

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

APEC Small and Medium Enterprises  
Working Group (SMEWG)

# 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

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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.

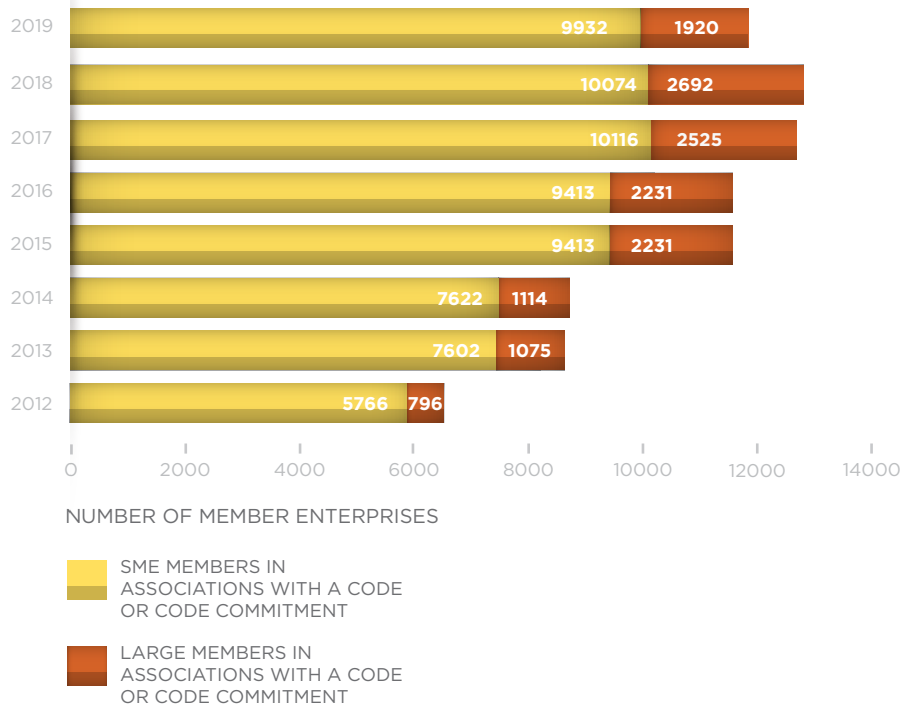
This report has been prepared for the 2019 APEC Business Ethics for SMEs Forum, to indicate where progress has been made since 2012, and where challenges remain, for the region's medical device sector industry associations in (A) code governance, (B) code alignment with the APEC Principles, (C) member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

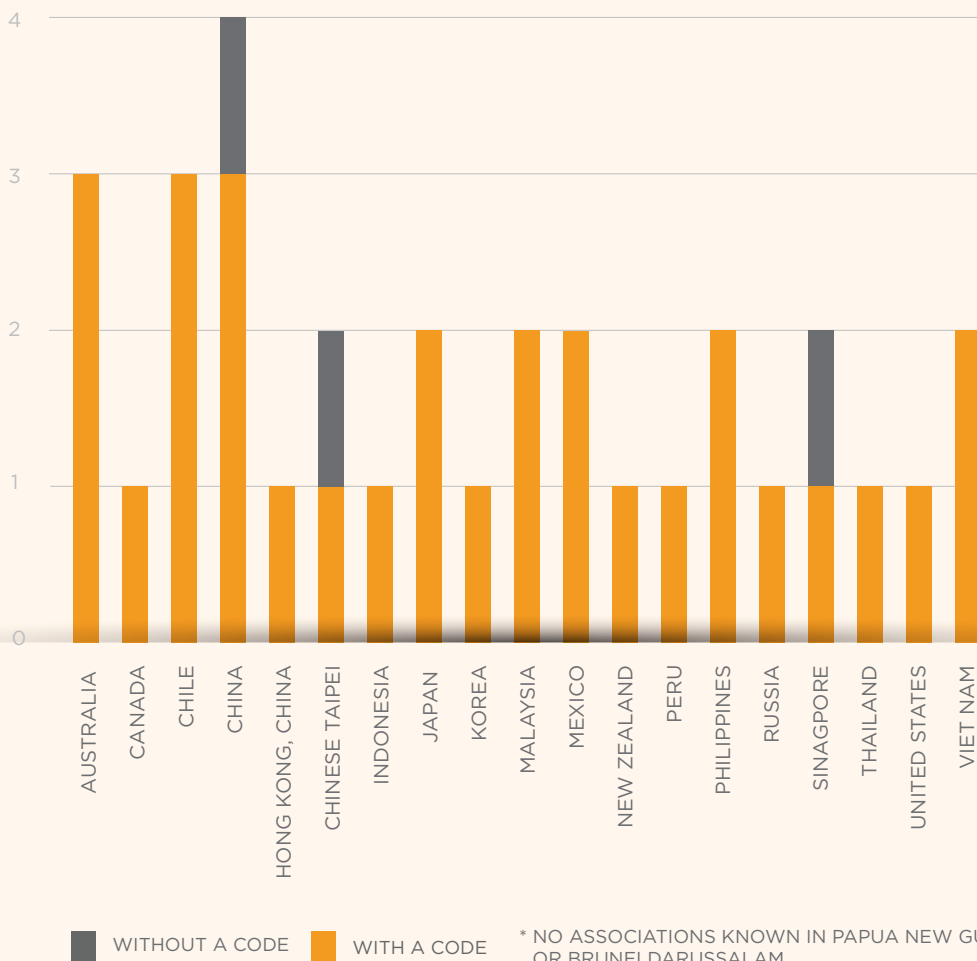


### ENTERPRISE MEMBERSHIP OF ASSOCIATIONS WHO HAVE ADOPTED A CODE OR CODE COMMITMENT



# Regional Overview

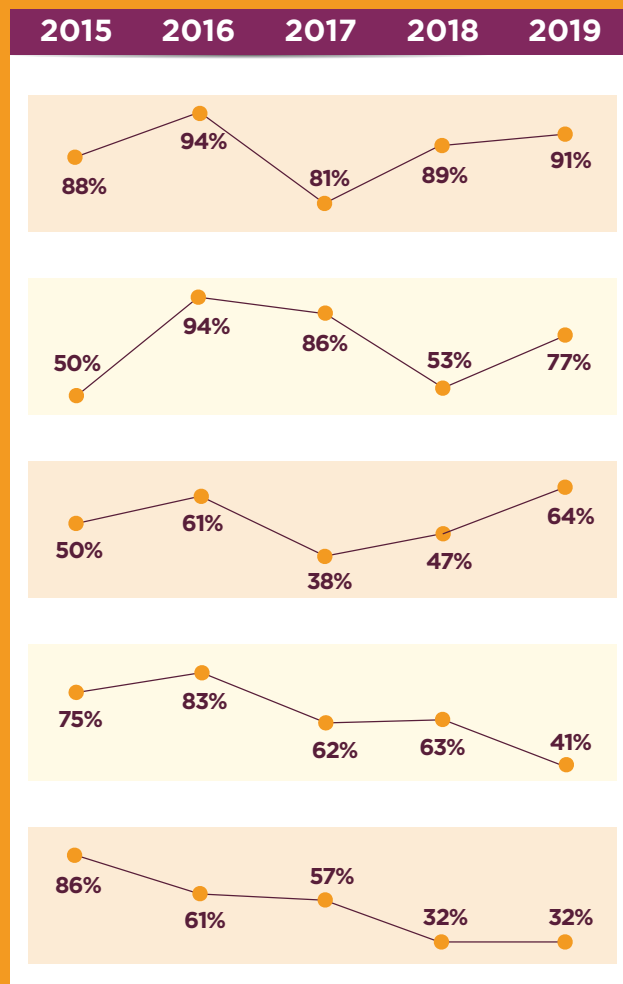
2019 REGIONAL BREAKDOWN\*



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

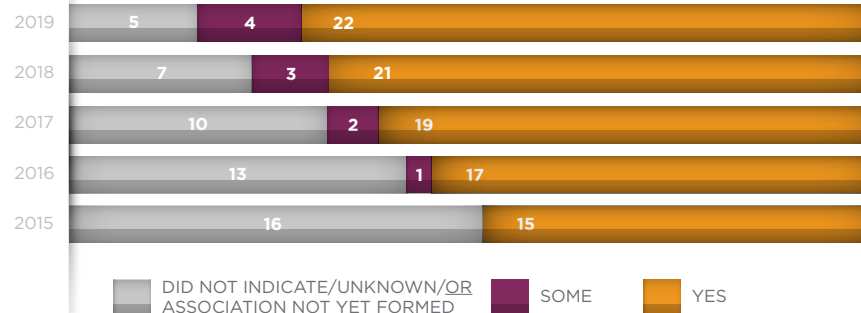


# Alignment with the APEC Kuala Lumpur Principles

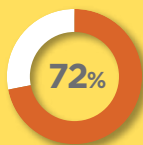
The *Business Ethics for APEC SMEs Initiative* has conducted eight medical device sector capacity-building programs since 2012 and has extended support for dozens of local trainings to ensure that medical device industry association codes of ethics achieve alignment with the APEC

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.

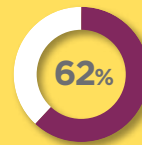
## REPORTED EMBRACE OF THE FIVE FUNDAMENTAL PRINCIPLES OF THE APEC KUALA LUMPUR PRINCIPLES BY ASSOCIATIONS WITH A CODE OR CODE COMMITMENT:



## 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)

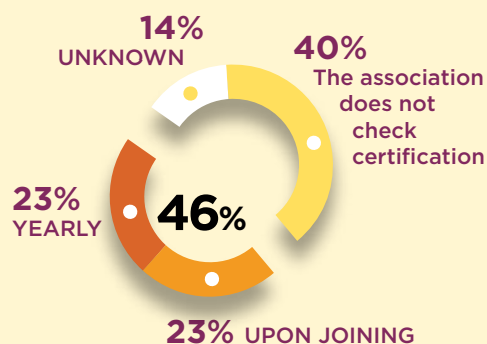


of associations have sought to align its code or practices with the Guidance

# 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.

Associations who require members to certify compliance with the code:



## ASSOCIATION MONITORING

Associations who maintain an active list of members who have certified compliance with the code of ethics:

**30%**

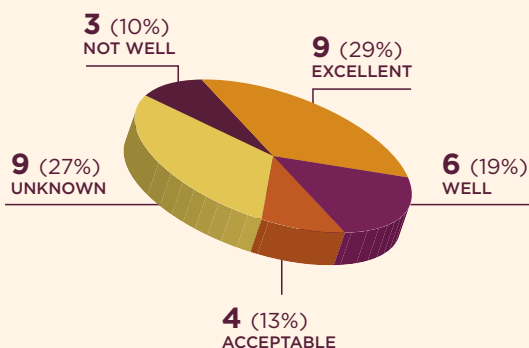
Associations who receive notification when members conduct external validation or audits to measure compliance with the code:

**0%**

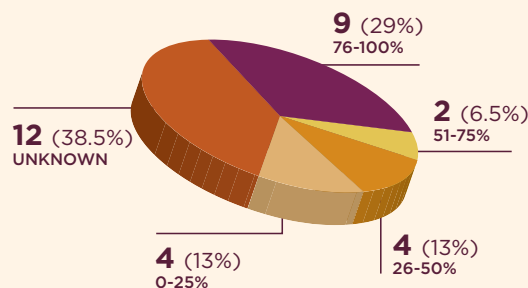
Associations who have a mechanism for individual sales representatives to certify to the code of ethics:

**24%**

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



## MEMBER IMPLEMENTATION RATE BY 31 ASSOCIATIONS WITH A CODE / COMMITMENT



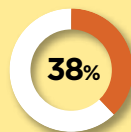


# External Engagement

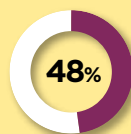
How medical device industry associations engage with external stakeholders (non-members) on their codes of ethics has emerged as fourth area of assessment in code implementation. While important for association members to adhere and implement their code, many encounter a “non-member dilemma” of how to 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.

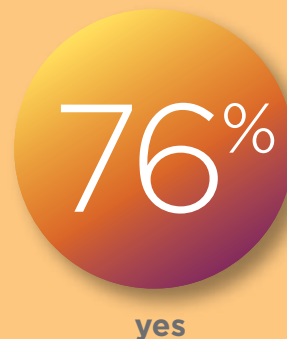
Associations reporting that they have distributed the code to non-members:



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		
<b>ADIA</b>	Australia	170	160	Yes	1974	2011	76-100%	Yes
<b>MTAA</b>	Australia	101	82	Yes	2001	2018	76-100%	Yes
<b>IDV Australia</b>	Australia	37	No Data	Yes	2010	2013	No Data	No
<b>MedTech Canada</b>	Canada	89	25	Yes	2005	2017	26-50%	Yes
<b>ADIMECH</b>	Chile	11	11	Yes	N/A	2019	76-100%	Yes
<b>APIS</b>	Chile	64	64	Yes	2018	2018	26-50%	Yes
<b>SCDM</b>	Chile	27	18	Yes	2013	2018	0-25%	Yes
<b>AdvaMed China</b>	China	40	0	Yes	2016	2017	No Data	No
<b>CAMDI</b>	China	1,350	1,053	Yes	2015	2016	26-50%	No
<b>CAME</b>	China	No Data	No Data	No	N/A	N/A	No Data	No
<b>CCCMHPIE</b>	China	1,650	1,485	Yes	2013	2017	26-50%	Yes
<b>HKMHDIA</b>	Hong Kong, China	178	150	Yes	2009	N/A	0-25%	No
<b>TAMTA</b>	Chinese Taipei	23	0	Yes	2015	2019	76-100%	No
<b>TMBIA</b>	Chinese Taipei	378	350	No	N/A	N/A	N/A	No
<b>Gakeslab</b>	Indonesia	375	362	Yes	2013	2015	0-25%	No
<b>AMDD</b>	Japan	58	0	Yes	2016	2016	No Data	No
<b>JFDA</b>	Japan	4,280	4,000	Yes	1993	2019	76-100%	Yes
<b>KMDIA</b>	Korea	825	788	Yes	2011	2017	No Data	No
<b>AMMI</b>	Malaysia	72	22	Yes	2013	2017	Unknown	No
<b>MMDA</b>	Malaysia	177	120	Yes	2013	2013	No Data	No
<b>AMID</b>	Mexico	32	5	Yes	2013	2019	76-100%	No
<b>ASEMED</b>	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		
<b>APACMed</b>	Multi	118	40	Yes	2016	2018	76-100%	No
<b>MTANZ</b>	New Zealand	102	54	Yes	2005	2016	26-50%	No
<b>COMSALUD-CCL</b>	Peru	186	174	Yes	2012	2012	0-25%	Yes
<b>MEPI</b>	Philippines	88	45	Yes	2015	N/A	N/A	No
<b>PAMDRAP</b>	Philippines	124	67	Yes	2015	2018	76-100%	No
<b>IMEDA</b>	Russia	50	0	Yes	2008	2013	51-75%	No
<b>AMD</b>	Singapore	111	81	No	N/A	N/A	N/A	No
<b>SMF-MTIG</b>	Singapore	94	48	Yes	2014	2017	0-25%	No
<b>THAIMED</b>	Thailand	120	120	Yes	2008	2018	76-100%	No
<b>AdvaMed</b>	United States	400+	300+	Yes	1992	2019	51-75%	No
<b>MDDSC</b>	Viet Nam	22	0	Yes	2017	2019	Unknown	Yes
<b>VIMEDAS</b>	Viet Nam	1,000	750	Yes	2015	2016	No Data	Yes



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