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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.

Preamble

As developed and developing countries strive to address pressing health challenges in the complex and fast-evolving healthcare environment, collaboration between all partners is essential in ensuring proper delivery of the most appropriate care for patients worldwide.

In the 1980s international codes and guidelines were approved including the first IFPMA Code of Pharmaceutical Marketing Practices in 1981 and the WHO Ethical Criteria for Medicinal Drug Promotion in 1985. Since then progress has been made to ensure appropriate interactions and ethical promotion of medicines globally, including through self-regulatory and voluntary mechanisms such as codes of conduct and principles. These highlight the need for patients' organisations, healthcare professionals, and the pharmaceutical industry to work together for the benefit of patients, while recognizing each other's professional role in the context of the healthcare value delivery chain and maintaining their professional independence.

There is an important link between patients, healthcare professionals, the pharmaceutical industry and their organisations in providing best solutions to patients' health needs and each partner has a unique role and responsibility in ensuring that patients receive the most appropriate care. Patients must be informed and empowered to, along with their caregivers, decide on the most appropriate treatment options for their individual health needs and to participate responsibly in use of health resources and managing their own health. In this respect, healthcare professionals must ensure that the treatment options they offer to patients are appropriate. In turn, the pharmaceutical industry has a duty to provide accurate, fair, and scientifically grounded information for their products, so that the responsible use of medicines can be facilitated.

The **Consensus Framework for Ethical Collaboration** is characterized by four overarching principles: Put Patients First; Support Ethical Research and Innovation; Ensure Independence and Ethical Conduct; and Promote Transparency and Accountability. The Consensus Framework outlines some of the key areas that should be considered by all partners to help guide ethical collaborations at the individual and organisational levels¹, and is based on the common elements within the documents listed in the Tools and Resources section of the Framework. It encompasses a shared commitment of organisations representing patients, healthcare professionals, and the pharmaceutical industry to continually improve global health and ensure, in collaboration with other stakeholders, that all patients receive appropriate treatment. This Framework aims to complement the various national, regional and global codes and guidelines and serve as a model for similar joint initiatives between patient organisations, healthcare professionals and pharmaceutical industry associations at the national level.

The Consensus Framework is currently supported by IAPO², ICN³, IFPMA⁴, FIP⁵WMA⁶ and IHF⁷ as all partners have a mutual interest in ensuring that the relationship between patients, healthcare professionals, the pharmaceutical sector, and their organisations, is based on ethical and responsible decision making. The Consensus Framework is a living document and is open to other key partners working in life-sciences and healthcare delivery, which are welcome to endorse it and comment upon it.

¹The Joint Framework is based on the common elements within the documents listed in the Tools & Resources section.

²International Alliance of Patients' Organizations (IAPO)

³International Council of Nurses (ICN)

⁴International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

⁵International Pharmaceutical Federation (FIP)

⁶World Medical Association (WMA)

⁷International Hospital Federation (IHF)

Put Patients First

Patients are our priority.

For example:

- 1 **Optimal Care for All** - Working as partners, at both the individual and organization level, to ensure that collaboration between patients, healthcare professionals, and pharmaceutical companies support patients and their caregivers in making the best decision regarding their treatment.
- 2 **Partnerships** – All partners working in healthcare have a right and responsibility to collaborate to improve healthcare access and delivery. Establishing partnerships will aim to deliver greater patient benefits.

Support Ethical Research and Innovation

Partners encourage clinical and related research conducted to generate new knowledge about effective and appropriate use of health treatments.

For example:

- 3 **Clinical Research** – Continuing to advocate and support the principle that all human subject research must have a legitimate scientific purpose, aims to improve health outcomes, and be ethically conducted, including that participants are appropriately informed as to the nature and purpose of the research.
- 4 **Objective Clinical Results** – Continuing to ensure that compensation for research is appropriate and does not compromise objective clinical results of the research.

Ensure Independence and Ethical Conduct

Interactions are at all times ethical, appropriate and professional.

For example:

- 5 **Gifts** – Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence. No financial benefit or benefit in kind should be sought, offered, provided or accepted in exchange for prescribing, recommending, dispensing or administering medicines.
- 6 **Sponsorship** – Continuing to advocate that the purpose and focus of all symposia, congresses, scientific or professional meetings (an “Event”) for healthcare professionals and patient organisations should be to provide scientific or educational information. The primary purpose of an event must be to advance knowledge and all materials and content must be balanced and objective. All events must be held in an appropriate venue. Moderate and reasonable refreshments and/or meals incidental to the main purpose of the event can be provided to participants of the event.
- 7 **Affiliation** – Business arrangements and professional relationships between partners should not inappropriately influence their practice, compromise their professional integrity or their obligations to patients. Business arrangements and relationships should respect professional integrity and should be transparent.

Promote Transparency and Accountability

Partners support transparency and accountability in their individual and collaborative activities.

For example:

- 8 **Fees for Services** – Working together to ensure that all arrangements requiring financial compensation for services, such as consultancy or clinical research, have a legitimate purpose and a written contract or agreement in place in advance of the commencement of services. Remuneration for services rendered should not exceed that which is commensurate with the services provided.
- 9 **Clinical Research Transparency** – Continuing to support the premise that both the positive and negative outcomes of research evaluating medicines, other products and services should be disclosed. Clinical research in patients and related results should be transparent while respecting patient privacy.

Implementation, Monitoring and Reporting Mechanism

Partners are encouraged to develop their own self-regulatory codes and principles for ethical collaboration and interactions and ensure their effective implementation. Systems to monitor and report breaches of the set standards should be established to support ethical practices and ensure accountability both at the institutional and individual levels. These may include, for example, public statements detailing collaborative agreements and external review mechanisms.

Tools and Resources

- ◆ WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects (2013)
<http://www.wma.net/en/30publications/10policies/b3/>
- ◆ IAPO Healthcare Industry Partners Framework (2012)
<http://www.patientsorganizations.org/partners>
- ◆ FIP Rules of Procedure – Guidelines for Sponsorship (2012) (*internal document*)
- ◆ IFPMA Code of Practice (established in 1981; last revision 2019)
<https://www.ifpma.org/subtopics/new-ifpma-code-of-practice-2019/>
- ◆ ICN Code of Ethics for Nurses (2012)
<http://www.icn.ch/about-icn/code-of-ethics-for-nurses/>
- ◆ WMA Statement Concerning the Relationships b/w Physicians and Commercial Enterprises (2009)
<http://www.wma.net/en/30publications/10policies/r2/>
- ◆ ICN Position Statement: Informed Patients (2008)
http://www.icn.ch/images/stories/documents/publications/position_statements/E06_Informed_Patients.pdf
- ◆ FIP/WHO Developing pharmacy practice – a focus on patient care (2006); Chapter II-3: Information management and the use of evidence.
http://www.fip.org/good_pharmacy_practice
- ◆ ICN Position Statement: Nurse Industry Relations (2006)
http://www.icn.ch/images/stories/documents/publications/position_statements/E09_Nurse_Industry_Relations.pdf
- ◆ IAPO Organizational Values (2005)
<http://www.patientsorganizations.org/attach.pl/700/278/IAPO7s0Organizational0Values.pdf>
- ◆ FIP Statement on Professional Standards – Code of Ethics for Pharmacists (2004)
www.fip.org/statements
- ◆ WHO Ethical Criteria for Medicinal Drug Promotion (1985)
<http://archives.who.int/tbs/promo/whozip08e.pdf>