2021 Report on

Code of Ethics Implementation

by Medical Device Industry Associations in the APEC Region

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KEY TRENDS 2020-2021

ADOPTION – Positive (low)
- Code or Code Commitment
- Enterprise Membership

IMPLEMENTATION – Positive (high)
- Governance
- Alignment
- Adherence
- Performance
- Certification Method
- Certification Frequency

ENGAGEMENT – Negative (medium)
- Non-Members
- Stakeholders
- Third-Party Intermediaries

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 2021. 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 2021 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 2021 and 2020, as well as publicly available information.

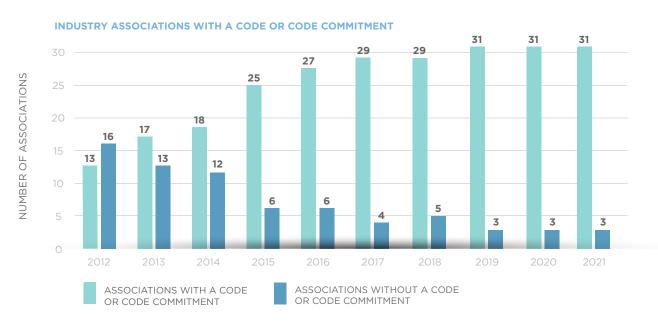**To learn more about the Business
Ethics for APEC SMEs Initiative, please visit
https://klprinciples.apec.org/.**

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.
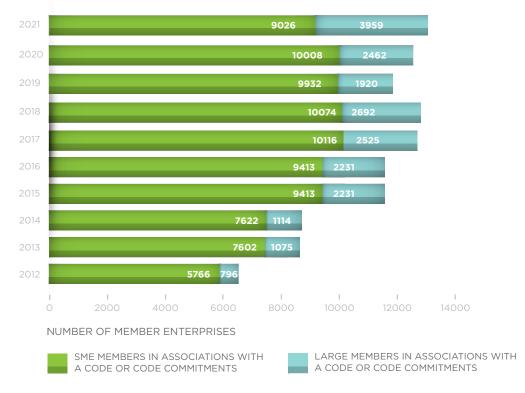
Overview of Code Adoption in the APEC Region

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

INDUSTRY ASSOCIATIONS WITH A CODE OR CODE COMMITMENT

Year	With a code	Without a code
2012	13	16
2013	17	13
2014	18	12
2015	25	6
2016	27	6
2017	29	4
2018	29	5
2019	31	3
2020	31	3
2021	31	3

NUMBER OF ASSOCIATIONS

ASSOCIATIONS WITH A CODE OR CODE COMMITMENT
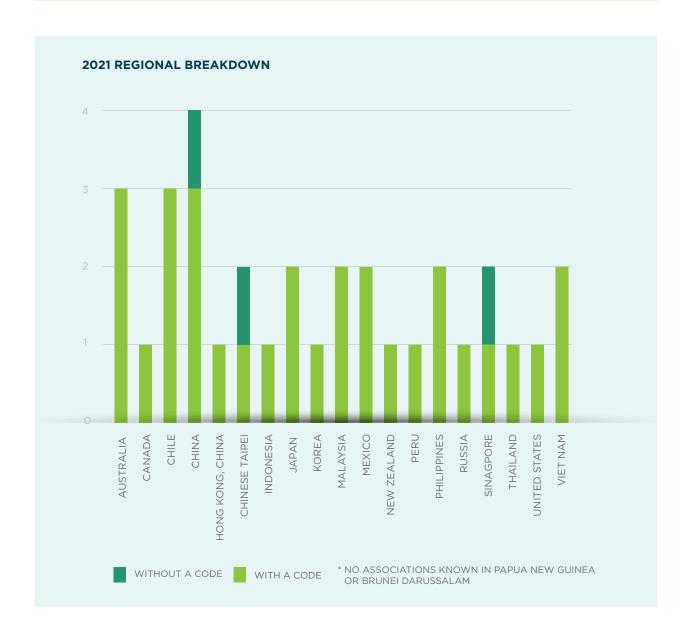ASSOCIATIONS WITHOUT A CODE OR CODE COMMITMENT

SMES CONTINUE TO DOMINATE ASSOCIATION MEMBERSHIP WITH MORE THAN 9,000 COVERED BY A CODE OR CODE COMMITMENT IN APEC

MEMBERS OF ASSOCIATIONS THAT HAVE ADOPTED A CODE OR CODE COMMITMENT

Year	SME members	Large members
2021	9026	3959
2020	10008	2462
2019	9932	1920
2018	10074	2692
2017	10116	2525
2016	9413	2231
2015	9413	2231
2014	7622	1114
2013	7602	1075
2012	5766	796

NUMBER OF MEMBER ENTERPRISES

SME MEMBERS IN ASSOCIATIONS WITH A CODE OR CODE COMMITMENTS
LARGE MEMBERS IN ASSOCIATIONS WITH A CODE OR CODE COMMITMENTS

2021 REGIONAL BREAKDOWN

| | WITHOUT A CODE | | WITH A CODE | * NO ASSOCIATIONS KNOWN IN PAPUA NEW GUINEA OR BRUNEI DARUSSALAM |

STATUS REPORT	2012	2021
Associations with a Code / Code Commitment:	13	31 (increase of 18)
Total Member Enterprises:	6,500+	12,900+ (increase of 6,400+)
SME Member Companies:	5,700+	9,000+ (increase of 3,300+)

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 2021, 95 percent of associations had distributed the code to members and 42 percent distributed the code to non-members at some point in the last two years.

On training, 70 percent of associations offer code of ethics training to members and 37 percent offer training to non-members. Associations tend to focus on firm-level capacity building, with only 26 percent offering training programs for individual sales representatives.

For reactive measures, 65 percent of associations offer a code complaint or violation reporting procedure. However, this procedure has been used in only 40 percent of associations. For monitoring, none (0%) of associations answered that they receive notification when members conduct external validations or audits to measure code compliance.

GOVERNANCE TRENDS

2015	2016	2017	2018	2019	2020	2021

Associations that offer code of ethics training to members
50% — 94% — 86% — 53% — 77% — 75% — 70%

Associations that distributed the code to all members within the last two years
88% — 94% — 81% — 89% — 91% — 88% — 95%

Associations with a code complaint or violation procedure
50% — 61% — 38% — 47% — 64% — 56% — 65%

CODE ALIGNMENT refers to associations aligning codes of ethics with the Business Ethics for APEC SMEs Initiative's APEC Kuala Lumpur Principles. 90 percent of associations indicated full alignment, 10 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 Sect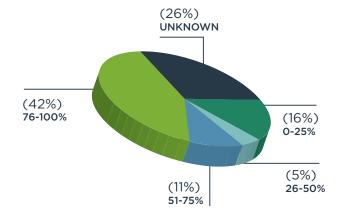or with which 60 percent of associations reported seeking alignment. For the first time, a majority of associations reported including specific guidance to strengthen ethical relationships between medical device companies and third party intermediaries in current code of ethics. Meanwhile, only ten percent of associations reported offering standalone guidance on strengthening ethical relationships between medical device companies and third party intermediaries in current code of ethics.
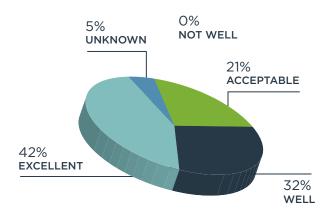
APEC ALIGNMENT

90% Code fully aligned with APEC Kuala Lumpur Principles

65% Code includes specific guidance on strengthening ethical relationships with third party intermediaries

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

❝ **For the first time, a majority of associations reported including specific guidance to strengthen ethical relationships between medical device companies and third party intermediaries in current code of ethics.** ❞
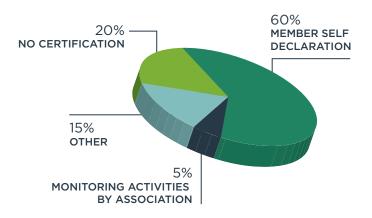
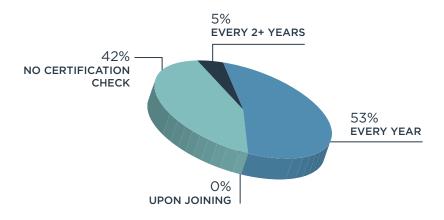**MEMBER CODE CERTIFICATION RATE PER RESPONDING ASSOCIATIONS WITH A CODE OF ETHICS**

(26%)
UNKNOWN

(42%)
76-100%

(16%)
0-25%

(5%)
26-50%

(11%)
51-75%

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

5%
UNKNOWN

0%
NOT WELL

21%
ACCEPTABLE

42%
EXCELLENT

32%
WELL

CERTIFICATION METHOD PER RESPONDING ASSOCIATIONS WITH A CODE OF ETHICS

20%
NO CERTIFICATION

60%
MEMBER SELF
DECLARATION

15%
OTHER

5%
MONITORING ACTIVITIES
BY ASSOCIATION

MEMBER CERTIFICATION FREQUENCY PER RESPONDING ASSOCIATIONS WITH A CODE OF ETHICS

5%
EVERY 2+ YEARS

42%
NO CERTIFICATION
CHECK

53%
EVERY YEAR

0%
UPON JOINING

Global Distributor Compliance Toolkit

OVERVIEW

In coordination with APEC to empower small and medium-sized medical technology distributors with the tools and resources needed to build and implement an effective compliance program, AdvaMed and its member companies created a comprehensive Global Distributor Compliance Toolkit ("GDC Toolkit") for use by all organizations in the global medical technology supply chain. The GDC Toolkit's 50+ compliance assets include training slides, compliance forms, communication templates, infographics and more, spread across the six Key Areas of Global Compliance. It is highly customizable and neutrally branded; we encourage you to adapt this Toolkit as your own. The Toolkit is available in English, Spanish, Portuguese, Chinese, and Japanese.

ASSETS COMPENDIUM (ENGLISH)

INTRODUCTORY MATERIAL
- [ ] Welcome Page – PDF | Word
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RECOGNIZING GOVERNMENT OFFICIALS
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IDENTIFYING CONFLICTS OF INTEREST
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KEEPING GOOD BOOKS & RECORDS
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INTERACTING WITH HCPS & GOS
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- [ ] Introductory Training Slides – PDF | PowerPoint
- [ ] Main Training Slides – PDF | PowerPoint
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- [ ] Infographic – PDF | Word
- [ ] Meeting, Event or Training Packet – PDF | Word
- [ ] Meeting Sign-in Sheet – PDF | Word
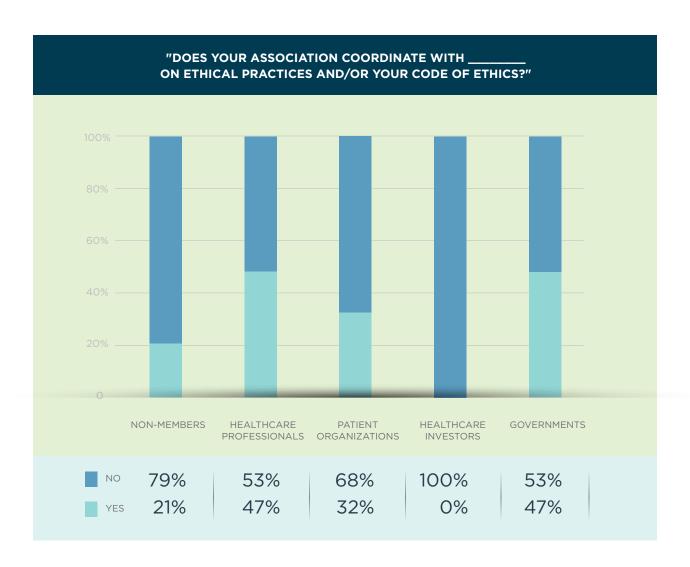- [ ] Sample Code of Conduct – PDF | Word
- [ ] Do's & Don'ts Brochure – PDF

REPORTING A CONCERN
- [ ] Cover Slide – PDF | PowerPoint
- [ ] Contact Information Slide – PDF | PowerPoint
- [ ] Speak Up! Postcard – PDF | Word

Multi-Stakeholder & Third-Party Intermediary Engagement

Multi-stakeholder and third-party intermediary engagements are 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 2021 survey gauged if associations currently coordinate with each of these entities:

"DOES YOUR ASSOCIATION COORDINATE WITH _____ ON ETHICAL PRACTICES AND/OR YOUR CODE OF ETHICS?"

	NON-MEMBERS	HEALTHCARE PROFESSIONALS	PATIENT ORGANIZATIONS	HEALTHCARE INVESTORS	GOVERNMENTS
NO	79%	53%	68%	100%	53%
YES	21%	47%	32%	0%	47%

The 2021 survey collected data on **non-member engagement** and found that 42 percent of responding associations have distributed their code of ethics to non-members within the last two years and 37 percent offer code of ethics training to non-members.

The 2021 survey found inconsistent levels of **government engagement**. Although governments represent 47 percent of association co-ordination, only 16 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. None (0%) 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. **For the first time, a majority (65 percent) of associations reported including specific guidance on strengthening ethical relationships between medical device manufacturers and third-party intermediaries in their code.** However, the 2021 survey results also show that only half (50 percent) of associations engage third-party intermediaries by offering code of ethics training. Altogether, the 2021 survey results indicate positive but uneven progress in engaging third-party intermediaries.

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

OPPORTUNITIES

- "Government is friendly to the Code of Ethics… [and] Government supports the dissemination and implementation of the Global Distributor Compliance Toolkit"

- "Engaging with Government to ensure it is mandatory for all Medical Device Companies… [to] adopt and abide by the Code of Practice"

- "We are working with the government on an Ethic Consensus Framework with very good understanding from the central government on ethical business practice"

CHALLENGES

- "Government has its own anti-corruption policy and guideline"

- "Lack of monitoring of agreements [with Government]"

- "Involving more stakeholders: ex payors, health care institutions private or public"

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	
ADIA		Australia	205	197	Yes	1974	2017	76-100%
MTAA	▲	Australia	87	62	Yes	2001	2020	76-100%
Pathology Technology Australia		Australia	37	No data	Yes	2010	2013	No data
Medtech Canada	▲	Canada	98	37	Yes	2005	2017	51-75%
ADIMECH	▲	Chile	12	12	Yes	N/A	2019	76-100%
APIS	▲	Chile	65	65	Yes	2018	2020	76-100%
SCDM	▲	Chile	16	12	Yes	2013	2018	51-75%
AdvaMed China	▲	China	40	0	Yes	2016	2017	0-25%
CAMDI		China	2148	1230	Yes	2015	2016	26-50%
CAME		China	No data	No data	No	N/A	N/A	No data
CCCMHPIE		China	1840	1688	Yes	2013	2017	26-50%
HKMHDIA		Hong Kong, China	178	150	Yes	2009	2018	0-25%
TAMTA	▲	Chinese Taipei	31	0	Yes	2015	2019	Unknown
TMBIA		Chinese Taipei	378	350	No	N/A	N/A	N/A
Gakeslab	▲	Indonesia	889	No Data	Yes	2013	2021	76-100%
AMDD	▲	Japan	62	No Data	Yes	2016	2021	0-25%
JFMDA	▲	Japan	4,280	3,300	Yes	1993	2021	79-100%
KMDIA		Korea	825	788	Yes	2011	2017	No data
AMMI	▲	Malaysia	79	19	Yes	2013	2017	Unknown
MMDA	▲	Malaysia	160	100	Yes	2013	2013	Unknown

▲ PROVIDED RESPONSE TO THE 2021 SURVEY. ALL OTHER DATA WAS COLLECTED IN OR BEFORE 2020 AND FROM PUBLICLY AVAILABLE INFORMATION.

Association		Economy	Member Enterprises		Code Adoption *Code Commitment**			Member Implementation
			TOTAL	SMEs	Yes/No	Year Adopt	Last Update	
AMID	▲	Mexico	40	15	Yes	2013	2019	76-100%
ASEMED		Mexico	No data	No data	Yes	No Data	No data	No data
APACMed	▲	Multi	93	59	Yes	2016	2020	Unknown
MTANZ	▲	New Zealand	109	64	Yes	2005	2016	26-50%
COMSALUD-CCL	▲	Peru	129	101	Yes	2012	2012	•
MEPI		Philippines	88	45	Yes	2015	N/A	N/A
PAMDRAP		Philippines	146	78	Yes	2015	2017	76-100%
IMEDA	▲	Russia	65	0	Yes	2008	2019	Unknown
AMDI		Singapore	111	81	No	N/A	N/A	N/A
SMF-MTIG		Singapore	94	48	Yes	2014	2017	0-25%
THAIMED		Thailand	120	120	Yes	2008	2018	76- 100%
AdvaMed	▲	United States	500	375	Yes	1992	2020	0-25%
MDDSC	▲	Viet Nam	25	0	Yes	2017	2019	No Data
VIMEDAS	▲	Viet Nam	35	30	Yes	2015	2020	76-100%

▲ PROVIDED RESPONSE TO THE 2021 SURVEY. ALL OTHER DATA WAS COLLECTED IN OR BEFORE 2020 AND FROM PUBLICLY AVAILABLE INFORMATION.

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

APEC

**Asia-Pacific
Economic Cooperation**