

2019 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 CODE ALIGNMENT WITH THE APEC
KUALA LUMPUR PRINCIPLES

6 MEMBER ENTERPRISE
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.

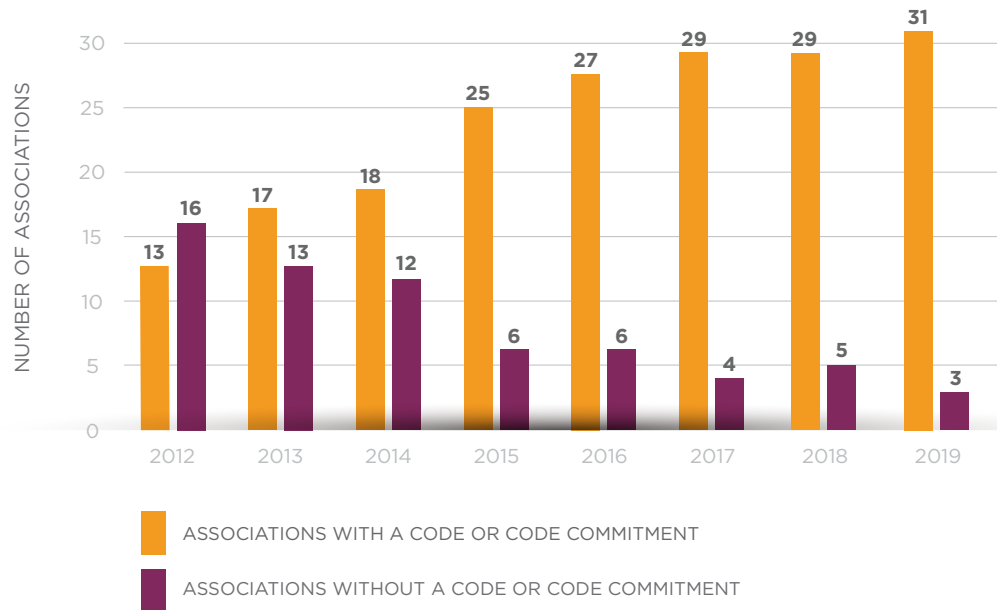
When this initiative's capacity-building program was launched in 2012 to support implementation of the APEC Kuala Lumpur Principles, 13 of these monitored medical device sector industry associations had a code of ethics. In 2019, 31 of these associations have a code of ethics or formalized commitment. The initiative remains dedicated to realizing all medical device sector industry associations that have adopted a code also achieve implementation of code 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 three associations located in China, Singapore, and Chinese Taipei.

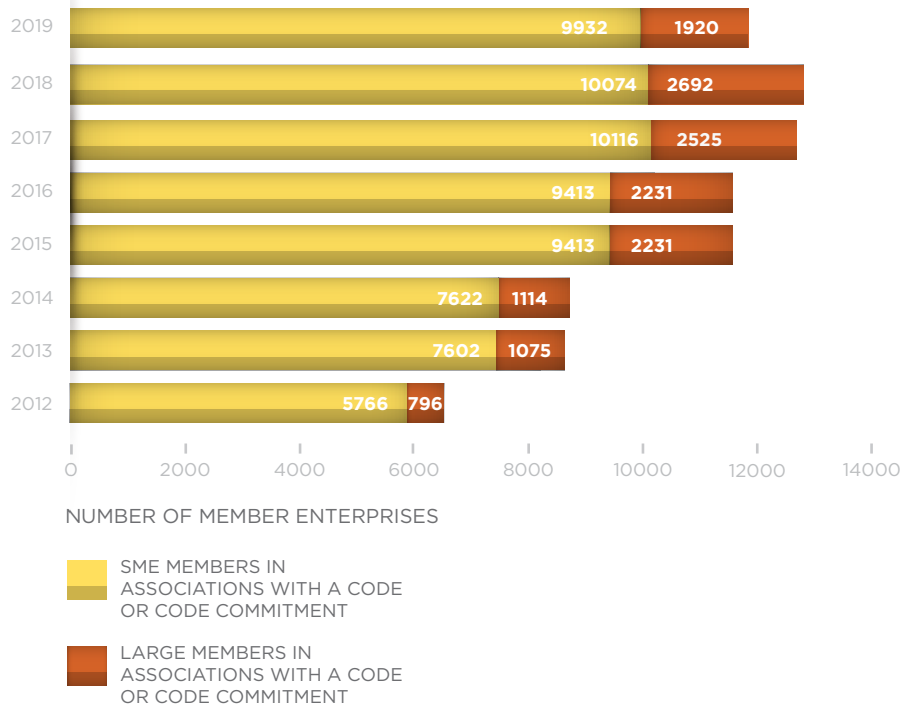
This report has been prepared for the 2019 APEC Business Ethics for SMEs Forum, to indicate where progress has been made since 2012, and where challenges remain, for the region's medical device sector industry associations in (A) code governance, (B) code alignment with the APEC Principles, (C) member enterprise implementation of the code, and (D) external stakeholder engagement on the code. 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

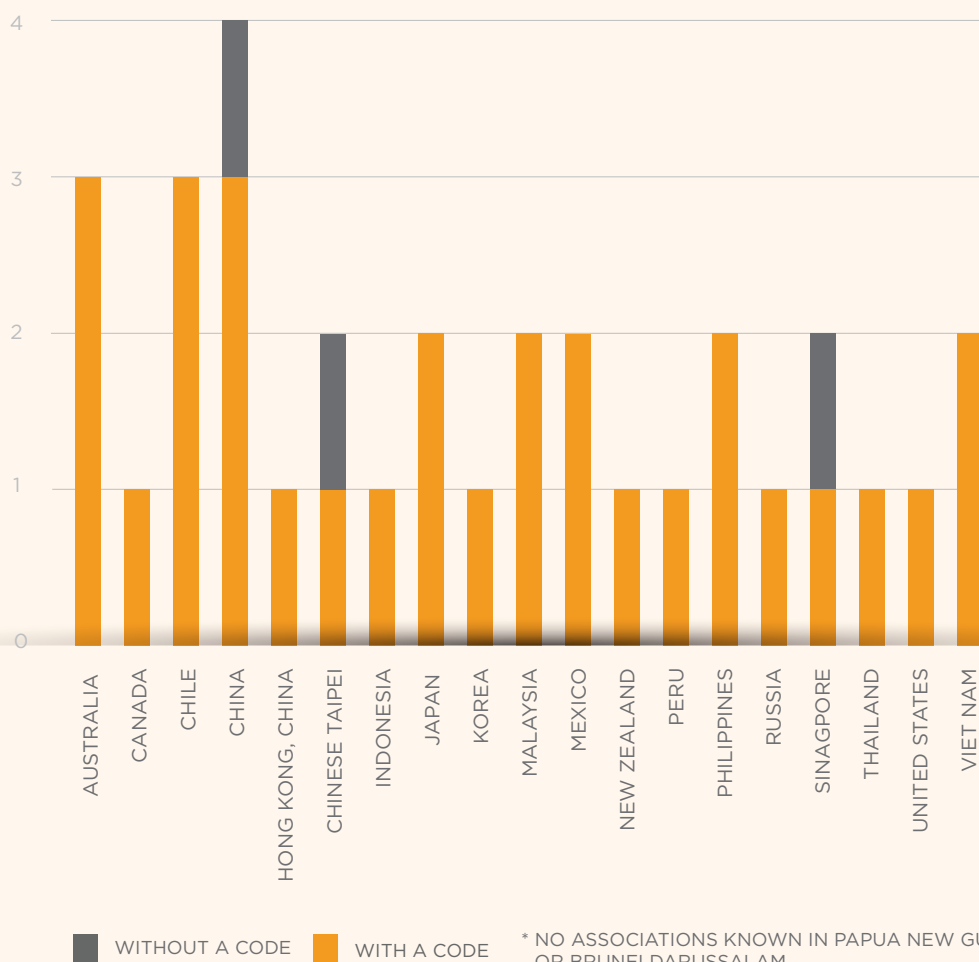


ENTERPRISE MEMBERSHIP OF ASSOCIATIONS WHO HAVE ADOPTED A CODE OR CODE COMMITMENT



Regional Overview

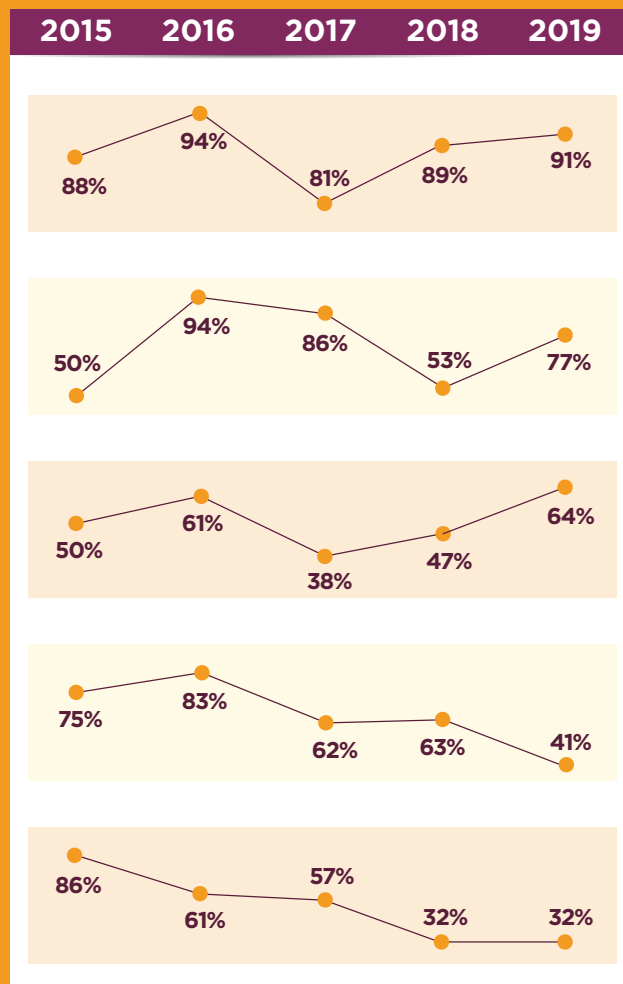
2019 REGIONAL BREAKDOWN*



STATUS REPORT	2012	2019
Associations with a Code / Code Commitment:	13	31 (up 18)
Total Member Enterprises:	6,500+	12,300+ (up 5,800+)
SME Member Companies:	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 2019 survey (22 of the 31 with codes or commitments) indicate there has been a decline in 2019 in associations with procedures in place to review the code and ensure it is up-to-date along with continued challenges with sufficient resources to support the code. Areas of growth include associations offering one-on-one assistance, distribution of the code to all members, and an increase in associations with a code complaint or violation procedure.



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

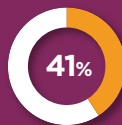
Associations that distributed the code to all members within the last two years

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

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

Associations with a code complaint or violation procedure

APEC GUIDANCE FOR ETHICAL THIRD PARTY INTERMEDIARY RELATIONSHIPS IN THE MEDICAL TECHNOLOGY SECTOR - TRAINING



Associations offering code of ethics training for third party enterprises such as sales and marketing intermediaries (e.g. distributors and other service providers for medical device companies)



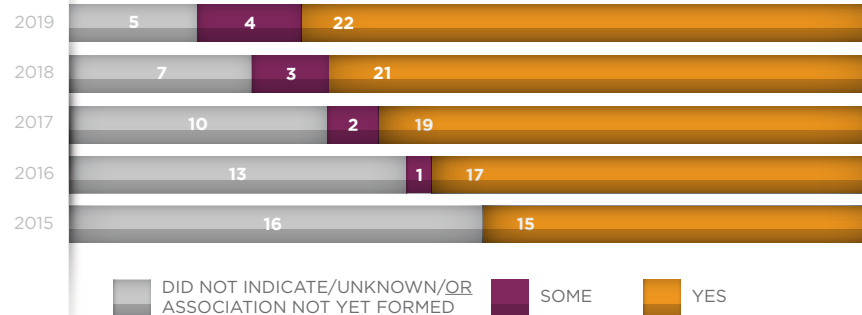
Association offering code of ethics training to individual sales representatives

Alignment with the APEC Kuala Lumpur Principles

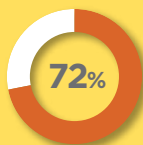
The *Business Ethics for APEC SMEs Initiative* has conducted eight medical device sector capacity-building programs since 2012 and has extended support for dozens of local trainings to ensure that medical device industry association codes of ethics achieve alignment with the APEC

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.

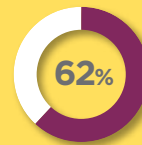
REPORTED EMBRACE OF THE FIVE FUNDAMENTAL PRINCIPLES OF THE APEC KUALA LUMPUR PRINCIPLES BY ASSOCIATIONS WITH A CODE OR CODE COMMITMENT:



APEC GUIDANCE FOR ETHICAL THIRD PARTY INTERMEDIARY RELATIONSHIPS IN THE MEDICAL TECHNOLOGY SECTOR - ALIGNMENT:



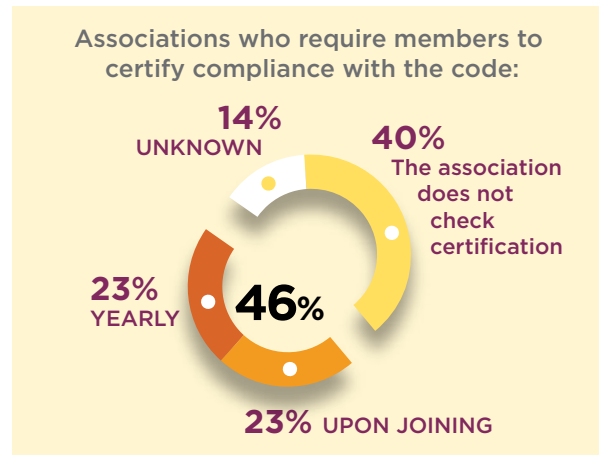
of associations report that the current code of ethics includes specific guidance to strengthen ethical relationships between medical device companies (such as manufacturers) and third party intermediaries (such as distributors)



of associations have sought to align its code or practices with the Guidance

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 2019 survey (22 of the 31 associations with codes or code commitments), 50% 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:

30%

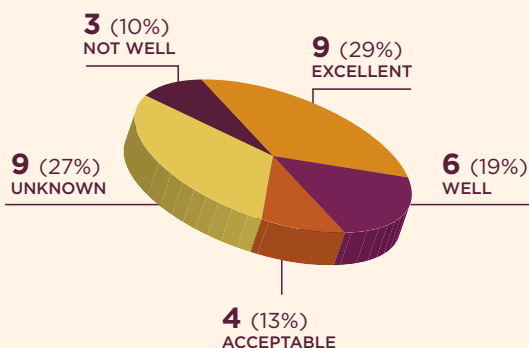
Associations who receive notification when members conduct external validation or audits to measure compliance with the code:

0%

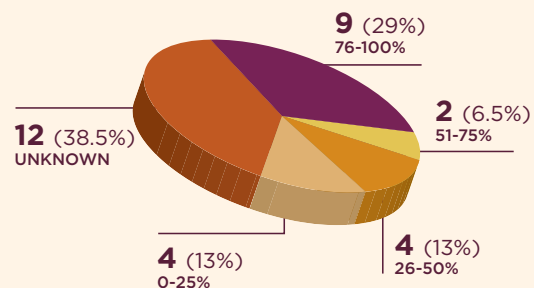
Associations who have a mechanism for individual sales representatives to certify to the code of ethics:

24%

SELF-ASSESSMENT ON CODE PERFORMANCE BY 31 ASSOCIATIONS WITH A CODE / COMMITMENT



MEMBER IMPLEMENTATION RATE BY 31 ASSOCIATIONS WITH A CODE / COMMITMENT

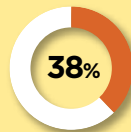


External Engagement

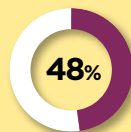
How medical device industry associations engage with external stakeholders (non-members) on their codes of ethics has emerged as fourth area of assessment in code implementation. While important for association members to adhere and implement their code, many encounter a “non-member dilemma” of how to 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 2019 survey (22 of the 31 associations with codes or code commitments), 38% report they have distributed the code to non-members. 76% of associations report they are interested to heighten external stakeholder engagement on their code of ethics.

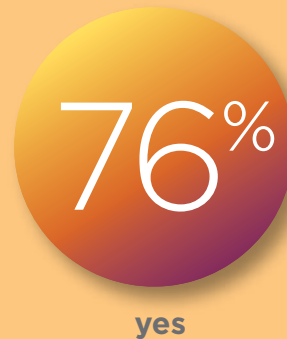
Associations reporting that they have distributed the code to non-members:



Associations building awareness for code of ethics with non-members through formalized collaborations such as consensus frameworks: :



Interest to Heighten External Stakeholder Engagement:



Association	Economy	Member Enterprises		Code Adoption <i>Code Commitment*</i>			Member Implementation	Participation in Consensus Framework Agreement
		TOTAL	SMEs	Yes/No	Year Adopt	Last Update		
ADIA	Australia	170	160	Yes	1974	2011	76-100%	Yes
MTAA	Australia	101	82	Yes	2001	2018	76-100%	Yes
IDV Australia	Australia	37	No Data	Yes	2010	2013	No Data	No
MedTech Canada	Canada	89	25	Yes	2005	2017	26-50%	Yes
ADIMECH	Chile	11	11	Yes	N/A	2019	76-100%	Yes
APIS	Chile	64	64	Yes	2018	2018	26-50%	Yes
SCDM	Chile	27	18	Yes	2013	2018	0-25%	Yes
AdvaMed China	China	40	0	Yes	2016	2017	No Data	No
CAMDI	China	1,350	1,053	Yes	2015	2016	26-50%	No
CAME	China	No Data	No Data	No	N/A	N/A	No Data	No
CCCMHPIE	China	1,650	1,485	Yes	2013	2017	26-50%	Yes
HKMHDIA	Hong Kong, China	178	150	Yes	2009	N/A	0-25%	No
TAMTA	Chinese Taipei	23	0	Yes	2015	2019	76-100%	No
TMBIA	Chinese Taipei	378	350	No	N/A	N/A	N/A	No
Gakeslab	Indonesia	375	362	Yes	2013	2015	0-25%	No
AMDD	Japan	58	0	Yes	2016	2016	No Data	No
JFDA	Japan	4,280	4,000	Yes	1993	2019	76-100%	Yes
KMDIA	Korea	825	788	Yes	2011	2017	No Data	No
AMMI	Malaysia	72	22	Yes	2013	2017	Unknown	No
MMDA	Malaysia	177	120	Yes	2013	2013	No Data	No
AMID	Mexico	32	5	Yes	2013	2019	76-100%	No
ASEMED	Mexico	No Data	No Data	Yes	No Data	No Data	No Data	No

Association	Economy	Member Enterprises		Code Adoption <i>Code Commitment*</i>			Member Implementation	Participation in Consensus Framework Agreement
		TOTAL	SMEs	Yes/No	Year Adopt	Last Update		
APACMed	Multi	118	40	Yes	2016	2018	76-100%	No
MTANZ	New Zealand	102	54	Yes	2005	2016	26-50%	No
COMSALUD-CCL	Peru	186	174	Yes	2012	2012	0-25%	Yes
MEPI	Philippines	88	45	Yes	2015	N/A	N/A	No
PAMDRAP	Philippines	124	67	Yes	2015	2018	76-100%	No
IMEDA	Russia	50	0	Yes	2008	2013	51-75%	No
AMD	Singapore	111	81	No	N/A	N/A	N/A	No
SMF-MTIG	Singapore	94	48	Yes	2014	2017	0-25%	No
THAIMED	Thailand	120	120	Yes	2008	2018	76-100%	No
AdvaMed	United States	400+	300+	Yes	1992	2019	51-75%	No
MDDSC	Vietnam	22	0	Yes	2017	2019	Unknown	Yes
VIMEDAS	Vietnam	1,000	750	Yes	2015	2016	No Data	Yes



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