APEC Multi-Stakeholder Consensus Frameworks

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APEC BIOPHARMACEUTICAL ETHICS INITIATIVE - Information and Contacts

http://www.mcprinciples.org

http://mcprinciples.apec.org
COMPLEX ENVIRONMENT

- Growing Latin American Anti-Corruption Movements
- UK Bribery Act
- EFPIA Transparency Guidelines
- Nanjing Declaration
- APEC Mexico City Principles
- Patient Group Codes and Guidelines
- Association Codes
- Growing Number of Multi-Stakeholder Consensus Frameworks
- US Foreign Corrupt Practices Act
- Health Care Professional Codes
- Academic institutions and guidelines
- IFPMA
TRUST AND TRANSPARENCY

Trust
Credibility
Integrity
Relationship
Partnership
Respect
Communication
Transparency
Openness
Listening
Honesty
Ethical Leadership
HARMONIZING ETHICAL PRACTICES

Building Trust and Ethical Behavior is vital to Better Health Care & Innovation.
Business Ethics for APEC SMEs
Biopharmaceutical Sector
APEC NANJING DECLARATION
2020 GOALS

1. Universal industry association codes of ethics
2. Implementation of industry association codes by a majority of their member companies
3. **Consensus Frameworks for Multi-Stakeholder Ethical Collaboration in every APEC economy**
Business Ethics for APEC SMEs
Biopharmaceutical Sector

Consensus Framework for Ethical Collaboration between Patients’ Organisations, Healthcare Professionals and the Pharmaceutical Industry

A Consensus Framework established for ethical collaboration between patients’ organisations, healthcare professionals and the pharmaceutical industry, in support of high quality patient care. This Consensus Framework and the accompanying resources are intended to serve as a toolkit for those associations, groups and alliances who wish to develop their own policies. It neither aims to be comprehensive nor does it constitute a single common policy of the organisations involved. The individual policies of the participating organisations set out each organisation’s detailed commitments and offer more diverse and in depth information and guidance.

Guide to Implement Multi-Stakeholder Ethical Collaborations in the Medical Device and Biopharmaceutical Sectors

Purpose: Consideration
Submitted by: United States

41st Small and Medium Enterprises Working Group Meeting
Iloilo, Philippines
23-24 September 2015
Consensus and principles-based, voluntary agreement between pharmaceutical and/or medical technology industry associations and leading non-industry health system stakeholders to collaborate in strengthening ethical business practices across these sectors using a “whole of system” approach.
## WHAT IS A CONSENSUS FRAMEWORK?

### KEY ELEMENTS

- Voluntary and principles-based agreement, achieved through consensus
- Three or more national parties:
  - Core: industry associations and healthcare professional groups
  - Possible: patients’ organizations, third party intermediaries, hospitals/providers, governments/payers
- Provisions are customized to the local situation, aligned with international best practices
- Open to new parties, does not expire, and calls for a shared work plan
- Trust-building platform to exchange ideas and undertake joint implementation activities
- Consensus Frameworks are *not* codes of ethics
**WHAT IS A CONSENSUS FRAMEWORK?**

<table>
<thead>
<tr>
<th>POTENTIAL JOINT ACTIVITIES</th>
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<td>• Regular conference of the parties (hosted on a rotating basis) to exchange best practices, build capacity, and/or assess the environment for opportunities/challenges</td>
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<td>• Code of ethics compendium and comparison to drive alignment with best practices</td>
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<td>• Joint ethics and integrity curriculum development / training for organization members</td>
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<td>• Other ethics and integrity initiatives aimed to strengthen the health system</td>
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<td>• Draw shared attention to bad actors in the health system</td>
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<td>• Develop a foundation of trust to strengthen dialogue on other challenges in the sector</td>
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THE GLOBAL CONSENSUS FRAMEWORK (2014)

- **Sector:** Life Sciences
- **Parties (7):** Industry (R&D/Generic), Healthcare Professionals (HCPs), Patients, and Hospitals
- **Key Provisions:**
  - Serves as a toolkit for parties to develop their own policies, based on several common principles
  - Patient Centricity (optimal care / partnerships)
  - Ethical Research and Innovation (clinical research and objective clinical results)
  - Independence Ethical Conduct (gifts, sponsorship, affiliation)
  - Transparency and Accountability (fees for service, clinical research transparency)
  - Commitment to local implementation, monitoring, and reporting mechanisms
CANADIAN
CONSENSUS
FRAMEWORK
FOR ETHICAL
COLLABORATION
CANADIAN CONSENSUS FRAMEWORK (2016)

• **Sector:** Pharmaceutical
• **Parties (6):** Industry (R&D), HCPs, Patients
• **Coordinator:** Industry

**Key Provisions:**
- **Shared Solution** (common ethical principles, patient-centricity, and set clear rules)
- **Shared Outcomes** (enhance credibility, regular dialogue, and increase public confidence)
- Declared commitment to patients
- Alignment on practices in research, innovation, and knowledge translation, such as continuing medical education and conferences.
- Alignment on relationships and conduct
- Implementation and accountability mechanism
PERUVIAN CONSENSUS FRAMEWORK (2016)

- **Sector:** Pharmaceutical and Medical Device
- **Parties (24):** Industry (R&D/Generic/Devices), HCPs, Patients, Government, Pharmacies, Hospitals
- **Coordinator:** Ministry of Health
- **Key Provisions:**
  - **Shared Purpose** (build trust, codes of ethics, capacity-building, early challenge identification)
  - **Shared Commitment** (alignment with international best practices, clear expression of common values)
  - **Shared Outcomes** (enhanced credibility, strengthen public confidence, improve health outcomes)
  - **Patient Focus** (declaration of patient centricity)
  - **Implementation, Monitoring, Reporting** (aligned codes of ethics, work program, regular meetings)
VIET NAM CONSENSUS FRAMEWORK (2017)

- First in Asia
- **Sector:** Pharmaceutical and Medical Device
- **Parties (9):** Industry (MNC & Domestic), HCPs, and Women’s Union
- **Coordinator:** Industry (MNC & Domestic)
- **Key Provisions:**
  - Shared Purpose (common principles for patient-centricity, ethical research and innovation, independence and ethical conduct, and promoting transparency and accountability).
  - Shared Commitment (high-standard and aligned codes, public confidence, dialogue and trust)
  - Declaration on patient-centricity, knowledge translation, and relationships/conduct
  - Implementation (aligned codes, joint activities)
Colegio Médico y Cámara de la Innovación Farmacéutica de Chile acuerdan marco ético de relaciones

Para que el actuar entre profesionales de la Medicina y los Laboratorios de Innovación asociados a CIF se desarrolle en un marco de pleno cumplimiento de las disposiciones éticas, el presidente del Colegio Médico de Chile, Dr. Enrique Paris, y el presidente de la Cámara de la Innovación Farmacéutica de Chile, Richard Nevaes, firmaron un Acuerdo de Marco Ético de Relaciones.

El Acuerdo, es la culminación de un trabajo de aproximadamente un año entre los Departamentos de Ética de ambas instituciones, que permitió acercar posiciones y aunar criterios respecto a las normativas que rigen a ambas organizaciones: el Código de Ética del Colegio Médico, en un caso, y el Código IFPMA de Buenas Prácticas, que regula a los Laboratorios de Innovación de CIF. De esta manera se busca acordar una forma de actuar conjunta frente a acciones que pudieren transgredir dichos Códigos.

Entre las materias que se estipulan en el Acuerdo la obligatoriedad de entregar información a los organismos correspondientes en caso de transgresión ética y el análisis en forma conjunta de los problemas que se pudieren suscitir en relación con este Acuerdo.

Respecto a la interacción entre laboratorios y médicos, el Acuerdo establece que, si bien los laboratorios asociados a CIF pueden legítimamente efectuar promoción y publicidad, ello no considera la entrega directa de rozales y donaciones que comprometan una redistribución de parte de los profesionales médicos.
ADAPTING TO THE ENVIRONMENT

- Adapting and co-creating principles vs just finding common ground
- Finding the right people to sit around the table
- Take action and the initiative
• What do we have in common?

• Where can we mutually benefit from our collaboration to achieve the best health outcomes for patients?
GRACIAS

THANK YOU