



Status Report on Consensus Frameworks in the APEC Region

2020 APEC Business Ethics for SMEs Virtual Forum 13-27 October 2020











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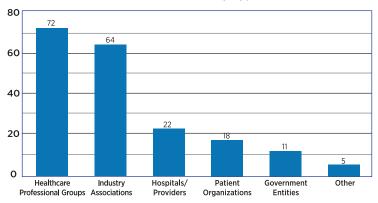


INTRODUCTION

Ethical collaboration among medical device and biopharmaceutical enterprises, industry associations, third-party intermediaries, healthcare professionals and providers, patients, health regulators, and other stakeholders is essential to the delivery of high-quality patient care, patient access to life-saving and health-enhancing medical technologies and therapies, and the development of innovations that meet patient needs. Multi-stakeholder, consensus-based collective action is also vital to successful implementation of the APEC Kuala Lumpur Principles for the medical device sector¹ and APEC Mexico City Principles for the biopharmaceutical sector.² No single group can achieve an ethical environment in these sectors alone. Ethical collaboration among diverse stakeholders also strengthens the ability of APEC economies to respond to and recover from the COVID-19 pandemic, and collaboration underpins the ability of thousands of small and medium-sized enterprises (SMEs) to sustainably operate and engage in cross-border trade. For this reason, APEC Foreign and Trade Ministers, APEC Ministers Responsible for Trade, and APEC SME Ministers have welcomed and encouraged the advancement of formalized "consensus frameworks" for ethical collaboration though the Business Ethics for APEC SMEs Initiative, the world's largest public-private partnership to strengthen ethical business conduct in these sectors. The APEC Nanjing Declaration (2014)³, the APEC Guide

to Facilitate Multi-Stakeholder Ethical Collaborations in the Medical Device and Biopharmaceutical Sectors (2018)⁴, and the annual APEC Business Ethics for SMEs Forum have served as instruments to advance consensus frameworks by diverse parties within APEC economies. Since 2016, nine APEC economies have adopted unique consensus frameworks (Australia, Canada, Chile, China, Japan, Mexico, Peru, The Philippines, and Viet Nam) while parties in several APEC economies actively consider one (such as New Zealand, Thailand, and the United States). These APEC economy-driven efforts build upon the Consensus Framework for Ethical Collaboration adopted in 2014 among several leading international organizations. Several non-APEC economies, such as Brazil, India, and the United Arab Emirates have also been inspired to advance similar consensus framework initiatives. Today, consensus frameworks in the APEC region have brought together 192 public and private organizations representing thousands of companies, hundreds of thousands of healthcare professionals, and millions of patients. This Report provides an overview of the implementation status of each consensus framework currently in place, including the members and activities under each agreement, the greatest successes and challenges, and the impact of COVID-19 on the parties given the importance of reinforcing business ethics and integrity in healthcare amidst the pandemic.

Consensus Framework Parties (By Type)



Top Three Successes and Challenges (2020)

GREATEST SUCCESS:

- Open and Transparent Dialogue
- 2 Engagement and Awareness Building
- **3** Generating Solutions to Challenging Problems

GREATEST CHALLENGES:

- 1 Sustainable Governance
- 2 Sustainable Resourcing and Funding
- Limited Government Engagement

¹ APEC Kuala Lumpur Principles (Medical Device Sector): http://mddb.apec.org/Documents/2011/MM/SMEMM/11 smemm 009.pdf

² APEC Mexico City Principles (Biopharmaceutical Sector): http://mddb.apec.org/Documents/2011/SOM/CSOM/11_csom_021.pdf

³ Nanjing Declaration on Promoting Ethical Environments in the Medical Device and Biopharmaceutical Sectors through 2020: http://mddb.apec.org/Documents/2014/MM/SMEMM/14 smemm 020a.pdf

⁴ APEC Guide to Facilitate Multi-Stakeholder Ethical Collaborations in the Medical Device and Biopharmaceutical Sectors: http://mcprinciples.apec.org/wp-content/uploads/2020/01/18_smewg47_014-1.pdf















International Consensus Framework

Year Proposed: 2013

Date Launched (Month/Year): January 2014

Please indicate the number of parties to the Consensus Framework as of May 2020: 6

Please indicate the Consensus Framework's Stakeholder Participants by Type:

- Patient Organizations
- · Hospitals / Healthcare Centers
- · Biopharmaceutical Industry
- Healthcare Professionals

Were government authorities involved, either as members or supporters, in the Framework from its outset?



Complete List of Parties as of May 2020:

World Medical Association (WMA)

International Alliance of Patient's Organizations (IAPO)

International Pharmaceutical Federation (FIP)

International Council of Nurses (ICN)

International Hospital Federation (IHF)

International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

Please describe the organizational structure of the Consensus Framework:

Roundtable of equal partners with a rotating secretariat.

Does the Consensus Framework receive operational or in-kind funding, either from parties or external sources?

X Yes, from the parties.

Have the Consensus Framework parties held meetings in 2020?

X Yes, on 30 March, 5 May and 6 June

Describe the priorities and activities of the Framework to date:

- Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.
- Align the Framework's parties' codes of ethics.
- Enhance the integrity and credibility of organizations in the healthcare sector.
- Promote public confidence and trust in the health system.
- Enhance public awareness of the Framework and the parties' commitment to ethical conduct.
- Gather additional signatories or endorsers of the Framework.

What next steps are being considered by your Framework?

- Schedule additional Framework meetings (virtual or in-person) every two months; virtual format for the time being
- Gather additional signatories or endorsers of the Framework.

What has been the greatest success of the Consensus Framework?

The consensus framework is a powerful platform for multistakeholder collaboration. The parties have leveraged the platform to work together in strengthening ethics and business integrity as well as a range of additional issues, including anti-microbial resistance, counterfeit medicines, and regulatory standards.

What has been the greatest challenge of the Consensus Framework?

Ensuring close collaboration on a sustained basis, with equitable commitments and contributions.

If the Consensus Framework has sought to advance new or specialized collaborations as a result of the COVID-19 crisis, please share those considerations and/or actions:

The consensus framework has been utilized to discuss draft guidance documents amidst COVID-19, including the IFPMA "Ethical Considerations for resuming F2F interactions with HCPs". The consensus framework partners also support each other on reinforcing common messages on social media platforms.











Australian Ethical Health Alliance

Year Proposed: 2017

Date Launched (Month/Year): July 2018

Number of Parties (2019): 71

Please indicate any changes to the number of parties as of May 2020: 72

Stakeholder Participants by Type (2019):

Medical Device Industry; Third Parties / Distributors; Patient Organizations; Hospitals / Healthcare Centers; Biopharmaceutical Industry; Healthcare Professionals; Government Authorities; Additional Stakeholders Not Listed

Please indicate any additions or changes to the type of stakeholder participants:

• Private Medical Healthcare Funds (Addition)

Were government authorities involved, either as members or supporters, in the Framework from its outset?

X Yes.

Complete List of Parties (2020):

Arthroplasty Society of Australia Assistive Technology Suppliers Australia Audiology Australia

Australasian College of Cosmetic Surgery Australasian College of Dermatologists

Australasian College of Health Service Management

Australasian College of Paramedicine Australasian College of Phlebology Australasian College of Sport and Exercise Physicians

Australasian Leukemia and Lymphoma Group Australasian Sleep Association

Australian and New Zealand Association of Oral and Maxillofacial Surgeons

Australian and New Zealand College of Anaesthetists

Australian and New Zealand Sarcoma Association

Australian and New Zealand Society for Geriatric Medicine

Australian and New Zealand Society for Vascular Surgery

Australian and New Zealand Society of Cardiac and Thoracic Surgeons

Australian and New Zealand Urogenital and Prostate Cancer Trials Group Ltd

Australian College of Emergency Medicine Australian College of Nursing Australian Dental Association

Australian Hand Surgery Society

Australian Healthcare and Hospitals Association

Australian Knee Society

Australian Orthopaedic Association

Australian Orthopaedic Association Medical Legal Society

Australian Orthopaedic Foot and Ankle Society

Australian Orthopaedic Trauma Society

Australian Paediatric Orthopaedic Society

The Australian Pain Society

Australian Pharmacy Council

Australian Private Hospitals Association

Australian Society of Anaesthetists

Australian Society of Clinical Immunology and Allergy

Australian Society of Ophthalmologists Australian Society of Otolaryngology Head and Neck Surgery

Australian Society of Plastic Surgeons Australian Traditional Medicine Society Breast Cancer Trials

BUPA

Complementary Medicines Australia Consumer Healthcare Products Australia Consumers Health Forum of Australia Cosmetic Physicians College of Australasia Day Hospitals Australia

Gastroenterlogical Society of Australia General Surgeons Australia

Medical Technology Association of Australia

Medicines Australia Melanoma and Skin Cancer Trials Limited

Musculoskeletal Australia

National Prescribing Service (NPS) Medicinewise

National Rural Health Alliance Neurological Society of Australia

Painaustralia

Praxis Australia

Private Healthcare Australia

Royal Australasian College of Dental Surgeons

Royal Australasian College of Physicians Royal Australasian College of Surgeons Royal Australian and

New Zealand College of Obstetricians and Gynaecologists

Royal Australian and New Zealand College of Ophthalmologists

Royal Australian and New Zealand College of Psychiatrists

Royal Australian College of General Practitioners Royal College of Pathologists of Australasia Shoulder and Elbow Society of Australia

Skin Cancer College

Society of Hospital Pharmacists of Australia Spine Society of Australia

The Thoracic Society of Australia and New Zealand

Universities Australia

Urological Society of Australia & New Zealand

Please List Any Additions or Changes to the List of Parties as of May 2020:

• The Australian Pain Society (Addition)

Please describe the organizational structure of the Consensus Framework:

AEHA is an informal alliance. Participating organisations are members of the Australian Ethical Health Alliance and participate voluntarily. Initial members are those who were signatories of the ACF. At inception, all signatories were made members of AEHA. AEHA is not established as a separate legal entity. Member organisations may withdraw from participation at any time.

The AEHA Steering Committee was established by AEHA member organisations, as at May 2019, to act as a leadership group for the Alliance. The AEHA Steering Committee comprises representatives from member organisations. Their work is guided by terms of reference, which describes the composition and function of the Committee, including its role and responsibilities.

AEHA's structure also currently includes two working groups: The AEHA Symposium Working Group and the AEHA Communications and Media Working Group. These working groups have been established to progress the goals of AEHA, by expressions of interest amongst the member organisations, and report back to the AEHA Steering Committee.

Continued on next page













Australian Ethical Health Alliance (AEHA) continued

The following documents guide AEHA's governance and organizational structure:

- AEHA Governance
- <u>AEHA Steering Committee</u> Terms of Reference

Does the Consensus Framework receive operational or in-kind funding, either from parties or external sources?

X Yes.

AEHA received limited funding. In addition to this, it has received in-kind support from the Australian Orthopaedic Association and has been provided with meeting rooms by the Royal Australasian College of Surgeons and the Australian Government Department of Health.

Have the Consensus Framework parties held meetings in 2020?

X Yes.

Three meetings have occurred as follows:

- AEHA Steering Committee Meeting 25 February 2020
- AEHA Communications and Media Working Group Meeting – 23 April 2020
- AEHA Steering Committee Meeting 13 May 2020

Two meetings planned for late 2020:

- AEHA Steering Committee Meeting 10 August 2020
- AEHA Steering Committee Meeting 4 November 2020

Describe the priorities and activities of the Framework to date:

 Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.

- Enhance the integrity and credibility of organizations in the healthcare sector.
- Promote public confidence and trust in the health system.
- Enhance public awareness of the Framework and the parties' commitment to ethical conduct.
- Gather additional signatories or endorsers of the Framework.
- Develop common resources and tools for the education of Framework members and/or additional parties, such as training materials.
- Foster public-private coordination of Framework activities.

What next steps are being considered by your Framework?

Schedule additional Framework meetings.
 Dates and Type (virtual or in-person):

A regular schedule of four Steering Committee meetings has been determined to be held per year.

Two meetings are planned to be held for late 2020:

- AEHA Steering Committee Meeting 10 August 2020 (virtual)
- AEHA Steering Committee Meeting 4 November 2020 (virtual).
- Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.
- Develop one common code of ethics for all Framework parties.
- Align the Framework's parties' codes of ethics.
- Enhance the integrity and credibility of organizations in the healthcare sector.
- Promote public confidence and trust in the health system.

- Enhance public awareness of the Framework and the parties' commitment to ethical conduct.
- Gather additional signatories or endorsers of the Framework.
- Develop common resources and tools for the education of Framework members and/or additional parties, such as training materials.
- Foster public-private coordination of Framework activities.

What has been the greatest success of the Consensus Framework?

The greatest success has been in the engagement and awareness of the initiative. This is mostly attributed to the high-energy and committed group of leaders that make up the AEHA Steering Committee.

What has been the greatest challenge of the Consensus Framework?

One of the greatest challenges has been in securing funding to continue the initiative's initial momentum and sustain the progress made on encouraging a commitment to ethical practice.

If the Consensus Framework has sought to advance new or specialized collaborations as a result of the COVID-19 crisis, please share those considerations and/or actions:

The COVID-19 pandemic has provided a platform for greater engagement amongst AEHA member organisations. In addition to meetings of various groups within the healthcare sector, the AEHA community have been asked to share publications and/or position statements that align with the Australian Consensus Framework's principles that can be promoted through the Alliance, which is hoped to provide an opportunity for collaboration of resources during and beyond the pandemic.











Canadian Consensus Framework

Year Proposed: 2015

Date Launched (Month/Year): June 2016

Number of Parties (2019): 7

Please indicate any changes to the number of parties as of May 2020: 8

Stakeholder Participants by Type (2019):

Patient Organizations; Biopharmaceutical Industry; Medical Device Industry; Over the Counter Medications Industry; Healthcare Professionals; Government Authorities

Please indicate any additions or changes to the type of stakeholder participants:

- Medical Device Industry
- Government Authorities: Global Affairs Canada
- Additional Stakeholders Not Listed: Generic Pharmaceutical Industry

Were government authorities involved, either as members or supporters, in the Framework from its outset?

· Not initially, but later became involved.

Complete List of Parties (2019):

Best Medicines Coalition (BMC)
Canadian Medical Association (CMA
Canadian Nurses Association (CNA)
Canadian Pharmacists Association (CPhA)
Consumer Health Products Canada
Health Charities Coalition of Canada (HCCC)
Innovative Medicines Canada (IMC)

Please List Any Additions or Changes to the List of Parties as of May 2020

MedTech Canada

Please describe the organizational structure of the Consensus Framework:

The group meets on a quarterly basis. The Agenda is developed by consensus. Three subcommittees have been established.

1) Governance Sub-Comm 2) Membership/
Recruitment Sub-Comm 3) Consensus
Framework Document Review/ Renewal Sub-Comm (Including Vision 2025)

Does the Consensus Framework receive operational or in-kind funding, either from parties or external sources?



Have the Consensus Framework parties held meetings in 2020?

X Yes

Two meetings have taken place this year (January 13, 2020 and June 3, 2020). Sub Committees meet separately to advance their objectives.

Describe the priorities and activities of the Framework to date:

- Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.
- Enhance the integrity and credibility of organizations in the healthcare sector.
- Promote public confidence and trust in the health system.
- Enhance public awareness of the Framework and the parties' commitment to ethical conduct.
- Gather additional signatories or endorsers of the Framework.
- Develop common resources and tools for the education of Framework members and/or additional parties, such as training materials.
- Foster public-private coordination of Framework activities.

What next steps are being considered by your Framework?

- Schedule additional Framework meetings.
 Dates and Type (virtual or in-person):
 August and September 2020
- Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.
- Enhance the integrity and credibility of organizations in the healthcare sector.
- Promote public confidence and trust in the health system.
- Enhance public awareness of the Framework and the parties' commitment to ethical conduct.
- Gather additional signatories or endorsers of the Framework.
- Develop common resources and tools for the education of Framework members and/or additional parties, such as training materials.
- Foster public-private coordination of Framework activities.

What has been the greatest success of the Consensus Framework?

- We had a delegation of in 2019 Global Affairs funded 3 Canadian patient representatives to attend the meeting. A fourth Canadian patient representative is a Patient Co-Chair of the APEC Biopharmaceutical Working Group on Ethics; The Canadian delegation also included representation from: The Canadian Medical Association, Government of Canada/ Global Affairs, and Industry/Takeda Canada
- Expansion of membership: Identifying a growth strategy for including other stakeholders in the Canadian Consensus Framework
- Increased membership and participation in Consensus Framework Group - Inclusion of Medical Devices Industry Association as well as Consumer Health Products Association. Increased participation from Global Affairs Canada and participation from the Generic Industry Association
- Developed and disseminated a COVID- 19
 Statement reinforcing Ethics statement disseminated to the APEC community as well as to government officials
- Providing input on the future state of Nanjing Declaration and identifying ways that our Framework could support the identified goals and actions.

What has been the greatest challenge of the Consensus Framework?

- · Establishing a governance model
- Establishing a clear collaboration and twoway communications model with government
- Establishing sustainable resources and commitment to continue the work of the Consensus Framework Group
- Gaining Recognition of importance and relevance

If the Consensus Framework has sought to advance new or specialized collaborations as a result of the COVID-19 crisis, please share those considerations and/or actions:

- We have issued a statement on COVID 19 and the importance of Ethics
- Leveraged the statement to re-engage governments and stakeholders
- In collaboration with APEC Secretariat, organized a Patient Webinar to discuss the challenges of COVID-19 and the impact of patient organizations amongst APEC economies













Chilean Consensus Framework

Year Proposed: 2018

Date Launched: September 2019

Please indicate the number of parties to the Consensus Framework as of May 2020: 17

Please indicate the Consensus Framework's Stakeholder Participants by Type:

Medical Device Industry; Third Parties / Distributors; Patient Organizations; Healthcare Professionals; Government Authorities; Additional Stakeholders Not Listed: Fundación Politopedia

Were government authorities involved, either as members or supporters, in the Framework from its outset?



Complete List of Parties as of May 2020

Alianza Chilena de Agrupaciones de Pacientes (ACHAP)

Instituto de Salud Pública (ISP)

Cámara Nacional de Laboratorios (CANALAB)

Asociación Industrial de Laboratorios Farmacéuticos (ASILFA)

Sociedad Científica de Dispositivos Médicos (SCDM)

Cámara de Innovación Farmacéutica (CIF)

Asociación Gremial de Dispositivos Médicos de Chile (ADIMECH)

Asociación de Productores Locales de Medicamentos (PROLMED)

Asociación de Proveedores de la Industria de la Salud (APIS)

Fundación Politopedia

Dueños de Farmacias de Chile (UNFACH)

Asociación Gremial de Farmacias Independientes (AFFI)

Federación de Enfermedades Poco Frecuente (FENPOF)

Colegio de Enfermeras de Chile

Asociación Chilena de Agrupaciones Oncológicas (ACHAGO)

Asociación de Sociedades Científicas-Médicas de Chile (ASOCIMED)

Federación Chilena de Enfermedades Raras (FECHER

Please describe the organizational structure of the Consensus Framework:

Chair is lead by the Under-secretariat for international economic affairs (SUBREI) and ad-hoc groups of members to advance certain tasks.

Does the Consensus Framework receive operational or in-kind funding, either from parties or external sources?



Have the Consensus Framework parties held meetings in 2020?



Please indicate how many meetings and when they occurred:

In 2020, the first meeting was in January and then roughly every 2-3 weeks thereafter.

Describe the priorities and activities of the Framework to date:

- Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.
- Converge the Framework's parties to one common code of ethics.
- Align the Framework's parties' codes of ethics.
- Promote public confidence and trust in the health system.
- Enhance public awareness of the Framework and the parties' commitment to ethical conduct.
- Gather additional signatories or endorsers of the Framework.
- Foster public-private coordination of Framework activities.

What next steps are being considered by your Framework?

- Schedule additional Framework meetings.
 Dates and Type (virtual or in-person):
 Every 2-3 Weeks
- Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.
- Align the Framework's parties' codes of ethics.
- Enhance public awareness of the Framework and the parties' commitment to ethical conduct.
- Gather additional signatories or endorsers of the Framework.
- Foster public-private coordination of Framework activities.

What has been the greatest success of the Consensus Framework?

This public-private partnership has fostered trust, alignment, and commitment among diverse parties to create an ecosystem that provides open and transparent dialogue for the first time.

What has been the greatest challenge of the Consensus Framework?

Generated consensus towards a common ethical standard as well as enhanced awareness to consider the patient at the center of any decision-making process among the stakeholders.

If the Consensus Framework has sought to advance new or specialized collaborations as a result of the COVID-19 crisis, please share those considerations and/or actions:

The Chilean Consensus Framework has prepared a statement reinforcing our commitment to high standard ethics and integrity amidst the COVID-19 pandemic.















Chinese Consensus Framework

Year Proposed: 2017

Date Launched (Month/Year): July 2018

Number of Parties (2019): 25

Please indicate any changes to the number of parties as of July 2020:

No Change

Stakeholder Participants by Type (2019):

Medical Device Industry; Third Parties / Distributors; Biopharmaceutical Industry; Hospitals / Healthcare Centers; Additional Stakeholders Not Listed

Were government authorities involved, either as members or supporters, in the Framework from its outset?



Complete List of Parties (2019):

China Pharmaceutical Industry Association (CPIA)

China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE)

R&D-based Pharmaceutical Association Committee of China Association of Enterprises with Foreign Investment (RDPAC)

China Association of Traditional Chinese Medicine (CATCM)

China Pharmaceutical Innovation and Research Development Association (PhIRDA)

China Association of Pharmaceutical Commerce (CAPC)

China Nonprescription Medicines Association (CNMA)

Chinese Hospital Association (CHA)

China Pharmaceutical Enterprises
Development Promote Association (CPEP)

China Association for Medical Devices Industry (CAMDI)

China Medicinal Biotech Association (CMBA)

China National Pharmaceutical Packaging Association (CNPPA)

China Pharmaceutical Association of Plant Engineering (CPAPE)

China Biochemical Pharmaceutical Industry Association (CBPIA)

Chinese Non-government Medical Institutions Association (CNMIA)

PSM Foundation

Beijing Pharmaceutical Profession Association (BPPA)

Shanghai Pharmaceutical Profession Association (SPPA)

Hebei Pharmaceutical Profession Association (HBPPA)

Shandong Pharmaceutical Profession Association (SDPPA)

Jiangsu Pharmaceutical Profession Association (JSPPA)

Shaanxi Pharmaceutical Profession Association (SPPA)

Liaoning Pharmaceutical Profession Association (LNPPA)

Fujian Pharmaceutical Profession Association (FJPPA)

Zhejiang Pharmaceutical Industry Association (ZJPIA)

Please describe the organizational structure of the Consensus Framework:

Informal structure with CPIA, CCCMHPIE, PhIRDA, and RDPAC serving a leadership role in consensus framework meeting organization as well as related activities, such as the annual China Consensus Framework survey and report.

Does the Consensus Framework receive operational or in-kind funding, either from parties or external sources?



Have the Consensus Framework parties held meetings in 2020?



Describe the priorities and activities of the Framework to date:

- Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.
- Align the Framework's parties' codes of ethics.
- Promote public confidence and trust in the health system.
- Enhance public awareness of the Framework and the parties' commitment to ethical conduct.
- Foster public-private coordination of Framework activities.

What next steps are being considered by your Framework?

- Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.
- Align the Framework's parties' codes of ethics.
- Promote public confidence and trust in the health system.
- Enhance public awareness of the Framework and the parties' commitment to ethical conduct.
- Foster public-private coordination of Framework activities.

What has been the greatest success of the Consensus Framework?

N/A

What has been the greatest challenge of the Consensus Framework?

N/A

If the Consensus Framework has sought to advance new or specialized collaborations as a result of the COVID-19 crisis, please share those considerations and/or actions:

N/A









Japanese Consensus Framework

Year Proposed: 2018

Date Launched (Month/Year): July 2018

Number of Parties: 8

Please indicate any changes to the number of parties as of May 2020: 8

Stakeholder Participants by Type (2019):

Medical Device Industry; Patient Organizations; Biopharmaceutical Industry; Healthcare Professionals; Government Authorities

Please indicate any additions or changes to the type of stakeholder participants (2020):

No Change

Were government authorities involved, either as members or supporters, in the Framework from its outset?

X Yes.

Complete List of Parties (2019):

Japan Patients Association
Japan Federation of Cancer Patient Groups
Japanese Nursing Association
The Federation of Pharmaceutical
Manufacturers' Associations of Japan
The Japan Federation of Medical Devices
Associations
Japan Pharmaceutical Association
Japan Medical Association
Ministry of Health, Labour, and Welfare

Please List Any Additions or Changes to the List of Parties as of May 2020:

No Change

Please describe the organizational structure of the Consensus Framework:

The Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ) serves as the current secretariat for the Japan Consensus Framework and all parties are of equal status.

Does the Consensus Framework receive operational or in-kind funding, either from parties or external sources?

X No.

Have the Consensus Framework parties held meetings in 2020?

X No.

Members agreed to meet in July 2020, but that was cancelled due to COVID-19. We will plan to meet in September ahead of the 2020 APEC Business Ethics for SMEs Forum. Our last meeting was held on 6 Dec 2019.

Describe the priorities and activities of the Framework to date:

- Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.
- Develop common resources and tools for the education of Framework members and/or additional parties, such as training materials.

What next steps are being considered by your Framework?

- Schedule additional Framework meetings.
- Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.
- Enhance public awareness of the Framework and the parties' commitment to ethical conduct.

What has been the greatest success of the Consensus Framework?

Our greatest successes include developing the first-ever local platform where relevant local healthcare stakeholders, especially patient groups (upholding the patients first principle), can get together and discuss business ethics matters and issues. We have also held periodically meetings and created a Tokyo Consensus Framework Memorial Day on July 20 to enhance public awareness.

What has been the greatest challenge of the Consensus Framework?

Our greatest challenge is to set collective goals for the members.

If the Consensus Framework has sought to advance new or specialized collaborations as a result of the COVID-19 crisis, please share those considerations and/or actions:

N/A











Council of Ethics and Transparency of the Pharmaceutical Indu

AGREEMENT FOR TRANSPARENCY IN
THE RELATIONSHIP
BETWEEN PHYSICIANS AND HEALTH
CARE INSTITUTIONS
WITH THE PHARMACEUTICAL
INDUSTRY

Mexico Agreement for Transparency

Year Proposed: 2007

Date Launched (Month/Year): October 2007

Please indicate the number of parties as of May 2020: 13

Please indicate any changes to the number of parties as of May 2020: No Change

Stakeholder Participants by Type (2019):

Medical Device Industry; Hospitals / Healthcare Centers; Biopharmaceutical Industry; Healthcare Professionals; Government Authorities; National Commission of Bioethics; Universities / Medicine Schools

Please indicate any additions or changes to the type of stakeholder participants:

Medical Device Industry
Third Parties / Distributors
Patient Organizations
Hospitals / Healthcare Centers
Biopharmaceutical Industry
Healthcare Professionals
Government Authorities

Were government authorities involved, either as members or supporters, in the Framework from its outset?

X Yes.

Complete List of Parties

(Full Names of Each Organization) (2019):

Academia Nacional de Medicina de México
Cámara Nacional de la Industria
Farmacéutica en México
Comisión Nacional de Bioética
Consejo de Ética y Transparencia de la
Industria Farmacéutica
Academia Mexicana de Cirugía
Academia Mexicana de Pediatría
Colegio Médico de México
Asociación Nacional de Hospitales Privados
Facultad de Medicina, Universidad Nacional
Autónoma de México
Escuela Superior de Medicina, Instituto

Politécnico Nacional Instituto Mexicano del Seguro Social Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado

Secretaría de Salud

Please List Any Additions or Changes to the List of Parties as of May 2020:

No Change

Please describe the organizational structure of the Consensus Framework:

The Head of the agreement is the General Council of Health and this entity has a follow-up committee that consistent of one representative from each signatory who is in charge of promoting compliance, identifying deviations, and suggesting appropriate measures to correct them.

Does the Consensus Framework receive operational or in-kind funding, either from parties or external sources?



Have the Consensus Framework parties held meetings in 2020?



Describe the priorities and activities of the Framework to date:

- Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.
- Align the Framework's parties' codes of ethics.
- Enhance the integrity and credibility of organizations in the healthcare sector.
- Promote public confidence and trust in the health system.
- Enhance public awareness of the Framework and the parties' commitment to ethical conduct.
- Gather additional signatories or endorsers of the Framework.
- Foster public-private coordination of Framework activities.

What next steps are being considered by your Framework?

- Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.
- Enhance the integrity and credibility of organizations in the healthcare sector.
- Promote public confidence and trust in the health system.
- Enhance public awareness of the Framework and the parties' commitment to ethical conduct.
- Gather additional signatories or endorsers of the Framework.
- Foster public-private coordination of Framework activities.

What has been the greatest success of the Consensus Framework?

- Solve specific problems in the interaction between Biopharmaceutical Industry and other Stakeholders, and reflect in laws agreements of the Consensus Framework.
- Enhance the dialogue about ethics, bioethics, integrity and transparency among different stakeholders.

What has been the greatest challenge of the Consensus Framework?

Follow-up for the parties has slowed because there are new public officials in government and it will require more time to resume this mechanism.













Peruvian Consensus Framework

Year Proposed: 2016

Date Launched (Month/Year): Sept 2016

Please indicate the number of parties as of May 2020: 22

Please indicate any changes to the number of parties as of May 2020: No Change.

Stakeholder Participants by Type (2019):

Medical Device Industry; Third Parties
/ Distributors; Patient Organizations;
Biopharmaceutical Industry; Healthcare
Professionals; Government Authorities;
Additional Stakeholders Not Listed:
Pharmacies associations, Clinics associations

Please indicate any additions or changes to the type of stakeholder participants:

- Medical Device Industry
- Third Parties / Distributors
- · Patient Organizations
- · Hospitals / Healthcare Centers
- · Biopharmaceutical Industry
- · Healthcare Professionals
- Government Authorities
- Additional Stakeholders Not Listed: Pharmacies association

Were government authorities involved, either as members or supporters, in the Framework from its outset?



Complete List of Parties (2019):

Dirección General de Medicamentos, Insumos y Drogas- DIGEMID

Superintendencia Nacional de Salud-SUSALUD

Centro Nacional de Abastecimiento de Recursos Estratégicos en SaludCENARES

Comision de Alto Nivel Anticorrupción-Presidencia del Consejo de Ministros

Sociedad de Comercio Exterior del Perú-COMEX Perú

Asociacion de Industrias Farmacéuticas Nacionales- ADIFAN

Confederacion Nacional de Instituciones Empresariales Privadas- CONFIEP

Comité de Productos para la Salud-COMSALUD -Cámara de Comercio de Lima

Asociación Nacional de Laboratorios Farmacéuticos- ALAFARPE Asociacion de Laboratorios Farmacéuticos Latinoamericanos- ALAFAL

Asocacion Nacional de Cadenas de Boticas -ANACAB

Colegio Médico del Perú

Colegio Químico Farmacéutico del Perú Asociacion de Clínicas Particulares del Perú ESPERANTRA

Asociacion PROSA

Asociacion Benéfica PRISMA Servicio de Medicinas PROVIDA

Red Peruana de Pacientes y Usuarios Sociedad Peruana de Farmacia Hospitalaria Accion Internacional para la Salud- AIS MeTA Peru

Please describe the organizational structure of the Consensus Framework:

The organizational structure is lead by DIGEMID and the participation of the other members.

Does the Consensus Framework receive operational or in-kind funding, either from parties or external sources?



Have the Consensus Framework parties held meetings in 2020?



Describe the priorities and activities of the Framework to date:

- Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.
- Converge the Framework's parties to one common code of ethics.
- Align the Framework's parties' codes of ethics.
- Enhance the integrity and credibility of organizations in the healthcare sector.
- Promote public confidence and trust in the health system.
- Enhance public awareness of the Framework and the parties' commitment to ethical conduct.
- Gather additional signatories or endorsers of the Framework.

- Develop common resources and tools for the education of Framework members and/or additional parties, such as training materials.
- Foster public-private coordination of Framework activities.

What next steps are being considered by your Framework?

- Schedule additional Framework meetings (virtual or in-person): virtual
- Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.
- Develop one common code of ethics for all Framework parties.
- Align the Framework's parties' codes of ethics.
- Enhance the integrity and credibility of organizations in the healthcare sector.
- Promote public confidence and trust in the health system.
- Enhance public awareness of the Framework and the parties' commitment to ethical conduct.
- Gather additional signatories or endorsers of the Framework.

What has been the greatest success of the Consensus Framework?

The greatest successes include promoting a better dialogue between the members as well as aligning the different code of ethics. The consensus framework has also enhanced the position of government leaders to promote ethical conduct in the health sector.

What has been the greatest challenge of the Consensus Framework?

The greatest challenges include getting additional members involved as well as gathering more significant data to pursue further objectives.

If the Consensus Framework has sought to advance new or specialized collaborations as a result of the COVID-19 crisis, please share those considerations and/or actions:

The consensus framework should be improving dialogue among members in virtual spaces to contribute on ethics on the health sector during the COVID -19 crisis.











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Philippines Consensus Framework

Year Proposed: 2018

Date Launched (Month/Year): Nov 2018

Number of Parties (2019): 17

Please indicate any changes to the number of parties as of May 2020: 18

Stakeholder Participants by Type (2019):

Medical Device Industry; Patient Organizations; Hospitals / Healthcare Centers; Biopharmaceutical Industry; Healthcare Professionals; Additional Stakeholders Not Listed

Were government authorities involved, either as members or supporters, in the Framework from its outset?



Complete List of Parties (2019):

Philippine Alliance of Patient Organizations (PAPO)

Philippine Medical Association (PMA)
Philippine Pharmacists Association (PPhA)
Philippine Nurses Association (PNA)

Pharmaceutical and Healthcare Association of the Philippines (PHAP)

Association of Nursing Service Administrators of the Philippines (for ceremonial signing)

Institute for Solidarity in Asia (ISA)

Philippine Association of Medical Device Regulatory Affairs Professionals (PAMDRAP)

Medicines Transparency Alliance (MeTA)

Region 1 Medical Center (R1MC)

Mariano Marcos Memorial Hospital and Medical Center

Tondo Medical Center

Navotas City Hospital

Southern Philippines Medical Center (SPMC) llocos Training and Regional Medical Center (ITRMC)

Philippine Hospitals Association (for ceremonial signing)

Dr. Paulino J. Garcia Memorial Research & Medical Center (for ceremonial signing)

Please List Any Additions or Changes to the List of Parties as of May 2020:

Association of Nursing Service Administrators of the Philippines (formally signed)

Philippine Hospitals Association (formally signed)

Dr. Paulino J. Garcia Memorial Research & Medical Center (formally signed)

Bataan General Hospital and Medical Center

Please describe the organizational structure of the Consensus Framework:

The main conveners are based in Metro Manila but several are based in various parts of the economy. There is no formal structure.

Does the Consensus Framework receive operational or in-kind funding, either from parties or external sources?



Have the Consensus Framework parties held meetings in 2020?

X No.

Describe the priorities and activities of the Framework to date:

- Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.
- Align the Framework's parties' codes of ethics.
- Enhance the integrity and credibility of organizations in the healthcare sector.
- Gather additional signatories or endorsers of the Framework.
- Develop common resources and tools for the education of Framework members and/or additional parties, such as training materials.
- Foster public-private coordination of Framework activities.

What next steps are being considered by your Framework?

- Schedule additional Framework meetings: virtual or in-person.
- Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.
- Align the Framework's parties' codes of ethics.
- Enhance the integrity and credibility of organizations in the healthcare sector.
- Gather additional signatories or endorsers of the Framework.
- Develop common resources and tools for the education of Framework members and/or additional parties, such as training materials.
- Foster public-private coordination of Framework activities.

What has been the greatest success of the Consensus Framework?

Successes include: (1) the involvement of Philippine affiliates of organizations that originally endorsed the Consensus Framework; and (2) the involvement of signatories from various parts of the economy.

What has been the greatest challenge of the Consensus Framework?

Challenges include: (1) meeting and updating all the signatories, and (2) confirming more signatories, including the government.

If the Consensus Framework has sought to advance new or specialized collaborations as a result of the COVID-19 crisis, please share those considerations and/or actions:

None to-date, but we believe there is opportunity to do so.















Viet Nam Consensus Framework

Year Proposed: 2017

Date Launched (Month/Year): Sept 2017

Please indicate the number of parties as of May 2020: 9

Please indicate any changes to the number of parties as of May 2020: No Change

Stakeholder Participants by Type (2019):

Medical Device Industry; Patient Organizations; Biopharmaceutical Industry; Healthcare Professionals; Additional Stakeholders Not Listed

Please indicate any additions or changes to the type of stakeholder participants:

No Change

Were government authorities involved, either as members or supporters, in the Framework from its outset?

X Yes. (Supporter)

Complete List of Parties (Full Names of Each Organization) (2019):

Viet Nam Medical Association

Viet Nam Women Union

Vietnamese Pharmaceutical Association

Viet Nam Pharmaceutical Companies Association

Viet Nam Medical Equipment Association

Healthcare Committee, American Chamber of Commerce in Viet Nam

Pharma Group, EuroCham

International Quality Medicines - Generic & Biosimilar (former International

biosimilar (former international

Quality Generics Sector Committee), EuroCham

Medical Devices and Diagnostics, EuroCham

Please List Any Additions or Changes to the List of Parties as of May 2020:

No Change

Please describe the organizational structure of the Consensus Framework:

Informal structure of equal parties. The Pharma Group serves as de facto secretariat for consensus framework sessions and activities.

Does the Consensus Framework receive operational or in-kind funding, either from parties or external sources?

X No.

Have the Consensus Framework parties held meetings in 2020?

X No.

Describe the priorities and activities of the Framework to date:

- Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.
- Enhance the integrity and credibility of organizations in the healthcare sector.
- Promote public confidence and trust in the health system.
- Foster public-private coordination of Framework activities.

What next steps are being considered by your Framework?

- Promote better dialogue, collaboration and interaction among organizations in and working with the healthcare sector.
- Enhance the integrity and credibility of organizations in the healthcare sector.
- Promote public confidence and trust in the health system.
- Foster public-private coordination of Framework activities.

What has been the greatest success of the Consensus Framework?

N/A

What has been the greatest challenge of the Consensus Framework?

N/A

If the Consensus Framework has sought to advance new or specialized collaborations as a result of the COVID-19 crisis, please share those considerations and/or actions:

N/A

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