

2022 Report on

Code of Ethics Implementation

by Medical Technology Industry Associations in the APEC Region



Asia-Pacific
Economic Cooperation

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

**APEC Small and Medium Enterprises
Working Group (SMEWG)**

November 2022

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Introduction

The *Business Ethics for APEC SMEs Initiative* (“Initiative”) is the world’s largest public-private partnership to strengthen ethical conduct and drive a level playing field for small and medium-sized enterprises (“SMEs”) in the medical technology sector. The fundamentals of ethical business conduct in this sector are contained in the APEC Kuala Lumpur Principles (“Principles”), recognized by APEC Economic Leaders and Ministers. With nearly all medical technology industry associations (“associations”) in the APEC region having successfully adopted a Codes of Ethics (“Codes”), the initiative monitors how effectively these Codes are implemented and provides actionable recommendations. The member companies of these associations, most of which are SMEs, constitute a majority of the firms that develop, manufacture, market, or distribute medical technology and diagnostic products in the region.

This report captures the latest information received from the region’s associations based on 2022 survey results, while further leveraging 2021 survey data and publicly available information where appropriate. The report presents available data in three sections: (1) code adoption; (2) code implementation; and (3) stakeholder engagement.

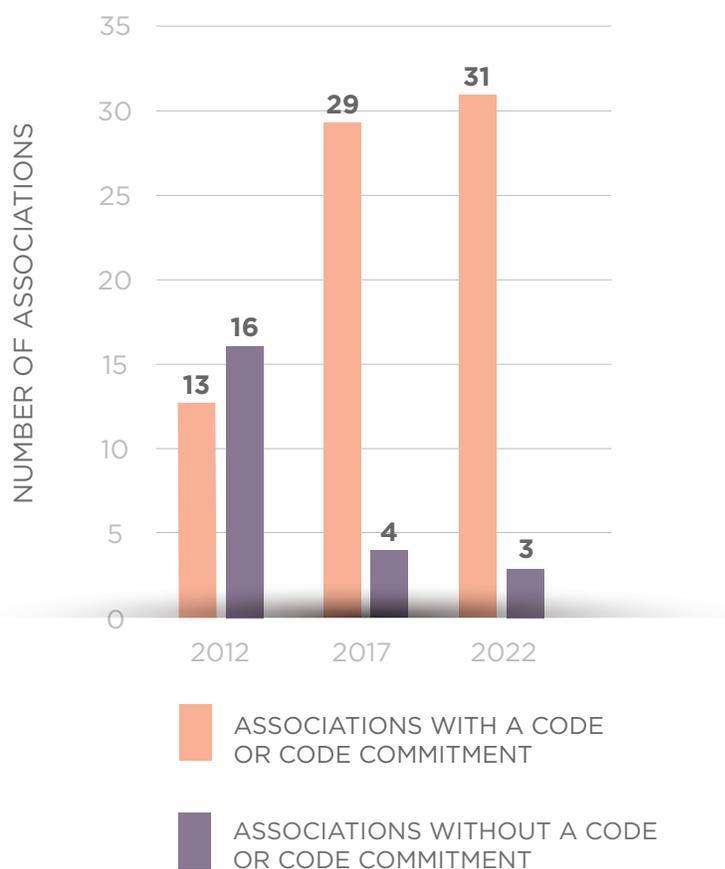
To learn more about the Business Ethics for APEC SMEs Initiative and to review prior reports, please visit <https://klprinciples.apec.org/>.

Disclaimer: The data presented in this Report is based on survey responses provided by medical technology 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

INDUSTRY ASSOCIATIONS WITH A CODE OR CODE COMMITMENT



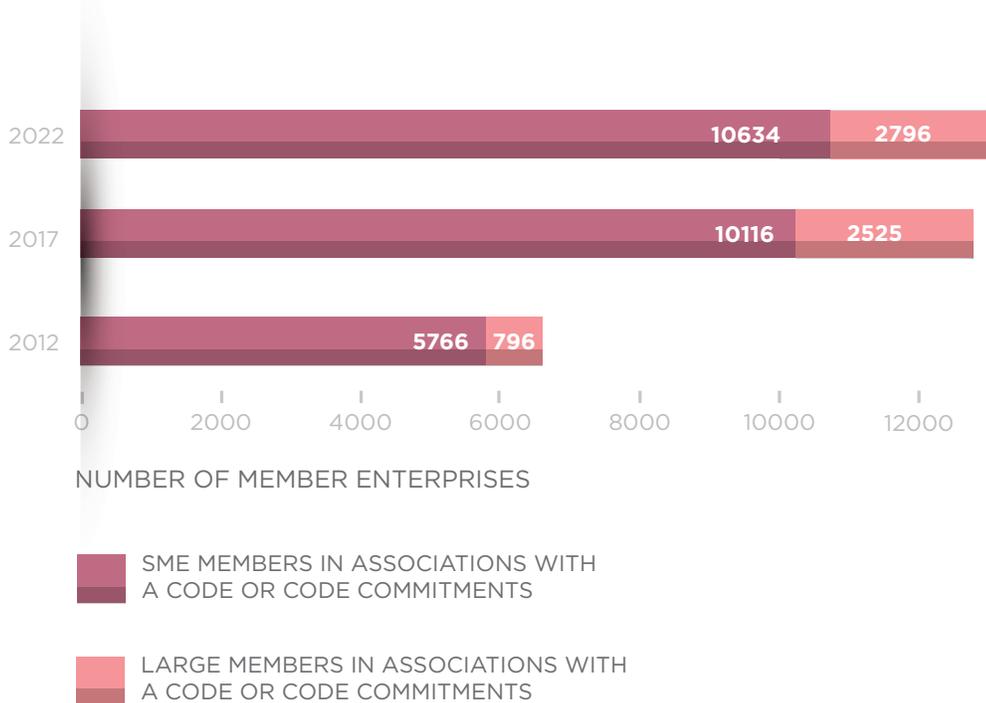
Nearly all medical technology industry associations have adopted Codes in the APEC region. Over the past decade, we have seen a transformation in Code adoption by associations across the APEC region, with a vast majority of those without a Code having adopted their first. This transition, in combination with continuous modernization of existing Codes as well as supporting newly formed associations adopt their first Code, has changed the Code to no-Code ratio from 13:16 to 31:3 and the adoption rate from 45% in 2012 to 91% in 2022. Without the APEC Kuala Lumpur Principles, this transition would not have been possible.

This heightened adoption rate indicates that 13,430 medical technology companies, including over 10,000 SMEs within the APEC region are covered by a high standard and highly aligned Codes in 2022, in comparison to 6,562 companies covered by unaligned Codes in 2012. While the Initiative continues to outreach to the remaining associations without a Code in China; Singapore; and Chinese Taipei, efforts are now focused on Code implementation by those who have already adopted one.

PART 1 continued

Medical technology associations represent over 10,600 SMEs and over 2,700 large members as part of the *Business Ethics for APEC SMEs Initiative*.

MEMBERS OF ASSOCIATIONS THAT HAVE ADOPTED A CODE OR CODE COMMITMENT



| STATUS REPORT | 2012 | 2022 | Percentage of Growth |
|---|--------|---------|----------------------|
| Associations with a Code / Code Commitment: | 13 | 31 | 138% |
| Total Member Enterprises: | 6,500+ | 13,400+ | 106% |
| SME Member Companies: | 5,700+ | 10,600+ | 86% |

PART 2

Association & Member Implementation

EFFECTIVE CODE GOVERNANCE and member adherence safeguards the operating environment for all relevant implementation activities. Associations govern member adherence to Codes through proactive (for example, through training and certification) and reactive (for example, complaint and monitoring procedures) measures.

The distribution of the Code is also central to implementation, as companies cannot implement a Code if they are unaware of its existence and/or routine updating. Of the region's associations surveyed in 2022, 100% of associations had distributed their Code to members within the past two years, while 62% have distributed to non-members.

On training, 62% of associations offer Code training to members and 31% offer training to non-members. Even though associations tend to focus on firm-level capacity building, 39% of associations report offering training programs for individual sales representatives.

For reactive measures, 69% of associations offer a code complaint or violation reporting procedure. However, this procedure has been used in only 39% of associations. *Note: The Initiative does not recommend any specific complaint or violation procedure as part of upholding the APEC Kuala Lumpur Principles.*

GOVERNANCE TRENDS

Percentages represent survey responses from 2017-2022

| 2017 | 2018 | 2019 | 2020 | 2021 | 2022 |
|------|------|------|------|------|------|
|------|------|------|------|------|------|



Associations that offer code of ethics training to members



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



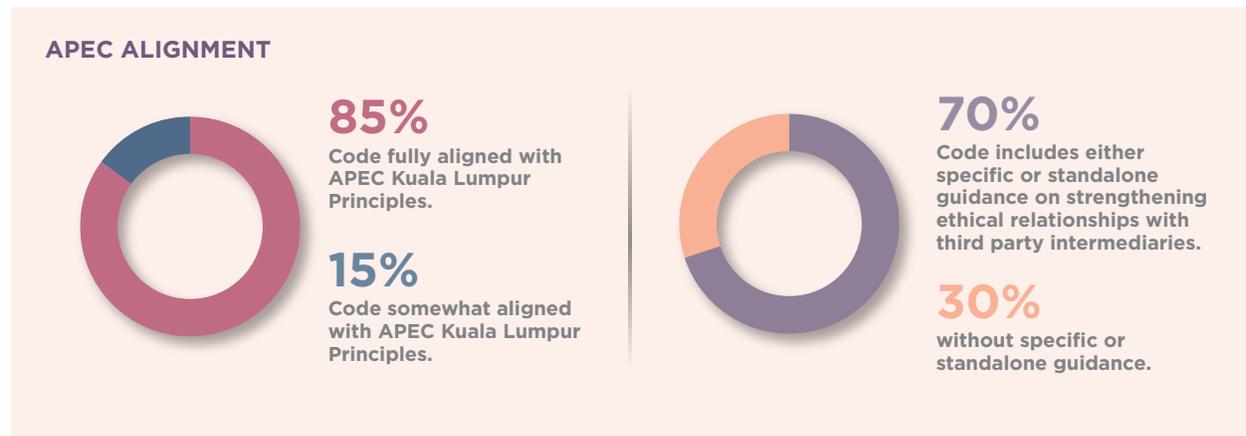
Associations with a code complaint or violation procedure

While associations are improving their focus on Code distribution and complaint and violation procedures, there is a slight decrease in routine Code trainings, which could indicate limitation of resources or other challenges.

PART 2 continued

The APEC Kuala Lumpur Principles are the foundation for the establishment of Codes in the medical technology industry in the APEC region. 85% of associations indicate full alignment with the Principles, while 15% percent indicate some alignment. In 2021, however, only 10% associations reported some alignment with the Principles. This increase from 10% to 15% may indicate that some associations are continuing to align their Code with the modernized Principles. None have 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. 54% of associations report seeking alignment with this Guidance, down from

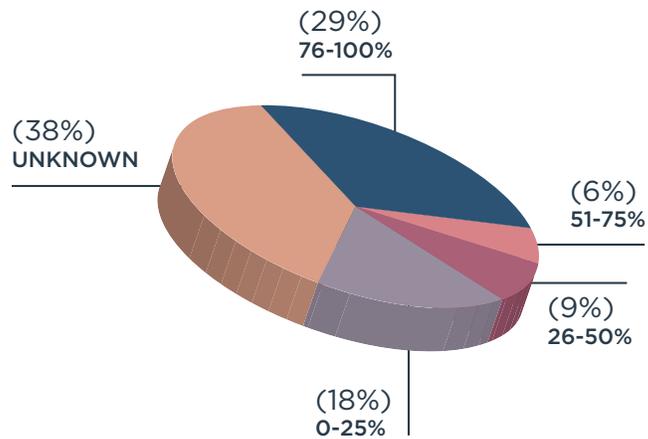
60% in 2021. However, this downward trend may indicate the Guidance is already successfully reflected into the Codes directly, with an encouraging 62% of associations reporting the inclusion of specific guidance within their Code to strengthen ethical relationships between medical technology companies and third-party intermediaries. Meanwhile, 8% percent of associations report offering standalone guidance on strengthening ethical relationships between medical technology companies and third-party intermediaries. While further upside remains, with a combined 70% of the region's associations now indicating they are recognizing this Guidance directly in their Code or as standalone guidance, 2022 represents the strongest uptake to-date.



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PART 2 continued

MEMBER CODE IMPLEMENTATION RATE PER RESPONDING ASSOCIATIONS WITH A CODE OF ETHICS

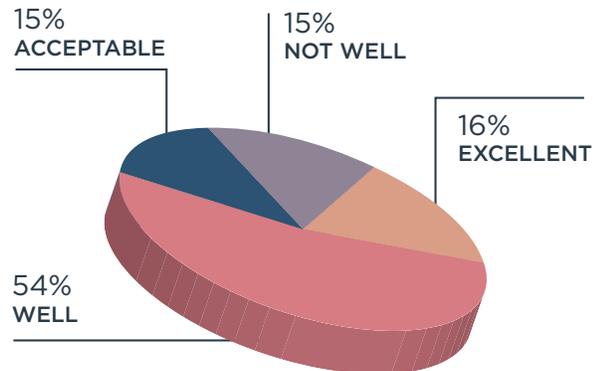


The Code Implementation rate indicates the percentage of an industry association's member companies who adhere to the association's Code in their everyday practices. While 38% of associations do not measure Code implementation among their members, 29% of associations indicate that 76-100% of their members uphold their association's Code. Importantly, 18% of associations indicate 0-25% of member companies uphold their Code.

This shows the need for additional efforts to effective monitoring code adherence, expand capacity-building activities, and pursue other strategies to spur adherence. This shows the need for additional efforts among industry associations to measure and create an effective monitoring mechanism to evaluate ethical practices within their membership.

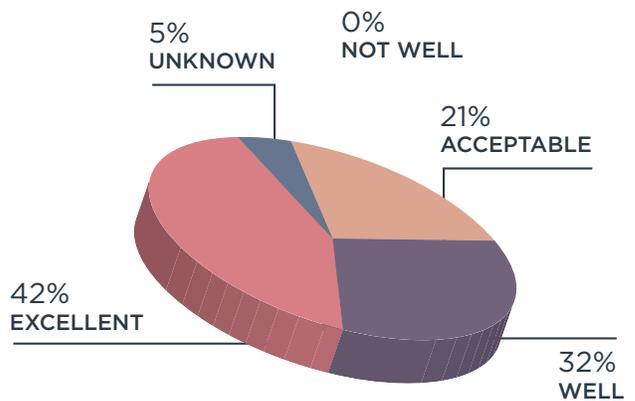
PART 2 continued

2022: SELF-ASSESSED CODE PERFORMANCE PER RESPONDING ASSOCIATIONS WITH A CODE OF ETHICS



The measurement of Code performance indicates how industry associations believe that their Code is being upheld by member companies. 54% of associations reported that they believe that their Code performance has been going well, with 16% of associations remarking that their Code performance has been excellent. While 0% reported Not Well, we have combined with an 'Unknown' response, as this is typically a proxy for those associations with low confidence in their Code performance. Thus, we can infer that 15% of associations do not trust that their Code is being adhered to, to the best of their members' ability.

2021: SELF-ASSESSED CODE PERFORMANCE PER RESPONDING ASSOCIATIONS WITH A CODE OF ETHICS

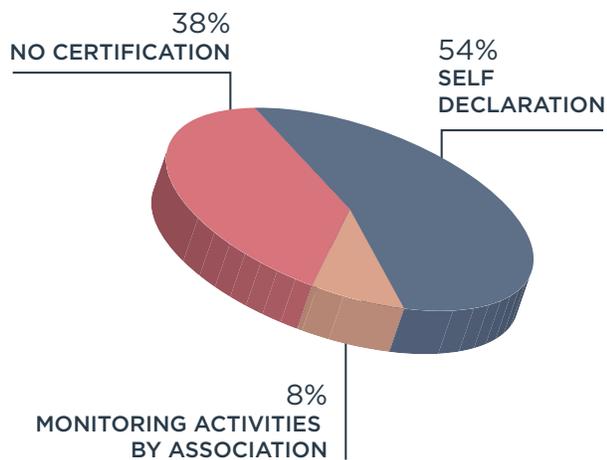


In comparison to 2022, in 2021 42% of associations reported that they believed their Code was performing excellently among its membership. A combined 95% of associations indicated that they believed they had a quality performance rate, compared to 85% in 2022. This might suggest a shift in member company priorities from ethics, or perhaps that their current member adherence procedure is not sustainable for maintaining momentum to uphold the Code.

PART 2 continued

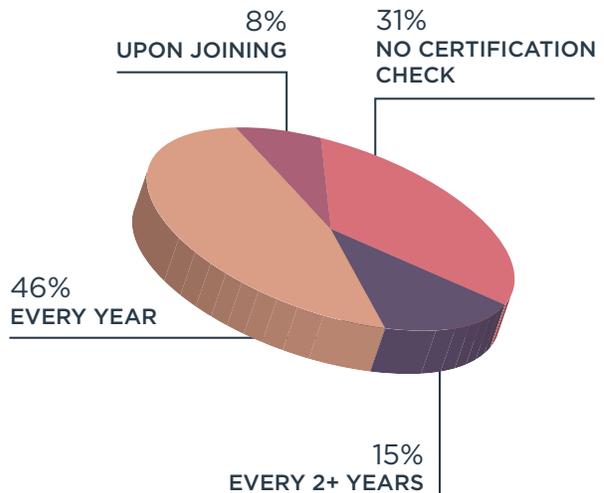
An industry association's certification method indicates the way industry associations monitor and evaluate the everyday implementation of the Code. In 2022, a majority of industry associations (54%) reported largely leaving the issue of Code certification to its member companies on a "self-declaration," or "honor system" basis. 38% of associations do not have any certification mechanism. 8% of industry associations indicate that each member company's Code implementation is monitored by its association through a series of pre-determined criteria.

MEMBER CERTIFICATION FREQUENCY PER RESPONDING ASSOCIATIONS WITH A CODE OF ETHICS



The rate of member certification frequency measures when industry associations monitor and evaluate their member companies' adherence to their Code. In 2022, a combined majority (61%) of industry associations report making their members certify their adherence to the Code either annually or bi-annually. 31% do not monitor member adherence at all, which could also explain the lower report of associations in the implementation of the Code by member companies compared to 2021.

CERTIFICATION METHOD PER RESPONDING ASSOCIATIONS WITH A CODE OF ETHICS

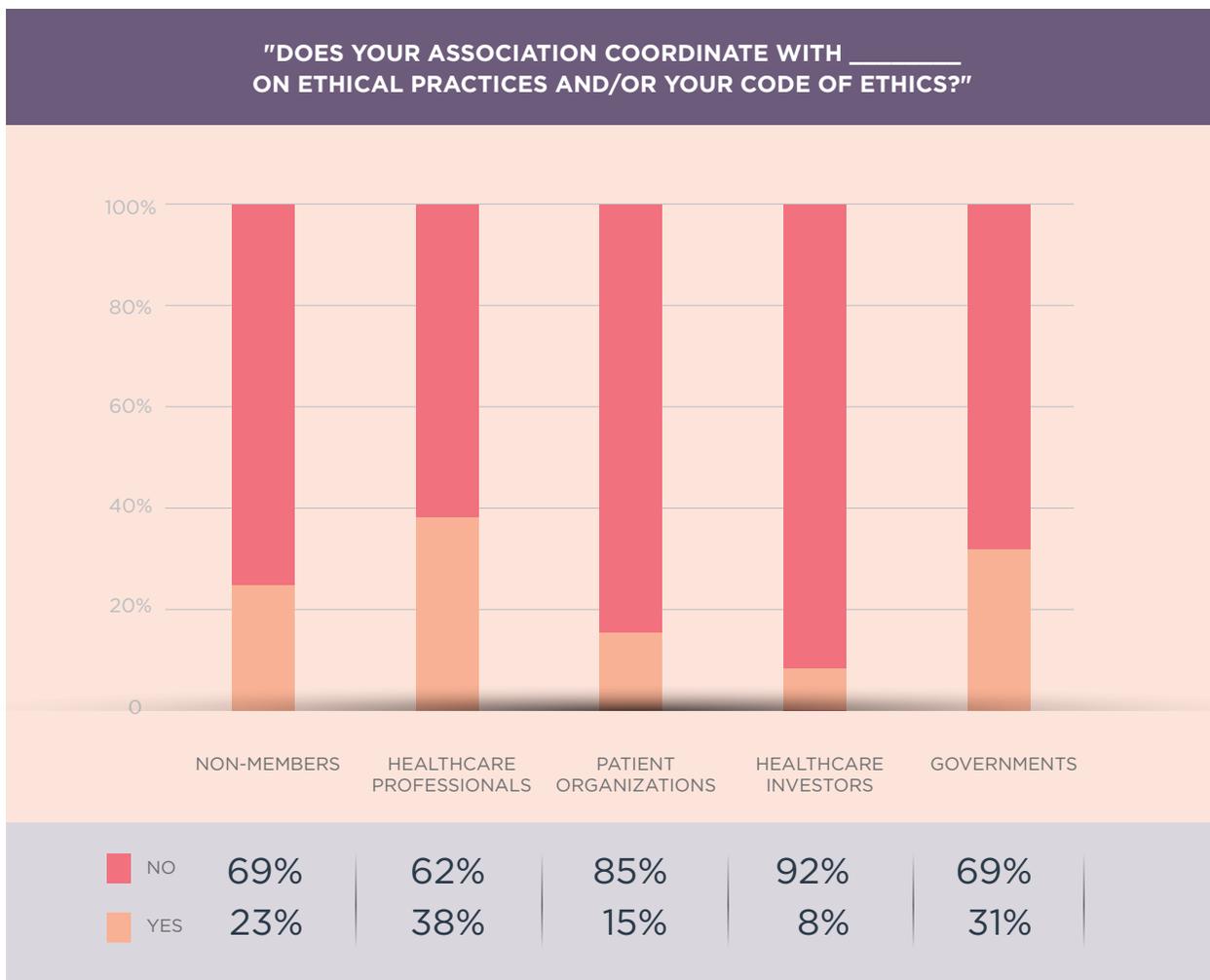


PART 3

Stakeholder Engagement

Engagement on ethical business practices between the medical technology industry and diverse health stakeholders, including patients, healthcare professionals, investors, providers, and regulators is crucial to full implementation of the APEC Kuala Lumpur Principles. For associations, this also includes engagement between their member companies with non-member companies as well as third-party intermediaries, such as distributors. In many APEC economies, such engagements have only

just begun and significant opportunities remain to further ethical collaboration. Among the region's associations today, the highest levels of reported engagement are taking place with healthcare professionals (38%) while the lowest is with healthcare investors (8%). With nearly all associations in the APEC region having adopted a high standard code of ethics, there remains exceptional upside to stakeholder engagement should such ethical collaboration be prioritized.



PART 3 continued

The 2022 survey also found that of 62% responding associations have distributed their code of ethics to non-member companies within the last two years, while 31% offer training on their code of ethics to non-members. These results demonstrate there is considerable interest among associations to go beyond their own members in driving a high-standard, level playing field across the sector. Heightened non-member outreach results in even greater benefits for SMEs.

The 2022 survey also found considerable room for upside in government engagement. While just 31% of associations reported engaging with governments on ethical practices or their Codes, only 23% have introduced the APEC resource guide on government strategies to encourage ethical business conduct to local public organizations. This indicates considerable upside remains in advancing new collaborations in support of these strategies.

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

OPPORTUNITIES

- Increased collaboration with industry
- Introduction to 'Government Strategies to Encourage Ethical Business Conduct'
- Engagement with trainings

CHALLENGES

- Bureaucracy
- Resources
- Mindset related to the importance of ethics

PART 4

Code of Ethics Compendium of APEC Medical Technology 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 | 88 | 30 | Yes | 2001 | 2021 | 76-100% |
| Pathology Technology Australia | Australia | 37 | No data | Yes | 2010 | 2013 | No data |
| Medtech Canada | ▲ Canada | 85 | 40 | Yes | 2005 | 2019 | 51-75% |
| ADIMECH | ▲ Chile | 14 | 0 | Yes | N/A | 2021 | 76-100% |
| APIS | ▲ Chile | 69 | 40 | 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 | 1150 | 920 | Yes | 2013 | 2021 | 76-100% |
| AMDD | Japan | 62 | No Data | Yes | 2016 | 2021 | 0-25% |
| JFMDA | ▲ Japan | 4,280 | 4,000 | Yes | 1993 | 2021 | 79-100% |
| KMDIA | Korea | 825 | 788 | Yes | 2011 | 2017 | No data |
| AMMI | ▲ Malaysia | 84 | 25 | Yes | 2013 | 2017 | Unknown |
| MMDA | ▲ Malaysia | 160 | 100 | Yes | 2013 | 2013 | Unknown |

▲ PROVIDED RESPONSE TO THE 2022 SURVEY. ALL OTHER DATA WAS COLLECTED IN OR BEFORE 2021 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 | 42 | 40 | Yes | 2013 | 2021 | 76-100% |
| ASEMED | Mexico | No data | No data | Yes | No data | No data | No data |
| APACMed | ▲ Multi | 259 | 118 | Yes | 2016 | 2020 | Unknown |
| MTANZ | ▲ New Zealand | 120 | 40 | Yes | 2005 | 2016 | 26-50% |
| COMSALUD-CCL | Peru | 129 | 101 | Yes | 2012 | 2012 | 0-25% |
| MEPI | Philippines | 88 | 45 | Yes | 2015 | N/A | N/A |
| PAMDRAP | ▲ Philippines | 138 | 56 | Yes | 2015 | 2021 | 76-100% |
| IMEDA | ▲ Russia | 74 | 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 | 76-100% |
| MDDSC | Viet Nam | 25 | 0 | Yes | 2017 | 2019 | No Data |
| VIMEDAS | ▲ Viet Nam | 40 | 40 | Yes | 2015 | 2020 | 76-100% |

▲ PROVIDED RESPONSE TO THE 2022 SURVEY. ALL OTHER DATA WAS COLLECTED IN OR BEFORE 2021 AND FROM PUBLICLY AVAILABLE INFORMATION.

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For Asia-Pacific Economic Cooperation Secretariat
35 Heng Mui Keng Terrace Singapore 119616
Tel: +65 6891 9600 Fax: +65 6891 9690

Email: info@apcc.org
Website: www.apcc.org

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