

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)

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Introduction

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.

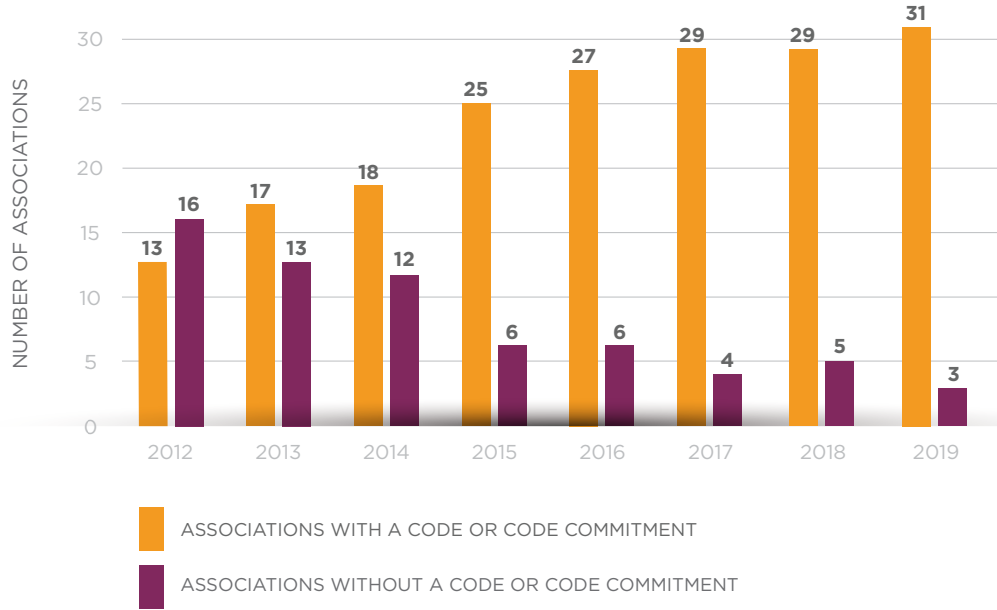
When this initiative's capacity-building program was launched in 2012 to support implementation of the APEC Kuala Lumpur Principles, 13 of these monitored medical device sector industry associations had a code of ethics. In 2019, 31 of these associations have a code of ethics or formalized commitment. 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.

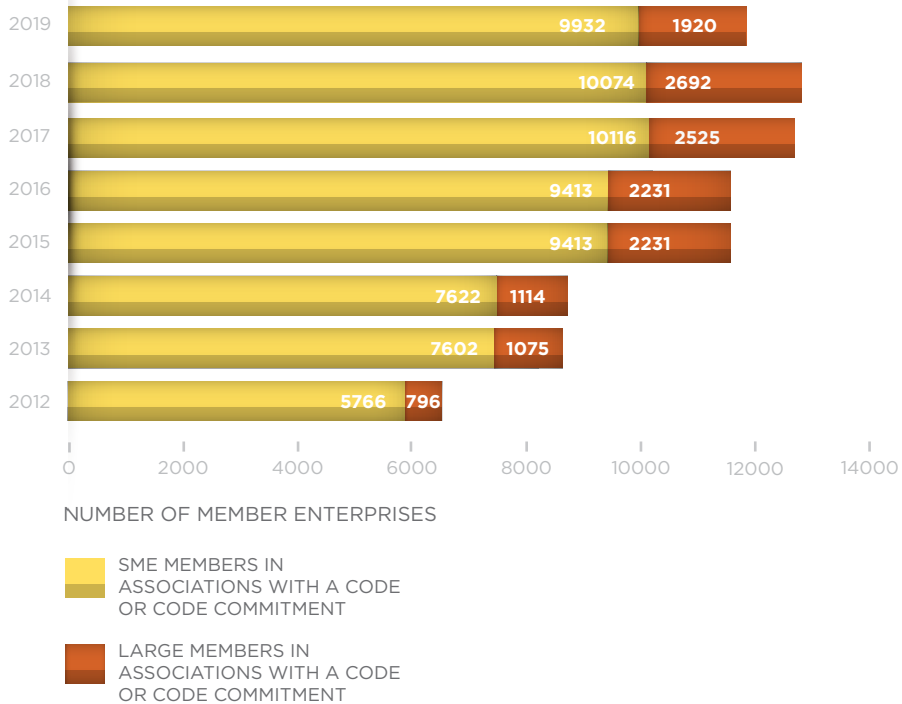
This report has been prepared for the 2019 APEC Business Ethics for SMEs Forum, to indicate where progress has been made since 2012, and where challenges remain, for the region's medical device sector industry associations in (A) code governance, (B) code alignment with the APEC Principles, (C) member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

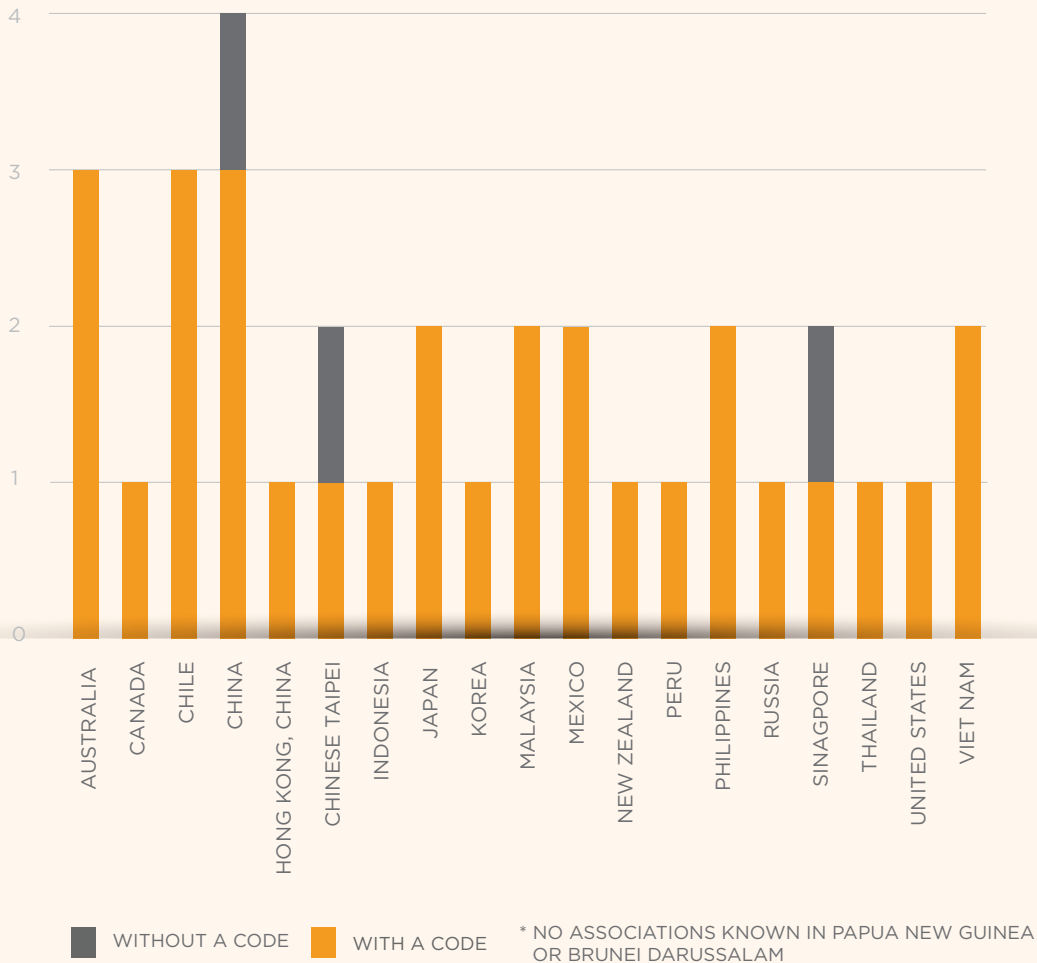


ENTERPRISE MEMBERSHIP OF ASSOCIATIONS WHO HAVE ADOPTED A CODE OR CODE COMMITMENT



Regional Overview

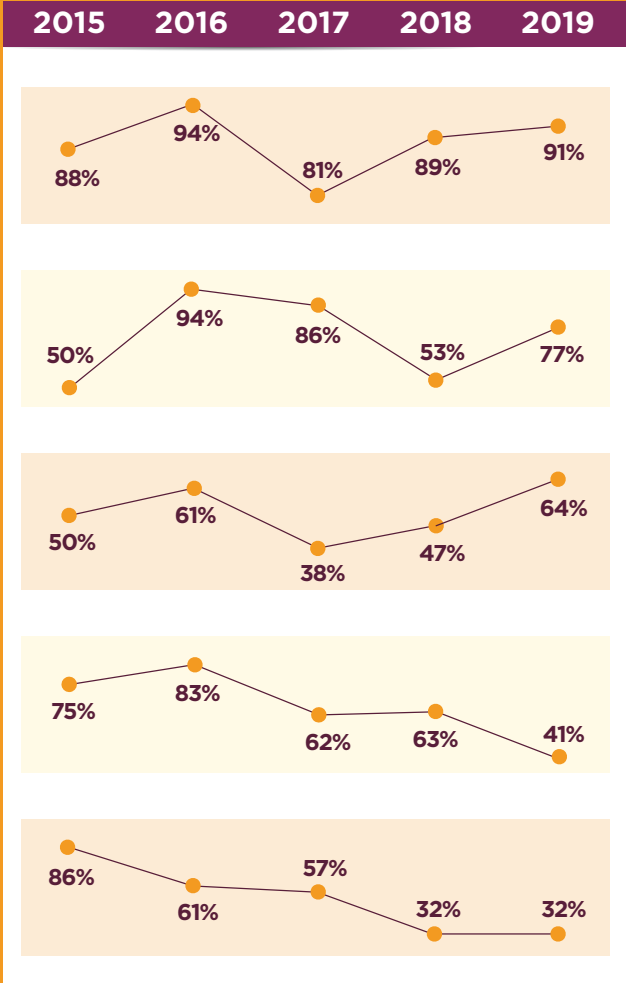
2019 REGIONAL BREAKDOWN*



| 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-one 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

41%

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)

36%

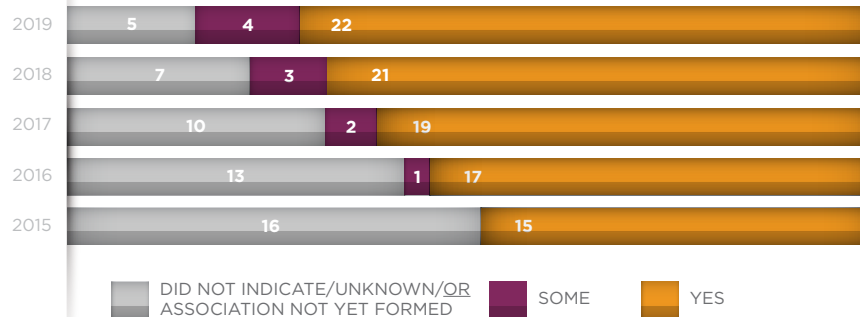
Association offering code of ethics training to individual sales representatives

Alignment with the APEC Kuala Lumpur Principles

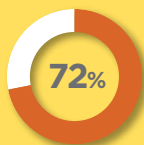
The *Business Ethics for APEC SMEs Initiative* has conducted eight medical device sector capacity-building programs since 2012 and has extended support for dozens of local trainings to ensure that medical device industry association codes of ethics achieve alignment with the APEC

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.

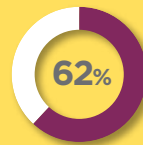
REPORTED EMBRACE OF THE FIVE FUNDAMENTAL PRINCIPLES OF THE APEC KUALA LUMPUR PRINCIPLES BY ASSOCIATIONS WITH A CODE OR CODE COMMITMENT:



APEC GUIDANCE FOR ETHICAL THIRD PARTY INTERMEDIARY RELATIONSHIPS IN THE MEDICAL TECHNOLOGY SECTOR - ALIGNMENT:



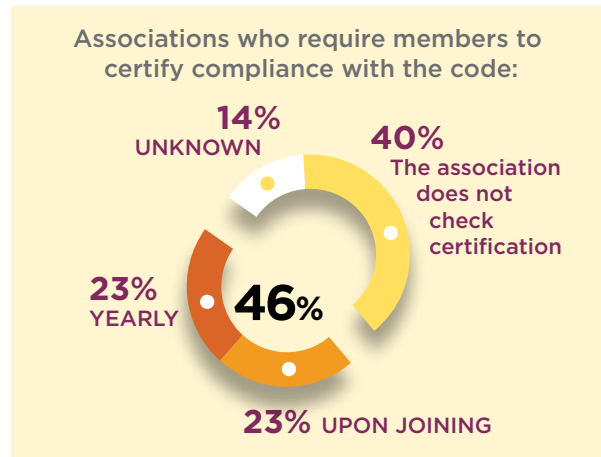
of associations report that the current code of ethics includes specific guidance to strengthen ethical relationships between medical device companies (such as manufacturers) and third party intermediaries (such as distributors)



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

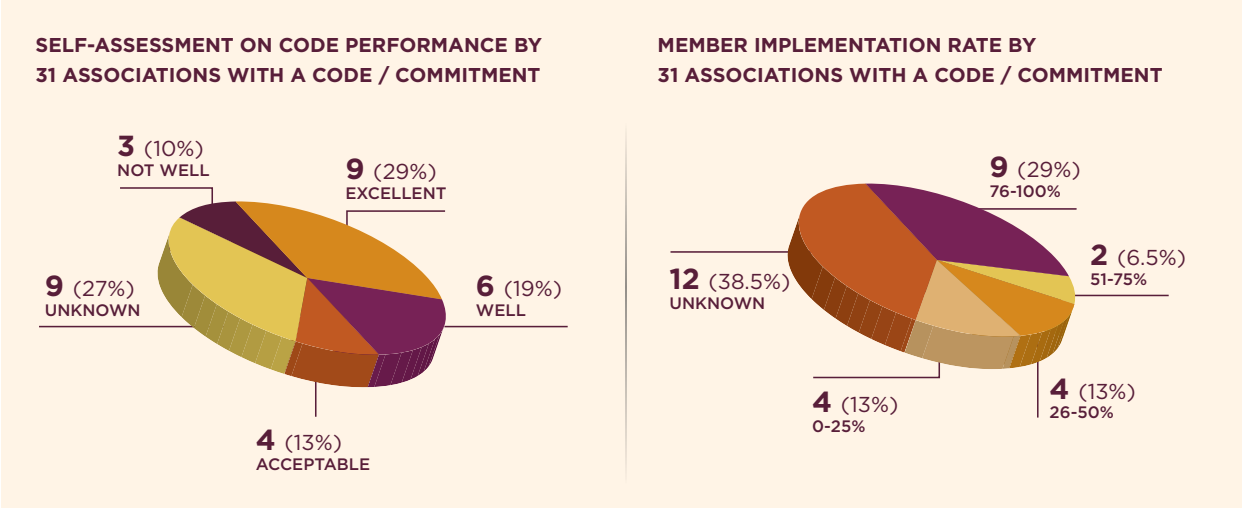
Member Implementation

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.



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% |

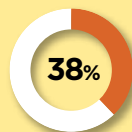


External Engagement

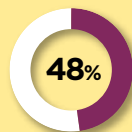
How medical device industry associations engage with external stakeholders (non-members) on their codes of ethics has emerged as fourth area of assessment in code implementation. While important for association members to adhere and implement their code, many encounter a “non-member dilemma” of how to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

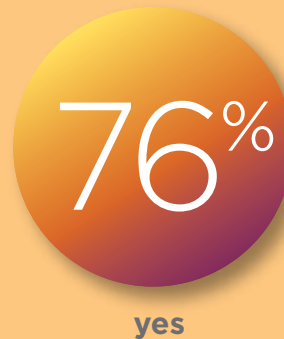
Associations reporting that they have distributed the code to non-members:



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



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