2017 Report on

Code of Ethics Implementation

by APEC Biopharmaceutical Industry Associations



Asia-Pacific Economic Cooperation Business Ethics for APEC SMEs Biopharmaceutical Sector







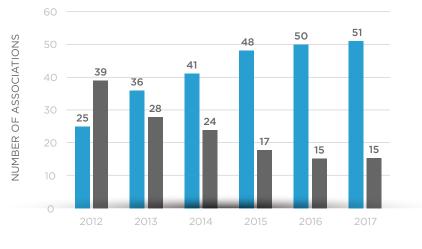
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Introduction

The Business Ethics for APEC SMEs Initiative monitors code of ethics development and implementation by 66 biopharmaceutical sector industry associations across the APEC region. These associations collectively represent nearly 10,000 member enterprises, of which over 6,000 are identified as SMEs. These enterprises constitute a significant majority of the firms that develop, manufacture, market, or distribute pharmaceutical and/or biological product in the region.

When this initiative's capacity-building program was launched in 2012 to support implementation of the APEC Mexico City Principles, 25 of these monitored biopharmaceutical sector industry associations had a code of ethics. In 2017, 51 of these associations have a code of ethics or formalized commitment. The initiative remains dedicated to realizing all biopharmaceutical sector industry associations that have adopted a code also achieve implementation of the code's provisions by a majority of their member enterprises. To achieve this outcome, the initiative has launched a pilot program in partnership with industry associations to survey member enterprises that will be expanded across the region in 2018. The initiative also continues to pursue universal code of ethics adoption by APEC biopharmaceutical sector industry associations by 2020.

This report has been prepared for the 2017 APEC Business Ethics for SMEs Forum, the 45th APEC SMEWG Meeting, and 24th APEC SME Ministerial Meeting to indicate where progress has been made since 2012, and where challenges remain, for the region's biopharmaceutical sector industry associations in (A) code governance, (B) code alignment with the APEC Principles, and (C) member enterprise implementation of 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

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

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



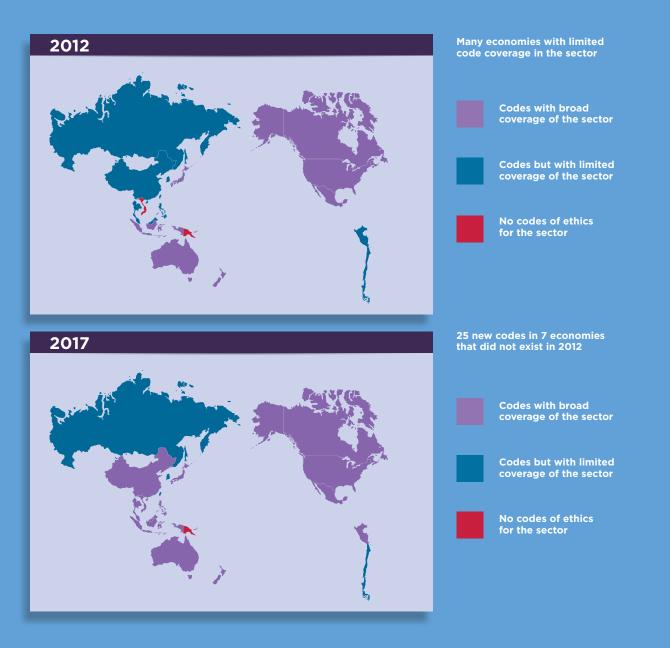
NUMBER OF MEMBER ENTERPRISES IN ASSOCIATIONS WITH A CODE



ASSOCIATIONS WITH A CODE OR CODE COMMITMENTS

LARGE MEMBERS IN ASSOCIATIONS WITH A CODE OR CODE COMMITMENTS

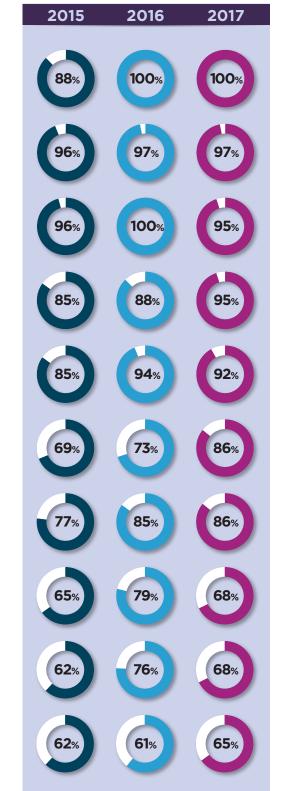
Regional Overview



| Industry Associations Monitored: | 66 | STATUS REPORT | 2012 | 2017 |
|---|------------------|---|--------|-----------------------|
| Total Member Enterprises: SME Members: | 9,600+ 6,300+ | Associations with a Code/ Code Commitment: | 25 | 51 (up 26) |
| SHE HEMBERS. | 0,000 | Total Member Enterprises: | 3,900+ | 8,300+ (up 4,400+) |
| | | SME Members: | 2,600+ | 5,900+ (up 3,300+) |

Code Governance

Biopharmaceutical 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 2017 survey (37 of the 51 with codes or commitments) indicate that most continue to have a valid governance structure in place. Of note, 100% continue to indicate their current leadership is committed to the code and there is a 13% increase over last year in the number of associations reporting sufficient resources to support code maintenance, promotion, and implementation. Most key governance areas assessed in 2017 saw a similar response as 2016, with declines in the number of associations distributing the code to non-members as well as those providing one-on-one assistance for members. There remains an opportunity for associations to expand regular code trainings, which remain low. Of note, 86% of the biopharmaceutical sector industry associations surveyed said an online training course designed to help their member companies certify adherence to the APEC Mexico City Principles would be very helpful or moderately helpful.



leadership committed to the code of ethics

Associations with current

Associations that distributed the code to members for input before adoption

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

Associations with procedures in place to review the code and ensure it is up-to-date

Associations that have designated staff or a member to oversee code maintenance, promotion, and implementation

Associations with sufficient resources to support code maintenance, promotion, and implementation

Associations with a code complaint or violation procedure

Associations that have distributed the code to nonmembers within the past year, including HCPs, third parties, patients, and governments

Associations that provide one-on-one assistance to members seeking to align their business practices with the code

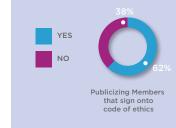
Associations who offer one or more code of ethics training to members

Code Alignment with the **APEC Mexico City Principles**

The Business Ethics for APEC SMEs Initiative has conducted six biopharmaceutical sector capacity-building programs since 2012 and has extended support for dozens of local trainings to ensure that new and existing biopharmaceutical industry association codes of ethics achieve alignment with the APEC Mexico City Principles. 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. Among the associations responding to the 2017 survey (37 of the 51 with code or commitments), 81% report their code embraces all six fundamental principles of the APEC Mexico City Principles, a 5% increase from the

2016 survey. A significant majority report they contain the Principles' 17 provisions. The two provisions of the APEC Mexico City Principles with the lowest adherence include public sector relationships and procurement as well as clinical trials. These two provisions similarly had the lowest adherence rate in the 2016 survey. While the 2017 survey saw a 10% increase over 2016 in the number of associations that report contributing to and participating in industry capacity-building, along with a 16% increase in those ensuring the code remains relevant and effective to address new business arrangements, the survey also saw an 11% decrease in the number of associations that make training available to health care professionals and other stakeholders.

2017 PERFORMANCE BY INDUSTRY ASSOCIATIONS TO IMPLEMENT APEC MEXICO CITY PRINCIPLES RECOMMENDATIONS:



3. Safety of Medicines

6. Entertainment

14. Clinical Trials

16. Patient Organizations

17. Adherence to Principles

9. Samples



Make training available to health care professionals and other stakeholders

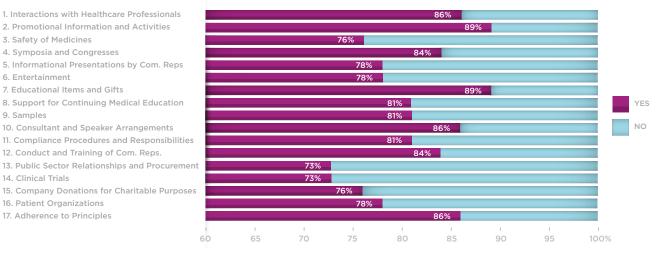


Contribute to and participate in industry . capacity building



Ensure the code remains relevant and effective to address new business arrangements

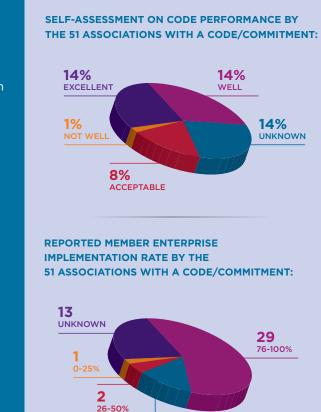
PERCENTAGE OF ASSOCIATION CODES OF ETHICS ALIGNED WITH EACH OF THE PROVISIONS OF THE APEC MEXICO CITY PRINCIPLES (2017):



2017 CODE OF ETHICS IMPLEMENTATION | APEC BIOPHARMACEUTICAL INDUSTRY ASSOCIATIONS

Member Enterprise Implementation

Assessing member enterprise implementation of a biopharmaceutical sector industry association's code of ethics remains the most difficult component of the initiative's monitoring activities. To-date, data is largely dependent on estimates provided by each association. To begin to address challenges in obtaining complete and accurate data, the initiative has launched a pilot program in partnership with industry associations to survey member enterprises directly. Initiated in the Philippines, this pilot will be expanded across the region in 2018. Among the associations responding to the 2017 survey (37 of the 51 associations with codes or code commitments), 76% report their code has performed "excellent" or "well" over the past year. Furthermore, 96% of these associations report that a majority of their members have implemented the association's code into daily practices. In examining all 51 associations with codes or commitments, at least 69% report that a majority of their members have implemented the code.



6 51-75%



| Economy | Member Enterprises | | Code Adoption Code Commitment* | | | Member Implementation | Participation in APEC Business Ethics Forur | | | |
|---------------------|--|---|---|--|---|---|--|---|---|---|
| | TOTAL | SMEs | Yes/ No | Year Adopt | Last Update | | 2014 | 2015 | 2016 | 2017 |
| Australia | 35 | 18 | Yes | 1960 | 2015 | 76-100% | Yes | Yes | No | Yes |
| Australia | 7 | 3 | Yes | 2010 | 2016 | 76-100% | No | No | No | No |
| Canada | 50 | 35 | Yes | 1988 | 2017 | 76-100% | Yes | Yes | Yes | Yes |
| Canada | 9 | 4 | Yes | 1998 | 2013 | No Data | No | No | No | No |
| Chile | 11 | 7 | No | N/A | N/A | N/A | No | No | No | No |
| Chile | 21 | 0 | Yes | 2006 | 2017 | 76-100% | No | No | Yes | Yes |
| China | 360 | 110 | Yes* | 2013* | 2015* | 26-50% | Yes | Yes | No | Yes |
| China | 1,840 | 1,688 | Yes* | 2013* | 2015* | 51-75% | Yes | Yes | Yes | Yes |
| China | 83 | 17 | Yes* | 2013* | 2015* | 76-100% | Yes | Yes | Yes | No |
| China | 39 | 11 | Yes | 1999 | 2017 | 76-100% | Yes | Yes | No | Yes |
| China | 700 | 500 | Yes* | 2013* | 2015* | 76-100% | Yes | No | No | No |
| China | 384 | 249 | Yes* | 2013* | 2015* | 51-75% | Yes | No | No | No |
| China | No Data | No Data | Yes* | 2013* | 2015* | No Data | No | No | No | No |
| China | No Data | No Data | Yes* | 2015* | N/A | No Data | No | No | No | No |
| China | No Data | No Data | Yes* | 2015* | N/A | No Data | No | No | No | No |
| China | 350 | No Data | Yes* | 2013* | 2015* | No Data | No | No | No | No |
| China | 350 | No Data | Yes* | 2015* | N/A | No Data | No | No | No | No |
| China | No Data | No Data | Yes* | 2015* | N/A | No Data | No | No | No | No |
| China | No Data | No Data | Yes* | 2013* | 2015* | No Data | No | No | No | No |
| China | No Data | No Data | Yes* | 2015* | N/A | No Data | No | No | No | No |
| China | No Data | No Data | Yes* | 2015* | N/A | No Data | No | No | No | No |
| China | No Data | No Data | Yes* | 2013* | 2015* | No Data | No | No | No | No |
| Hong Kong, China | 47 | 30 | Yes | 1971 | 2017 | 51-75% | Yes | Yes | Yes | Yes |
| Hong Kong, China | 38 | 35 | No | N/A | N/A | N/A | No | No | No | No |
| | Australia Australia Canada Canada Chile Chile China | EnterprisTOTALAustralia35Australia7Canada9Canada9Chile11Chile360China360China39China39China39China300China300China300China300China300China300China300China300China350China350China350ChinaNo DataChinaNo Data | EnterpriseTOTALSMEsAustralia3518Australia73Canada5035Canada94Chile117Chile210China36010China38417China3911China384249China384249ChinaNo DataNo DataChinaNo DataNo DataChina350No DataChina350No DataChina350No DataChina350No DataChinaNo DataNo Data | EnterprisesCodeTOTALSMEsYes/Australia3518YesAustralia73YesAustralia73YesCanada5035YesCanada94YesCanada94YesChile117NoChina36010Yes*China1,8401,688Yes*China3911Yes*China384249Yes*ChinaNo DataNo DataYes*ChinaNo DataNo DataYes*China350No DataYes*China350No DataYes*China350No DataYes*ChinaNo DataNo DataYes*China | EnterpriseCode Commit Yes/Yes/ AdoptAustralia35SMEsYes/ 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| Association | Economy | Member Enterprises | | Code Adoption Code Commitment* | | | Member Implementation | Participation in APEC Business Ethics Forum | | | |
|--------------------------|---------------------|-----------------------|-------|-----------------------------------|---------------|----------------|--------------------------|--|------|------|------|
| | | TOTAL | SMEs | Yes/ No | Year Adopt | Last Update | | 2014 | 2015 | 2016 | 2017 |
| PDAHK | Hong Kong, China | 44 | 44 | No | N/A | N/A | N/A | No | No | No | No |
| GP Farmasi | Indonesia | 2,900 | 2,300 | Yes | 2003 | 2016 | 51-75% | Yes | Yes | No | Yes |
| IPMG | Indonesia | 26 | 0 | Yes | 2001 | 2017 | 76-100% | Yes | Yes | No | Yes |
| JPMA | Japan | 72 | 5 | Yes | 1976 | 2017 | 76-100% | Yes | Yes | Yes | Yes |
| JGA | Japan | 42 | 29 | Yes | 2010 | 2014 | 76-100% | No | Yes | No | Yes |
| KRPIA | Korea | 40 | 5 | Yes | 2010 | N/A | 76-100% | No | No | No | No |
| КРВМА | Korea | 183 | 118 | Yes | 1994 | 2014 | 51-75% | Yes | No | No | No |
| КоВІА | Korea | 107 | 50 | No | N/A | N/A | N/A | No | No | No | No |
| ΜΟΡΙ | Malaysia | 41 | 32 | Yes | 2013 | 2016 | No Data | Yes | No | No | No |
| PhAMA | Malaysia | 41 | 7 | Yes | 1978 | 2017 | 76-100% | No | No | No | No |
| CANIFARMA | Mexico | 95 | 0 | Yes | 2005 | 2013 | 76-100% | No | No | No | No |
| CETIFARMA | Mexico | 113 | 63 | Yes | 2005 | 2015 | 76-100% | Yes | Yes | Yes | Yes |
| AMIIF | Mexico | 61 | 5 | Yes | 2005 | 2013 | 76-100% | No | No | No | No |
| ANAFAM | Mexico | 28 | 0 | Yes | 2005 | 2013 | 51-75% | Yes | Yes | Yes | No |
| Medicines New Zealand | New Zealand | 26 | 9 | Yes | 1962 | 2015 | 76-100% | No | No | No | No |
| ADIFAN | Peru | 13 | 13 | Yes | 2014 | N/A | 76-100% | Yes | Yes | Yes | Yes |
| ALAFARPE | Peru | 17 | 0 | Yes | 2016 | N/A | 76-100% | No | Yes | Yes | Yes |
| ALAFAL | Peru | 11 | 5 | Yes | 2016 | N/A | 76-100% | No | No | Yes | No |
| PCPI | Philippines | 115 | 100 | Yes | 2014 | N/A | 76-100% | Yes | Yes | No | No |
| РНАР | Philippines | 40 | 10 | Yes | 1993 | 2016 | 76-100% | Yes | Yes | Yes | Yes |
| MEPI | Philippines | 46 | 0 | Yes | 2015 | N/A | No Data | No | No | No | No |
| AIPM | Russia | 44 | 14 | Yes | 1998 | 2016 | 76-100% | No | No | No | No |
| ARPM | Russia | 20 | 0 | No | N/A | N/A | N/A | No | No | No | No |
| SAPI | Singapore | 40 | 0 | Yes | <2010 | 2016 | 76-100% | No | No | No | No |

| Association | Economy | Member Enterpri | | Adopti Commi | | Member Implementation | Participation in API Business Ethics For | | | | |
|--------------|-------------------|--------------------|---------|-----------------|---------------|--------------------------|---|------|------|------|------|
| | | TOTAL | SMEs | Yes/ No | Year Adopt | Last Update | | 2014 | 2015 | 2016 | 2017 |
| SMF-LSIG | Singapore | 48 | 30 | No | N/A | N/A | N/A | No | No | No | No |
| IRPMA | Chinese Taipei | 47 | 37 | Yes | 1994 | 2016 | 76-100% | No | No | No | Yes |
| TRPMA | Chinese Taipei | 28 | 28 | No | N/A | N/A | N/A | No | No | No | No |
| ТРМА | Chinese Taipei | 210 | 160 | No | N/A | N/A | N/A | No | No | No | No |
| TGPA | Chinese Taipei | 65 | 10 | No | N/A | N/A | N/A | No | No | No | No |
| САРА | Chinese Taipei | 125 | 115 | No | N/A | N/A | N/A | No | No | No | No |
| CPMDA | Chinese Taipei | 50 | 16 | No | N/A | N/A | N/A | No | No | No | No |
| NPCA | Chinese Taipei | No Data | No Data | No | N/A | N/A | N/A | No | No | No | No |
| TPADA | Chinese Taipei | 175 | 165 | No | N/A | N/A | N/A | No | No | No | No |
| ТРММА | Chinese Taipei | 55 | 55 | No | N/A | N/A | N/A | No | No | No | No |
| PReMA | Thailand | 38 | 14 | Yes | 1986 | 2016 | 76-100% | Yes | Yes | Yes | Yes |
| ТРМА | Thailand | 70 | 60 | Yes | 2016 | N/A | 26-50% | No | Yes | Yes | Yes |
| GPO | Thailand | 1 | 0 | Yes | 2015 | N/A | 76-100% | No | Yes | No | No |
| PhRMA | United States | 30 | 0 | Yes | 2002 | 2009 | 76-100% | Yes | Yes | Yes | Yes |
| VNPCA | Viet Nam | 168 | 100 | Yes | 2014 | 2016 | 0-25% | Yes | Yes | Yes | Yes |
| Pharma Group | Viet Nam | 26 | 0 | Yes | 2014 | 2016 | 76-100% | No | Yes | Yes | Yes |
| FIFARMA | Regional | 13 | 0 | Yes | 2014 | N/A | 76-100% | No | No | No | No |
| ALIFAR | Regional | N/A | N/A | No | N/A | N/A | N/A | No | No | No | No |



Asia-Pacific Economic Cooperation Business Ethics for APEC SMEs Biopharmaceutical Sector