

2020 Report on

# Code of Ethics Implementation

by Medical Device  
Industry Associations  
in the APEC Region



Asia-Pacific  
Economic Cooperation

Business Ethics for APEC SMEs  
Medical Device Sector

APEC Small and Medium Enterprises  
Working Group (SMEWG)

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## Introduction

### Initiative, Principles & Codes of Ethics

The *Business Ethics for APEC SMEs Initiative* monitors code of ethics adoption and implementation by 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 the monitored medical device sector industry associations had a code of ethics. By 2019, 31 of these associations had a code of ethics or formalized commitment, which remains consistent in 2020. With near-universal adoption of codes of ethics across medical device industry associations in the APEC region, the Initiative will now place emphasis on code implementation, as well as multi-stakeholder and third-party intermediary engagement.

This report has been prepared for the 2020 APEC Business Ethics for SMEs Forum to measure progress since 2012 and to identify remaining challenges for the region's medical device sector industry associations in (1) code adoption; (2) code implementation; and (3) multi-stakeholder and third-party engagement on the code. The insights in this report are based on survey data collected in 2020 and 2019, as well as publicly available information.

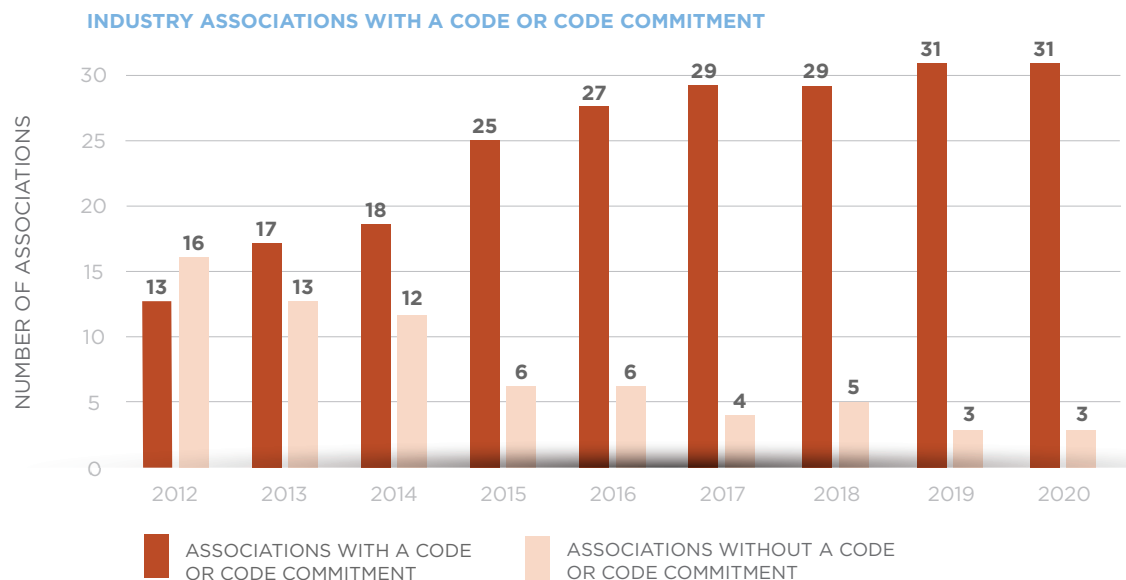
**To learn more about the Business Ethics for APEC SMEs Initiative, please visit <https://klprinciples.apec.org/>.**

*Disclaimer: The data presented in this Report is based on survey responses provided by medical device industry associations in the APEC region. The data has not been independently validated nor does the initiative conduct audits of the region's industry associations or their member companies.*

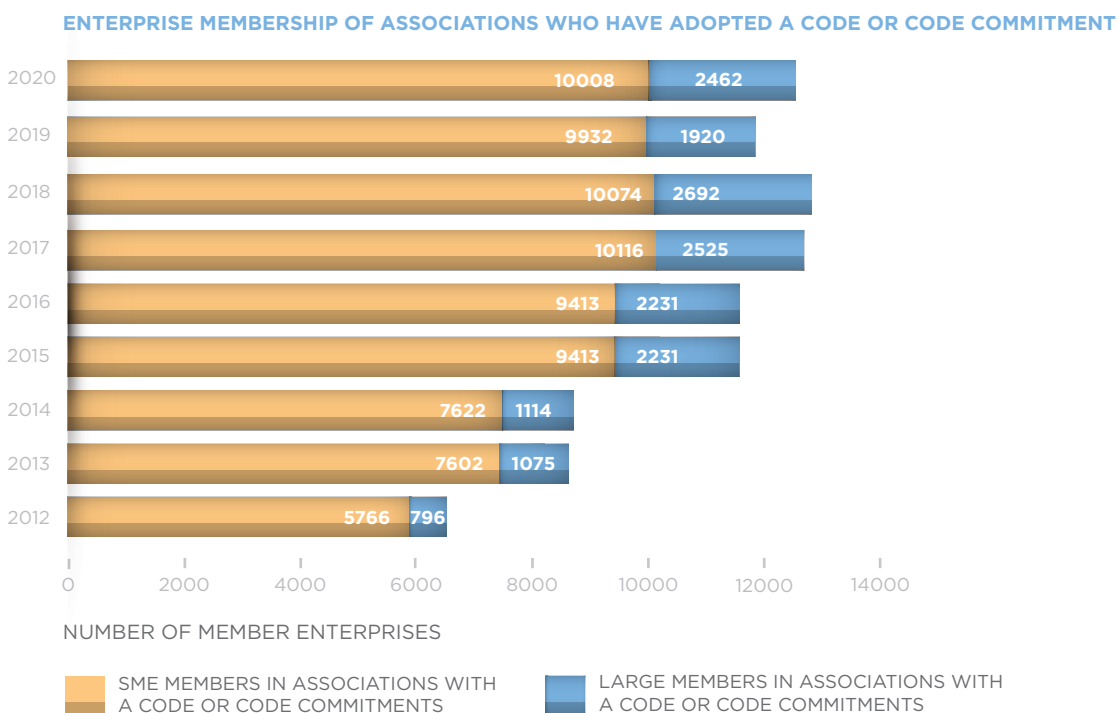
## PART 1

# Overview of Code Adoption in the APEC Region

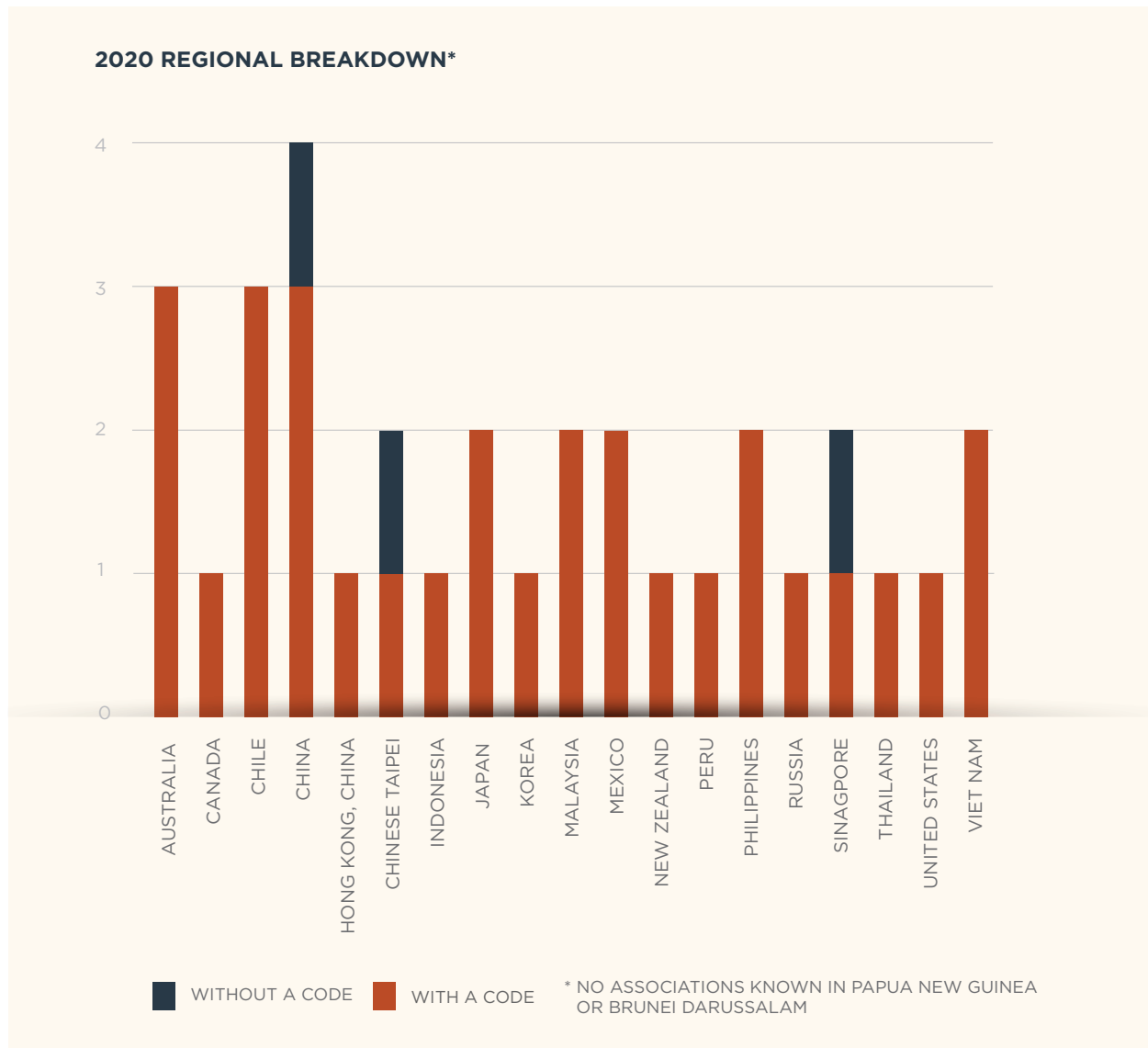
### CODE OF ETHICS ADOPTION BY MEDICAL DEVICE INDUSTRY ASSOCIATIONS IS NEARLY UNIVERSAL



### SMES CONTINUE TO DOMINATE ASSOCIATION MEMBERSHIP WITH MORE THAN 10,000 COVERED BY A CODE OR CODE COMMITMENT IN APEC



## PART 1 continued



STATUS REPORT	2012	2020
Associations with a Code / Code Commitment:	13	30 (increase of 17)
Total Member Enterprises:	6,500+	12,500+ (increase of 6,000+)
SME Member Companies:	5,700+	10,000+ (increase of 4,300+)

## PART 2

# Association & Member Implementation

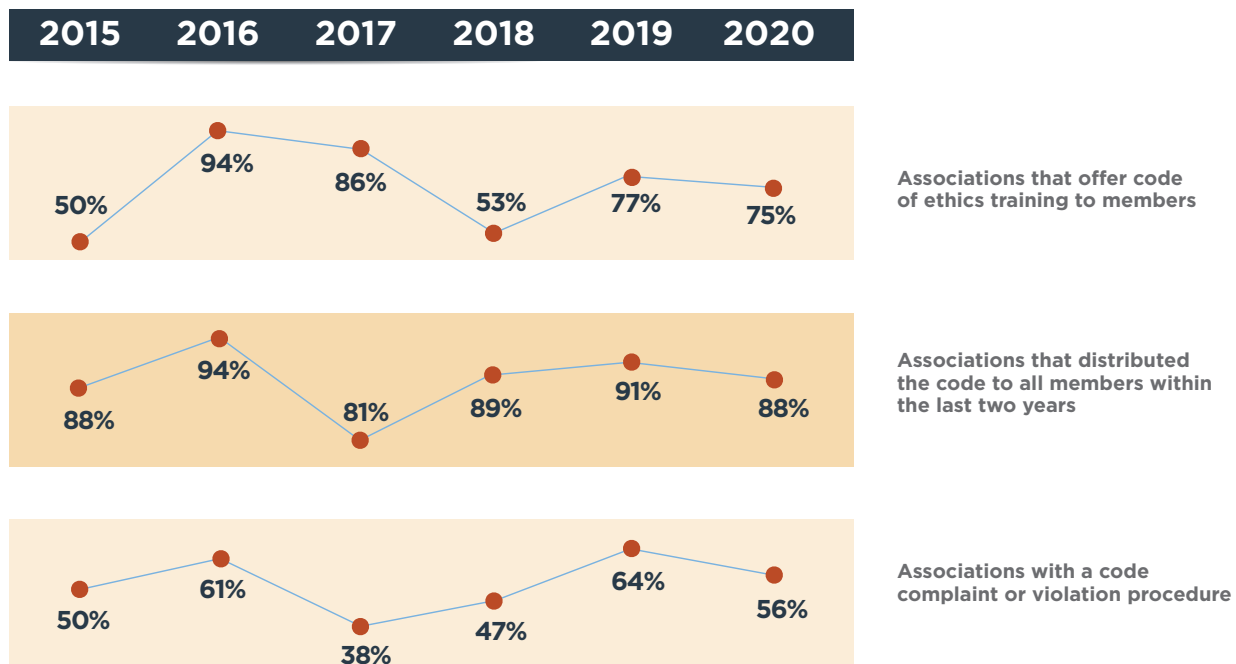
**CODE GOVERNANCE** safeguards the operating environment for all relevant code implementation activities. Associations govern member adherence to codes of ethics through proactive (distribution, training and certification) and reactive (complaint and monitoring procedures) measures. In light of the COVID-19 pandemic, associations report a best practice of assigning a focal point on ethics and integrity to any internal taskforce, committee, or coordinating body to ensure the issue is included as a core component of response activities.

Distributing the code is an association's usual first step following adoption. In 2020, 88 percent of associations had distributed the code to members and 47 percent distributed the code to non-members at some point in the last two years.

On training, 75 percent of associations offer code of ethics training to members and 31 percent offer training to non-members. Associations tend to focus on firm-level capacity building, with only 38 percent offering training programs for individual sales representatives.

For reactive measures, just over half of associations offer a code complaint or violation reporting procedure. However, this procedure has been used in only 33 percent of associations in the last two years. For monitoring, only 13 percent of associations answered that they receive notification when members conduct external validations or audits to measure code compliance.

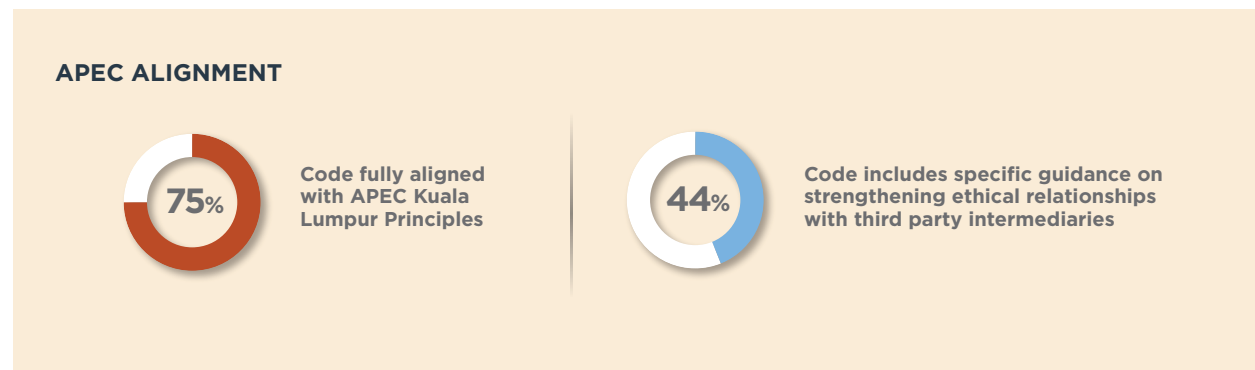
### GOVERNANCE TRENDS



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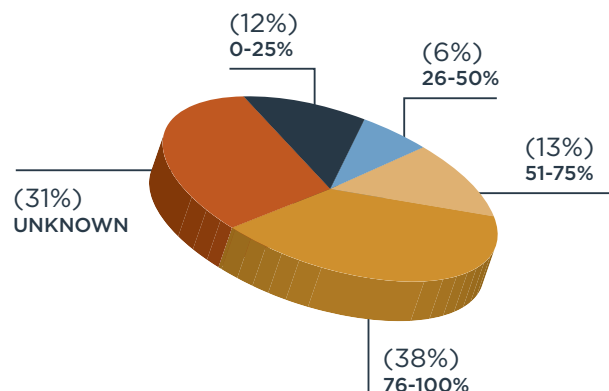
**CODE ALIGNMENT** refers to associations aligning codes of ethics with the *Business Ethics for APEC SMEs Initiative's* APEC Kuala Lumpur Principles. 75 percent of associations responding to the 2020 survey indicated full alignment, 25 percent indicated some alignment and none indicated no alignment. In addition to the Principles, the Initiative encourages associations to

align codes of ethics with the APEC Guidance for Ethical Third-Party Intermediary Relationships in the Medical Technology Sector. While 81 percent of responding associations indicated undertaking alignment efforts, only 44 percent reported specific guidance to strengthen ethical relationships between medical device companies and third party intermediaries in current code of ethics.



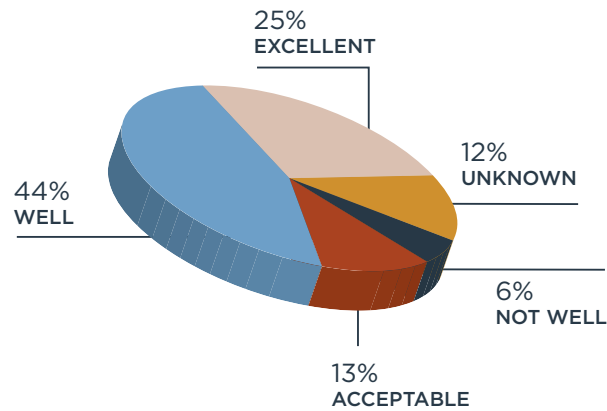
**CODE ADHERENCE** measures association implementation of codes of ethics at the firm level based on certification and performance indicators.

### MEMBER CODE CERTIFICATION RATE PER RESPONDING ASSOCIATIONS WITH A CODE OF ETHICS

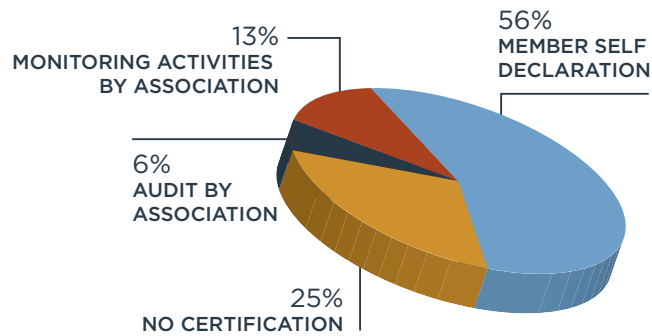


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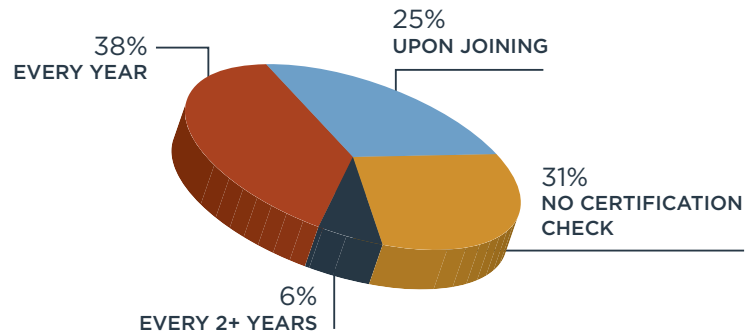
### SELF-ASSESSED CODE PERFORMANCE PER RESPONDING ASSOCIATIONS WITH A CODE OF ETHICS



### CERTIFICATION METHOD PER RESPONDING ASSOCIATIONS WITH A CODE OF ETHICS



### MEMBER CERTIFICATION FREQUENCY PER RESPONDING ASSOCIATIONS WITH A CODE OF ETHICS





# Insights on COVID-19

Key Recommendations by APEC medical device industry associations from the May 2020 *Special Webinar Session: COVID-19 & Business Ethics for APEC SMEs Initiative*:

- **Survey** member companies on current ethical issues and craft written guidance that fosters alignment in support of code of ethics and best practice ethical conduct.
- **Integrate** the importance of ethics and business integrity into COVID-19 communications with member companies, the media, and relevant stakeholders.
- **Designate** one or more individuals to serve as the focal point on ethics/integrity issues in internal task force, committee, or coordinating mechanism on COVID-19 to ensure ethics/integrity issues are included as a core component of their activities; and
- **Create** an ethics committee comprised of member companies to deliberate on relevant issues and oversee the code.
- **Coordinate** with fellow medical device industry associations to learn through collaboration and ensure alignment in approach.
- **Communicate** the importance of a culture of integrity and collective action to set a high standard of ethical business conduct in healthcare.
- **Lean** into collective action and multi-stakeholder collaboration to reinforce ethics and integrity wherever possible, such as consensus frameworks.
- **Prepare** to support virtual training and capacity-building. If member companies already offer virtual training for employees, then associations should help facilitate effective learnings between members. If member companies are not offering virtual training, then associations should offer virtual training on codes of ethics.



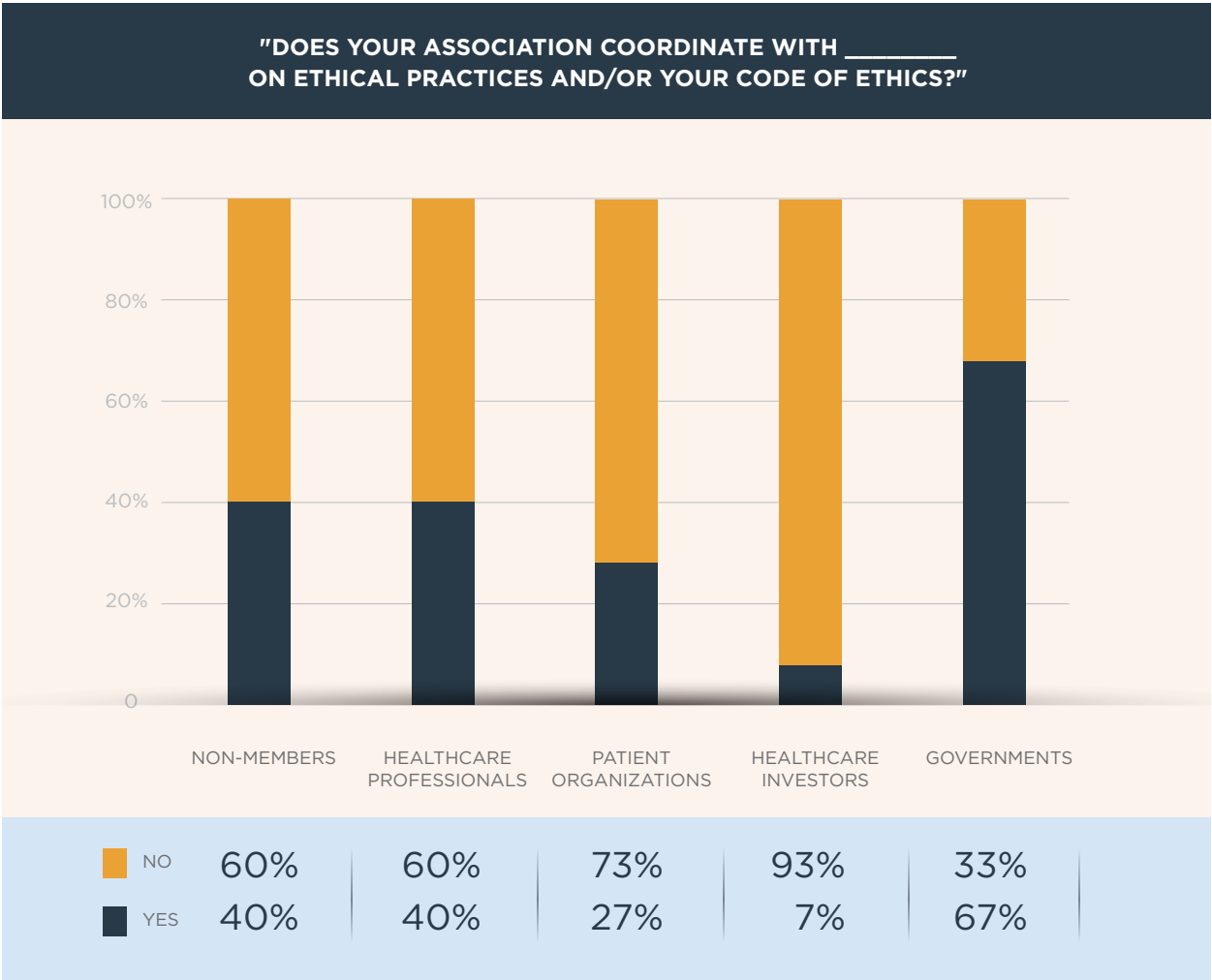


PART 3

# Multi-Stakeholder & Third-Party Intermediary Engagement

Multi-stakeholder and third-party intermediary engagement is essential to achieving an ethical business environment within the healthcare system. For the purposes of this report, stakeholders include non-association member firms,

patient groups, healthcare professionals, healthcare investors and governments. The 2020 survey gauged if associations currently coordinate with each of these entities:



## PART 3 continued

The 2020 survey collected data on **non-member engagement** and found that 47 percent of responding associations have distributed their code of ethics to non-members within the last two years and 31 percent offer code of ethics training to non-members.

The 2020 survey found inconsistent levels of **government engagement**. Although government are the target stakeholder of most association coordination (67 percent), only 20 percent of associations have introduced the APEC resource guide “Government Strategies to Encourage Ethical Business Conduct” to their government. Lastly, responders were asked if their association had been contacted by a government to consider adopting a code of ethics or to discuss code adoption. Only one responding association replied affirmatively.

Engaging **third-party intermediaries** (often referred to as “distributors”) represents the industry’s next greatest effort in harmonizing the medical device supply chain around ethical business practices. While less than half (44 percent) of associations include specific guidance on strengthening ethical relationships between medical device manufacturers and third-party intermediaries in their code, 80 percent of associations that have codes that do not include this guidance indicated they would be interested in distributing guidance focused on ethical relationships with third-parties to their member companies. The 2020 survey results also show that more than half (53 percent) of associations engage third-party intermediaries by offering code of ethics training. Altogether, the 2020 survey results indicate that the interest and infrastructure to engage third-party intermediaries already exists for the majority of associations.

### ASSOCIATIONS WERE ASKED TO DESCRIBE OPPORTUNITIES AND CHALLENGES TO WORKING WITH GOVERNMENT PARTNERS ON ETHICAL BUSINESS PRACTICES.

#### OPPORTUNITIES

- “There is an opportunity for a top-down approach for the top management of the Ministry of Health to drive the adoption of the code of ethics.”
- “Codifying codes in government procurement practices.”
- “The APEC Consensus Framework, since it leads 17 actors to collaborate to raise the standards of ethics in the country.”

#### CHALLENGES

- “Having an appropriate forum and sufficient access to government to engage on the code.”
- “Lack of regular information exchanges.”
- “The pandemic situation that leads to making decisions without necessarily following the established processes, generating a lack of transparency.”

## PART 4

# Code of Ethics Compendium of APEC Medical Device Industry Associations

Association	Economy	Member Enterprises		Code Adoption Code Commitment*			Member Implementation
		TOTAL	SMEs	Yes/No	Year Adopt	Last Update	
<b>ADIA</b>	Australia	205	197	Yes	1974	2017	76-100%
<b>MTAA</b> ▲	Australia	74	73	Yes	2001	2020	76-100%
<b>Pathology Technology Australia</b>	Australia	37	No data	Yes	2010	2013	No data
<b>Medtech Canada</b>	Canada	89	25	Yes	2005	2017	26-50%
<b>ADIMECH</b> ▲	Chile	9	0	Yes	N/A	2019	76-100%
<b>APIS</b>	Chile	64	64	Yes	2018	2018	26-50%
<b>SCDM</b> ▲	Chile	18	12	Yes	2013	2018	51-75%
<b>AdvaMed China</b>	China	40	0	Yes	2016	2017	No data
<b>CAMDI</b>	China	2148	1230	Yes	2015	2016	26-50%
<b>CAME</b>	China	No data	No data	No	N/A	N/A	No data
<b>CCCMHPIE</b>	China	1840	1688	Yes	2013	2017	26-50%
<b>HKMHDIA</b>	Hong Kong, China	178	150	Yes	2009	2018	0-25%
<b>TAMTA</b> ▲	Chinese Taipei	25	0	Yes	2015	2019	76-100%
<b>TMBIA</b>	Chinese Taipei	378	350	No	N/A	N/A	N/A
<b>Gakeslab</b>	Indonesia	452	388	Yes	2013	2015	0-25%
<b>AMDD</b> ▲	Japan	62	0	Yes	2016	2016	Unknown
<b>JFMDA*</b> ▲	Japan	4,280	4,000	Yes	1993	2019	Unknown
<b>KMDIA</b>	Korea	825	788	Yes	2011	2017	No data
<b>AMMI*</b> ▲	Malaysia	73	23	Yes	2013	2017	Unknown
<b>MMDA*</b> ▲	Malaysia	180	100	Yes	2013	2013	26-50%

▲ PROVIDED RESPONSE TO THE 2020 SURVEY. ALL OTHER DATA WAS COLLECTED IN 2019 OR FROM PUBLICLY AVAILABLE INFORMATION

Association	Economy	Member Enterprises		Code Adoption Code Commitment*			Member Implementation
		TOTAL	SMEs	Yes/No	Year Adopt	Last Update	
<b>AMID</b>	▲ Mexico	34	10	Yes	2013	2019	76-100%
<b>ASEMED</b>	Mexico	No data	No data	Yes	No Data	No data	No data
<b>APACMed</b>	▲ Multi	104	61	Yes	2016	2020	76-100%
<b>MTANZ</b>	▲ New Zealand	102	54	Yes	2005	2016	0-25%
<b>COMSALUD-CCL</b>	▲ Peru	129	101	Yes	2012	2012	•
<b>MEPI</b>	Philippines	88	45	Yes	2015	N/A	N/A
<b>PAMDRAP</b>	Philippines	124	67	Yes	2015	2018	76-100%
<b>IMEDA</b>	▲ Russia	50	0	Yes	2008	2019	Unknown
<b>AMDI</b>	Singapore	111	81	No	N/A	N/A	N/A
<b>SMF-MTIG</b>	Singapore	94	48	Yes	2014	2017	0-25%
<b>THAIMED</b>	Thailand	120	120	Yes	2008	2018	76- 100%
<b>AdvaMed</b>	▲ United States	400+	300+	Yes	1992	2020	0-25%
<b>MDDSC</b>	▲ Viet Nam	26	14	Yes	2017	2019	Unknown
<b>VIMEDAS</b>	▲ Viet Nam	1000	750	Yes	2015	2016	51-75%

▲ PROVIDED RESPONSE TO THE 2020 SURVEY. ALL OTHER DATA WAS COLLECTED IN 2019 OR FROM PUBLICLY AVAILABLE INFORMATION

APEC Project: SME 03 2019A  
Produced by Business Ethics  
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