

2022 Report on

Code of Ethics Implementation

by Biopharmaceutical
Industry Associations
in the APEC Region



**Business Ethics for APEC SMEs
Biopharmaceutical Sector**

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

November 2022

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Executive Summary

The Asia-Pacific Economic Cooperation (“APEC”) 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 in the biopharmaceutical sector. As of 2022, the initiative biopharmaceutical industry association (“Association”) partners represent 9,558 companies, of which 5,530 are small and medium size enterprises (“SMEs”). The basis of ethical business conduct in the biopharmaceutical sector are the APEC Mexico City Principles (“Principles”), recognized by APEC Economic Leaders and Ministers. This 2022 Report serves as the first review of ethics implementation activities of associations in the APEC region since the modernization of the Principles in 2021. Key updates to the Principles included:

- Refinement of the definition of the biopharmaceutical sector to include intermediaries
- Prohibition of promotional aids and permission for companies where permitted by law or local codes of ethics, to offer items specifically designed for the education of patients or healthcare professionals if the items are of modest cost, do not have independent value, and are not branded

- Inclusion of Environmental, Social, and Governance (ESG), focusing on enterprise governance

Previous reports have focused on collecting e-survey data on association’s Code of Ethics (“Code”) adoption and alignment with the APEC Principles. In 2022, the initiative recast and strengthened this process using an interview-based approach. This allowed the initiative to obtain further context and reasoning behind code implementation activities while also building upon existing survey data.

The interviews were held with 26 of the region’s biopharmaceutical associations to assess recent activities, challenges, and opportunities of the code implementation process. The 2022 report highlights the following categories:

1. Governance structure and leadership involvement in ethics
2. Code alignment with the Principles
3. External engagement including capacity building and multi-stakeholders
4. Communication and understanding of the Principles

Major Findings

1. The presence of an ethics committee helps to uphold code implementation as a priority of senior leadership.
2. Influencing factors of code revision include new local law mandates, modernization of the Principles or the IFPMA Code of Practice, industry regulation changes due to global circumstances (e.g. COVID-19), and member company advocacy.
3. Virtual ethics trainings and e-learning tools have increased associations' ability to expand their external-stakeholder engagement (e.g. governments, patient organizations, health-care professionals).
4. Emerging ethics-related issues for associations in the APEC region include: ESG standards, social media, artificial intelligence, data privacy, and fair competition.

ASSOCIATIONS MOST HEAVILY CITED THE FOLLOWING CHALLENGES AND OPPORTUNITIES IN CODE IMPLEMENTATION:

CHALLENGES	OPPORTUNITIES
<p>Prioritization: Maintaining momentum, relevancy, and visibility</p> <p>Perception: Cultural criticism viewed by some economies of the industry and lack of trust</p>	<p>Communication: Increased promotion of code implementation among member companies</p> <p>Partnership: Additional partnerships with external stakeholders</p>

PART 1

Governance and Alignment

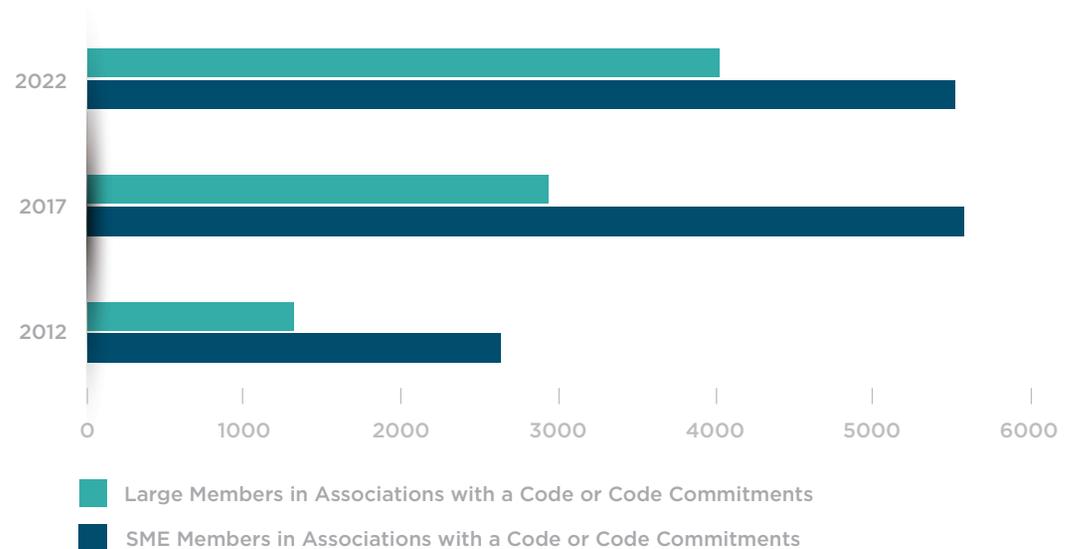
INDUSTRY ASSOCIATIONS WITH A CODE OR CODE COMMITMENT



Biopharmaceutical industry associations have nearly universally adopted Codes in the APEC region. Over the past decade, we have seen an immense increase in Code adoption by associations across the APEC region. This increase, in combination with the continuous modernization of existing Codes, **has transformed from a 25:40 Code to no-Code ratio, to a 55:15 Code to no-Code ratio, with a 120% growth rate.** The APEC Mexico City Principles play a key role in this transition.

The increase in adoption rate indicates that 9,558 biopharmaceutical companies, including 5,530 SMEs, within the APEC region are covered by a high standard and aligned Code in 2022, in comparison to 3,947 companies covered by unaligned Codes in 2012. The Initiative continues outreach to the remaining associations in China; Chile; Hong Kong, China; Korea; Mexico; Russia; Singapore; and Chinese Taipei to pursue code adoption.

INDUSTRY ASSOCIATION REPRESENTATION



part 1 continued

STATUS REPORT	2012	2022	Percentage of Growth
Associations with a Code of Ethics or Code Commitment	25	55	120%
Total Member Enterprises covered by a Code of Ethics	3,947	9,558	142%
SME Member Companies covered by a Code of Ethics	2,635	5,530	110%

Association leadership involvement in code governance and adherence helps to set the “tone at the top” for ethical standard expectations. This year’s interviews reveal that most associations have involved their senior leadership (e.g. CEOs of member companies and the Board of Directors) in the code governance process. A quarter of associations have formed independent committees composed of member enterprises, academics, and healthcare professionals to routinely review the code or determine next steps when there is a breach or complaint. To resolve complaints, some associations have chosen to

elect a body of representatives from each of their member companies who review cases with an equal voting structure. Of the interviewed industry associations who have ethics committees, more than half reported convening on a monthly, bi-monthly, or quarterly basis.

ALIGNMENT

Alignment with the Principles indicates when associations have chosen to make changes to their code of conduct based on the guidelines published in the Principles. In addition to the modernization of the Principles, the main factors that

contribute to associations’ decisions to revise their code include new local law regulations, member requests, and rapid societal changes (e.g. social media, COVID-19). These factors allow associations to stay current and responsive to internal and external stakeholders.

CODE GOVERNANCE SPOTLIGHT: JAPAN PHARMACEUTICAL MANUFACTURERS ASSOCIATION (JPMA)

JPMA created an APEC Mexico City Principles Subcommittee, whose first act of business was to translate the Principles into Japanese to aid members understanding of the content. The Subcommittee has since conducted member and employee trainings on the Principles as well as communicated development on the Principles to members, including 2021 revisions.

CODE ALIGNMENT SPOTLIGHT: VIET NAM PHARMACEUTICAL COMPANIES ASSOCIATION (VNPCA)

In 2018, VNPCA signed a commitment to support the implementation of laws on anti-corruption, aligned with VNPCA’s code and the APEC Principles. This commitment not only supports code implementation among their members, but code alignment with non-member businesses and organizations across the economy.

PART 2

External Engagement

Capacity Building

Capacity building and training activities by associations are necessary to ensure their members are well prepared to implement the code in daily business activities.

The interviews revealed that the best opportunity to provide training to association members is when new companies or individuals join the organization through member onboarding. Mandated training on codes for member companies is not common. For non-members, many associations offer training upon request only.

Associations also continue to extend capacity building and training activities in various forms, such as virtual and e-learning training tools, individualized trainings for member companies, and strictly in-person training. The rise of virtual tools has also proven to be a challenge given unequal access to digital tools in some APEC economies. New training subjects explored by interviewed associations include the modernized Principles and interactions between biopharmaceutical companies and patient organizations.

TRAINING ACTIVITIES:

- Virtual and e-learning training tools (e.g. APEC SME Leaders in Ethics and Integrity Program, LEIP)
- Individualized trainings for member companies
- Strictly in-person training

EMERGING ETHICAL AREAS OF INTEREST TO ASSOCIATIONS FOR FUTURE INFORMATION / TRAINING SESSIONS

- ESG
- Artificial intelligence
- Social media
- Data privacy
- Fair market competition

CODE CAPACITY BUILDING SPOTLIGHT: CAMARA NACIONAL DE LABORATORIOS (CANALAB), CHILE

“It is important to not only have trainings within companies, but also share the knowledge. The APEC SME Leaders in Ethics and Integrity Program (LEIP) was important to our association to help us interact with patient organizations and other stakeholders to build relationships and trust. LEIP was especially important to Camara Nacional de Laboratorios because we are a small team, and needed the support that the initiative provided us to make those connections.”

part 2 continued

STAKEHOLDER ENGAGEMENT

The strength of relationships between associations and external stakeholders are central to collaboration on ethical issues in the health system. Associations in economies such as Canada and Japan cited the economy's existing consensus framework as a main point of ethical collaboration with external stakeholders. Consensus frameworks serve as lasting platforms to facilitate the communication and identification of best ethical practices. There currently exist ten consensus frameworks within the APEC region, including Australia; Canada; Chile; China; Japan; Mexico; New Zealand; Peru; the Philippines; and Viet Nam, as well as an International Consensus Framework. Thailand is also in the process of developing one, with two biopharmaceutical associations participating.

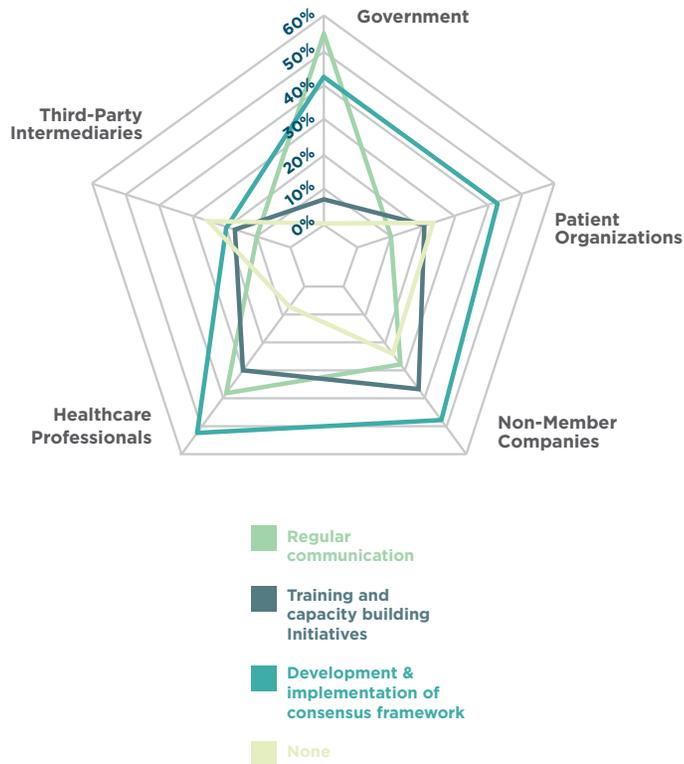
Associations interviewed cited a need to further engage with patient organizations and for trainings on interactions with patient organizations. Additionally, associations' relationships with government vary depending on the prioritization of ethics activities in that economy. For example, in Indonesia, associations have monthly reporting requirements for the Corruption Eradication Commission (KPK) and Ministry of Health. Across the region, pro-active ethical collaboration between associations and non-member companies is minimal.

CODE STAKEHOLDER ENGAGEMENT SPOTLIGHT: KOREAN RESEARCH-BASED PHARMACEUTICAL INDUSTRY ASSOCIATION (KRPIA)

KRPIA holds bi-annual code trainings for both their members as well as external stakeholders. KRPIA has established partnerships with the Korean Medical Association and the Korean Medical Device Industry Association (KMDIA) to conduct code trainings for healthcare professionals in response to a need cited by member companies.

part 2 continued

PERCENT OF INDUSTRY ASSOCIATIONS ENGAGING WITH SPECIFIC STAKEHOLDERS IN 2021



2022 INTERVIEW INSIGHTS ON MULTI-STAKEHOLDER ENGAGEMENT COMPARED TO 2021 DATA

Engagement with governments, patient organizations, healthcare professionals, third-party intermediaries and non-member companies enhances associations' ability to build relationships and advocate for aligned ethical business practices across the health system. Insights from the 2022 interviews indicate that, similar to 2021 insights, governments and healthcare professionals remain the stakeholders that associations communicate with most frequently. The comments on engagement with patient organizations, third parties, and non-member companies verified 2021 insights for these groups. One association said, "We are starting to build engagement for our association on ethics that includes the patient voice, however most of our interactions are with healthcare professionals." Consensus frameworks remain one of the main ways associations work with external stakeholders, with training and capacity building initiatives following.

Government engagement on ethics issues remains an area of continued interest by associations. In 2021, it was reported that roughly 55% of associations engage in regular communication with their governments. The 2022 interviews provided further context on these communications. For over half of those interviewed, the primary form of communications with government are around new laws or updates to their code.

For many association leaders, the external engagement and advocacy on ethics is a result of years of relationship development. However, as one association leader indicated, "the continuous leadership turnover within government and elsewhere has been a challenge for our association to progress ethical collaboration."

PART 3

Communication

Communication by associations on their code, both internally with members and externally with stakeholders, is a new area covered in the report and has significantly increased in importance amidst the pandemic in driving code implementation. Tools such as one-pagers, academic publications, and social media strategies allow associations to effectively disseminate information on its current code activities. Some associations have established strong communications tools, including routine member communications.

The 2022 interviews revealed that associations have various strategies for communicating regarding their codes. Internally, committee meetings, email communications, and member trainings have been the more successful ways that associations have been able to translate their ongoing ethics work to member companies and to their internal employees. Externally, engagement with stakeholders through consensus frameworks, external newsletters, social media posts, and annual meetings have proven useful to convey associations' messages on ethics.

The 2022 interviews also indicate that associations view there is great opportunity to communicate their work to external stakeholders. They seek to create further tools such as one pagers, additional trainings, and partnerships with academia and like-minded non-governmental organizations focused on ethics, that this will increase awareness about their ethics work to their larger communities. Associations are optimistic about the future of their communications strategies, citing communications as a critical need in the wake of the pandemic and resulting decrease in member engagement on ethics.

CODE COMMUNICATION SPOTLIGHT: MEDICINES NEW ZEALAND

Medicines New Zealand distributes a monthly newsletter to all members. Inside its pages, members can find information about the New Zealand Consensus Framework, upcoming trainings, and other ethics activities. The newsletter also highlights one question per month that was asked by a member company to help share knowledge with the rest of the membership.

Code of Ethics Compendium of Biopharmaceutical Industry Associations in the APEC Region

Association	Economy	Member Enterprises		Code Adoption Commitment**		Code		Member Implementation	Participation in Consensus Framework Agreement
		TOTAL	SMEs	Yes/No	Year Adopt	Last Update			
Medicines Australia ▲	Australia	29	0	Yes	1960	2020	76-100%	Yes	
GBMA	Australia	7	4	Yes	2010	2015	76-100%	No	
IMC ▲	Canada	41	25	Yes	1988	2022	76-100%	Yes	
CGPA	Canada	11	0	Yes	1998	2013	No Data	No	
ASILFA	Chile	9	0	No	N/A	N/A	N/A	Yes	
CIF ▲	Chile	25	0	Yes	2007			Yes	
Cámara Nacional de Laboratorios ▲	Chile	14	11	Yes	1999	2019	76-100%	Yes	
CPIA	China	510	145	Yes*	2013	2018	51-75%	Yes	
CCCMHPIE	China	1500	1350	Yes*	2011	2013	76-100%	Yes	
PhIRDA ▲	China	171	100	Yes	2018	2018	76-100%	Yes	
RDPAC-CAEFI ▲	China	45	0	Yes	2007	2019	76-100%	Yes	
CATCM	China	700	500	Yes*	2013	2015	76-100%	Yes	
CAPC	China	384	249	Yes*	2013	2015	51-75%	Yes	
All-China Federation	China	No Data	No Data	Yes*	2013	2015	No Data	Yes	
CMBA	China	300	250	Yes*	2015	N/A	No Data	Yes	
CMEA	China	No Data	No Data	Yes*	2015	N/A	No Data	Yes	
CNMA	China	350	No Data	Yes*	*2013	2015	No Data	Yes	
CPAPE	China	350	No Data	Yes*	2015	N/A	No Data	Yes	
CPEMA	China	No Data	No Data	Yes*	2015	N/A	No Data	Yes	
CPEP	China	150	No Data	Yes*	2013	2015	No Data	Yes	
CPPA	China	No Data	No Data	Yes*	2015	N/A	No Data	Yes	

Association	Economy	Member Enterprises		Code Adoption Commitment*		Code	Member Implementation	Participation in Consensus Framework Agreement
		TOTAL	SMEs	Yes/No	Year Adopt			
COAP	China	No Data	No Data	Yes*	2015	N/A	No Data	Yes
CRAECC	China	No Data	No Data	Yes*	2013	2015	No Data	Yes
HKAPI ▲	Hong Kong, China	70	15	Yes	1970	2019	76-100%	No
HKPMA	Hong Kong, China	38	35	No	N/A	N/A	N/A	No
PDAHK	Hong Kong, China	44	44	No	N/A	N/A	N/A	No
GP Farmasi	Indonesia	2400	1500	Yes	2003	2016	51-75%	No
IPMG ▲	Indonesia	27	0	Yes	2001	2021	76-100%	No
JPMA ▲	Japan	72	4	Yes	1976	2019	76-100%	Yes
JGA ▲	Japan	37	24	Yes	2010	2019	76-100%	Yes
KRPIA ▲	Korea	47	28	Yes	2009	2019	76-100%	No
KPBMA	Korea	200	150	Yes	1994	2017	76-100%	No
KoBIA	Korea	107	50	No	N/A	N/A	N/A	No
MOPI ▲	Malaysia	50	45	Yes	2013	2016	Unknown	No
PhAMA	Malaysia	35	1	Yes	1978	2020	76-100%	No
CANIFARMA ▲	Mexico	179	10	Yes	2005	2021	76-100%	Yes
CETIFARMA ▲	Mexico	201	140	Yes	2006	2021	76-100%	Yes
AMIIF ▲	Mexico	34	10	Yes	2006	2021	76-100%	No
ANAFAM	Mexico	6	0	Yes	2005	2013	Unknown	No
ANADIM	Mexico	No Data	No Data	No	N/A	N/A	No Data	No
Medicines New Zealand ▲	New Zealand	26	8	Yes	1962	2019	76-100%	Yes
ADIFAN	Peru	13	13	Yes	2014	N/A	76-100%	Yes
ALAFARPE ▲	Peru	22	2	Yes	2000	2020	76-100%	Yes
ALAFAL	Peru	10	5	Yes	2016	N/A	76-100%	Yes
PCPI	Philippines	100	90	Yes	2014	2014	51-75%	No

Association	Economy	Member Enterprises		Code Adoption	Code		Member Implementation	Participation in Consensus Framework Agreement
		TOTAL	SMEs	Commitment*	Yes/No	Year Adopt		
PHAP ▲	Philippines	40	15	Yes	1993	2021	76-100%	Yes
MEPI	Philippines	46	0	Yes	2015	N/A	No Data	No
AIPM ▲	Russia	32	19	Yes	1998	2020	76-100%	No
ARPM	Russia	20	0	No	N/A	N/A	N/A	No
SAPI	Singapore	34	0	Yes	<1980	2021	76-100%	No
SMF-LSIG	Singapore	48	30	No	N/A	N/A	N/A	No
IRPMA ▲	Chinese Taipei	47	0	Yes	2003	2019	76-100%	No
TRPMA ▲	Chinese Taipei	52	52	Yes	2020	2020	N/A	No
TPMA	Chinese Taipei	210	160	No	N/A	N/A	N/A	No
TGPA	Chinese Taipei	66	36	No	N/A	N/A	N/A	No
CAPA	Chinese Taipei	125	115	No	N/A	N/A	N/A	No
CPMDA	Chinese Taipei	50	16	No	N/A	N/A	N/A	No
NPCA	Chinese Taipei	No Data	No Data	No	N/A	N/A	N/A	No
TPADA	Chinese Taipei	8	0	No	N/A	N/A	N/A	No
TPMMA	Chinese Taipei	55	55	No	N/A	N/A	N/A	No
PReMA ▲	Thailand	31	14	Yes	1987	2019	76-100%	No
TPMA	Thailand	70	60	Yes	2015	2019	Unknown	No
GPO	Thailand	1	0	Yes	2015	N/A	76-100%	No
PhRMA ▲	United States	33	0	Yes	2002	2022	76-100%	No
AAM	United States	24	No Data	Yes	2018	2018	Unknown	No
VNPCA ▲	Viet Nam	200	150	Yes	2015	2017	51-75%	Yes
Pharma Group ▲	Viet Nam	22	0	Yes	2014	2020	76-100%	Yes
IQGx	Viet Nam	11	0	Yes*	2016	2019	76 -100%	Yes
FIFARMA ▲	Regional	19	0	Yes	2014	2021	76-100%	No
ALIFAR	Regional	N/A	N/A	No	N/A	N/A	N/A	No

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