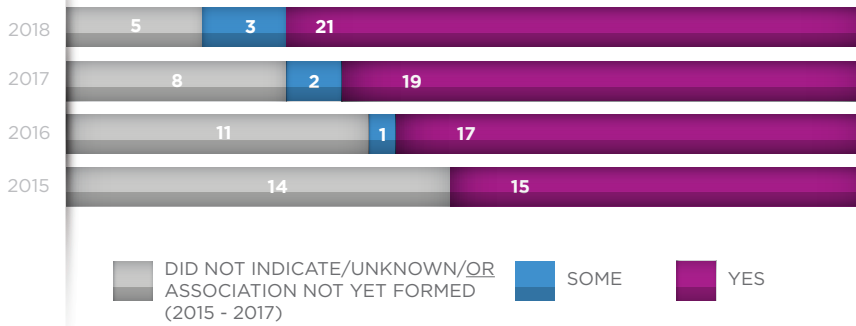


Alignment with the APEC Kuala Lumpur Principles

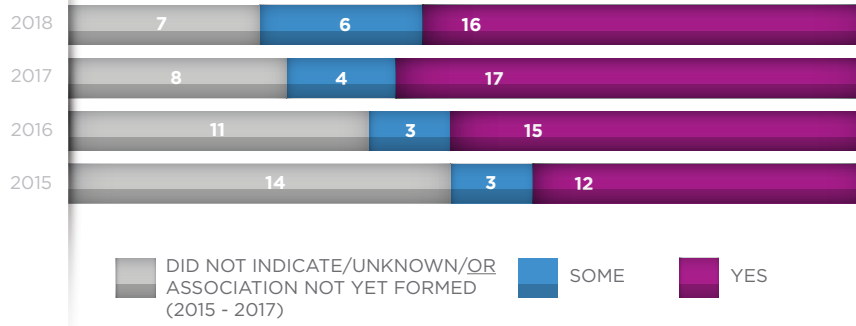
The *Business Ethics for APEC SMEs Initiative* has conducted seven medical device sector capacity-building programs since 2012 and has extended support for dozens of local trainings to ensure that new and existing medical device industry association codes of ethics achieve alignment with the APEC Kuala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

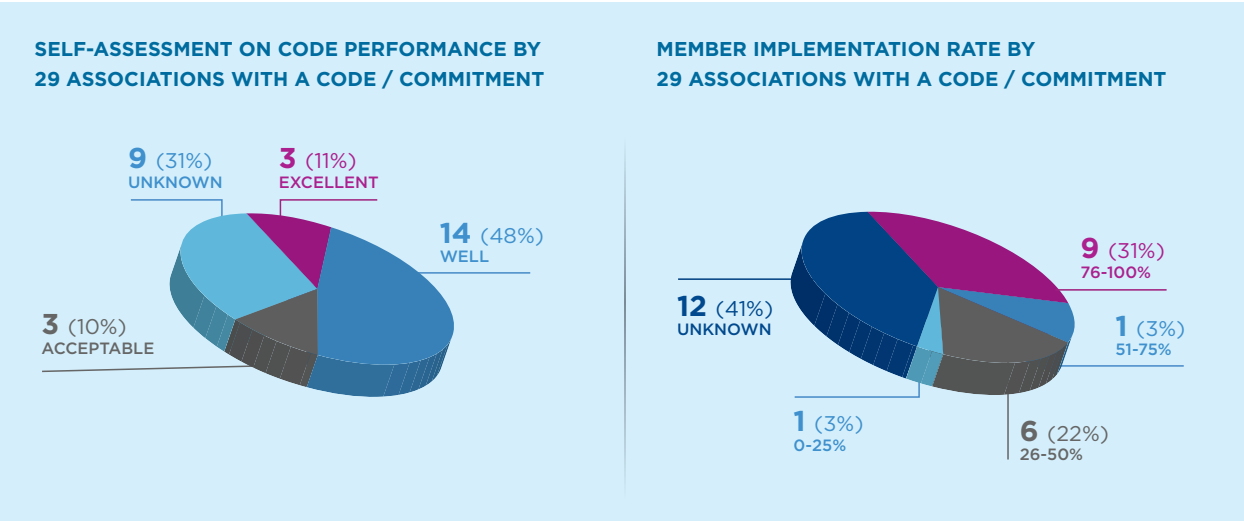


Member Implementation

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.



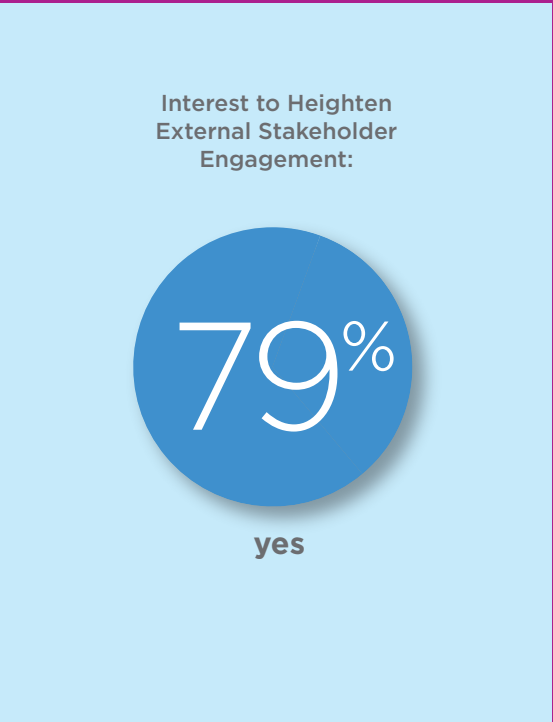
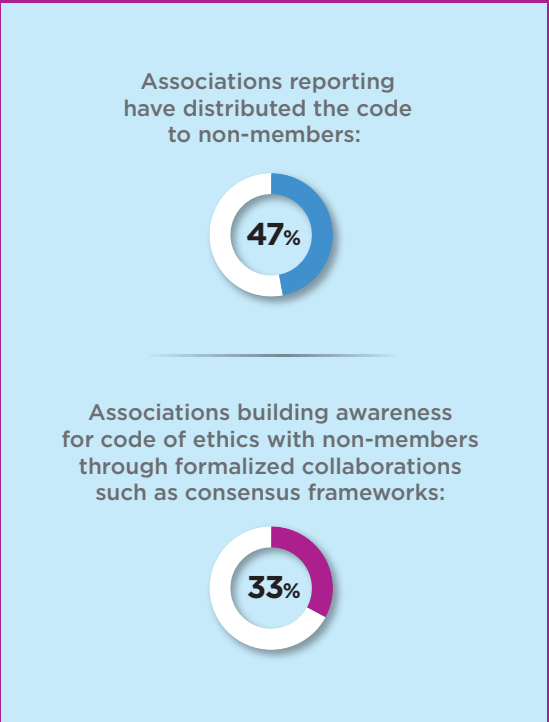
Association Monitoring	
Associations who maintain an active list of members who have certified compliance with the code of ethics:	28%
Associations who receive notification when members conduct external validation or audits to measure compliance with the code:	0%



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	Vietnam	20	0	Yes	2017	N/A	No Data	No	No	No	Yes	No
VIMEDAS	Vietnam	1,000	750	Yes	2015	2016	No Data	No	No	No	Yes	No



**Asia-Pacific
Economic Cooperation**

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