2021 Report on Code of Ethics Implementation by Medical Device Industry Associations in the APEC Region
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.
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 9,000 COVERED BY A CODE OR CODE COMMITMENT IN APEC
**STATUS REPORT**

### Part 1 continued

- **Associations with a Code / Code Commitment:**
  - 2012: 13
  - 2021: 31 (increase of 18)

- **Total Member Enterprises:**
  - 2012: 6,500+
  - 2021: 12,900+ (increase of 6,400+)

- **SME Member Companies:**
  - 2012: 5,700+
  - 2021: 9,000+ (increase of 3,300+)

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**2021 REGIONAL BREAKDOWN**

- **WITH A CODE**
  - Australia: 3
  - China: 3
  - Hong Kong, China: 3
  - Indonesia: 2
  - Japan: 2
  - Korea: 2
  - Mexico: 2
  - New Zealand: 2
  - Peru: 2
  - Philippines: 2
  - Russia: 2
  - Singapore: 2
  - Thailand: 2
  - United States: 2
  - Vietnam: 2
- **WITHOUT A CODE**
  - Canada: 1
  - Chile: 1
  - Chinese Taipei: 1
  - Japan: 1
  - Korea: 1
  - Malaysia: 1
  - Mexico: 1
  - New Zealand: 1
  - Peru: 1
  - Philippines: 1
  - Russia: 1
  - Singapore: 1
  - Thailand: 1
  - United States: 1
  - Vietnam: 1

*NO ASSOCIATIONS KNOWN IN PAPUA NEW GUINEA OR BRUNEI DARUSSALAM*
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

<table>
<thead>
<tr>
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<td>47%</td>
<td>64%</td>
<td>56%</td>
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</tbody>
</table>
**PART 2 continued**

**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 Sector 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.

**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**
PART 2 continued

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
- Introductory Slideshow - PDF | PowerPoint
- Key Areas Legend - PDF | Word
- Overview: Templates & Forms - PDF | Word

RECOGNIZING GOVERNMENT OFFICIALS
- Cover Slide - PDF | PowerPoint
- Definition - PDF | PowerPoint
- Examples - PDF | PowerPoint
- Case Studies - PDF | PowerPoint

IDENTIFYING CONFLICTS OF INTEREST
- Cover Slide - PDF | PowerPoint
- Definition & Examples - PDF | PowerPoint
- Case Studies - PDF | PowerPoint
- Infographic - PDF | Word
- Conflict of Interest Declaration - PDF | Word

PREVENTING BRIBERY & CORRUPTION
- Cover Slide - PDF | PowerPoint
- Definition & Examples - PDF | PowerPoint
- Case Studies - PDF | PowerPoint
- Infographic - PDF | Word
- Self-Certification - PDF | Word
- Sponsorship Packet - PDF | Word
- Grant or Donation Packet - PDF | Word
- Due Diligence Quick Check - PDF | Word

KEEPING GOOD BOOKS & RECORDS
- Cover Slide - PDF | PowerPoint
- Must’s & Must Not’s - PDF | PowerPoint
- Case Studies - PDF | PowerPoint
- Infographic - PDF | Word
- Expense Reimbursement - PDF | Word
- Notification on Use of Sub Distributors - PDF | Word
- Additional Guidance - PDF | Word

INTERACTING WITH HCPS & GOS
- Cover Slide - PDF | PowerPoint
- Introductory Training Slides - PDF | PowerPoint
- Main Training Slides - PDF | PowerPoint
- Case Studies - PDF | PowerPoint
- 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 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?"

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<th>Entity</th>
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<td>Non-members</td>
<td>79%</td>
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<td>Healthcare professionals</td>
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<tr>
<td>Patient organizations</td>
<td>68%</td>
<td>32%</td>
</tr>
<tr>
<td>Healthcare investors</td>
<td>100%</td>
<td>0%</td>
</tr>
<tr>
<td>Governments</td>
<td>53%</td>
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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 coordination, 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”
# Part 4

## Code of Ethics Compendium of APEC Medical Device Industry Associations

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<tr>
<th>Association</th>
<th>Economy</th>
<th>Member Enterprises</th>
<th>Code Adoption Code Commitment*</th>
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▲ PROVIDED RESPONSE TO THE 2021 SURVEY. ALL OTHER DATA WAS COLLECTED IN OR BEFORE 2020 AND FROM PUBLICLY AVAILABLE INFORMATION.
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<thead>
<tr>
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