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The Mexico City Principles: For Codes of Ethics in the Biopharmaceutical Sector

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The Mexico City Principles

For Codes of Ethics in the
Biopharmaceutical Sector

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The Mexico City Principles

For Voluntary Codes of Business Ethics in the Biopharmaceutical Sector

Ethical interactions help ensure that medical decisions are made in the best interests of patients. Relationships between Companies in the biopharmaceutical sector¹ (“Companies”) and Stakeholders including industry organizations, patient organizations, healthcare providers and professional organizations, health ministries and regulatory authorities, SME and economic ministries, anti-corruption authorities, researchers and academia, manufacturers, and third-party intermediaries, such as distributors and sales agents, (“Stakeholders”) should be guided by these six Principles:

Healthcare and Patient Focus means everything we do is intended to benefit patients.

Integrity means dealing ethically, honestly, and respectfully in everything we do.

Independence means to respect the need of autonomous decision-making of all parties, free from improper influence.

Legitimate intent means everything we do aligns with the spirit and the values of these Principles and is lawful.

Transparency means a commitment to be open about our actions while respecting the privacy of the parties concerned, the legitimate commercial and organizational sensitivities and intellectual property rights.

Accountability means a responsibility for our actions and interactions.

Through the application of these Principles in decision making, Companies and Stakeholders should seek to establish a culture of trust with patients and amongst each other.

Preamble

1. Companies and all Stakeholders are committed to following the highest ethical standards as well as all applicable laws and regulations. Companies and all Stakeholders are encouraged to respect these Principles and adopt consistent standards wherever possible.
2. Companies engage in the development, manufacturing, research, marketing, distribution, and/or sale of medicines to benefit patients.
3. Ethical relationships with all Stakeholders are critical to the mission of Companies to help patients by developing and making medicines available.
4. These Principles reinforce the intention that Companies’ interactions are professional exchanges designed to benefit patients and to enhance the practice of medicine. These Principles are based on the foundation that a healthcare professional’s care of their patient should be based solely on each patient’s medical needs and the healthcare professional’s medical knowledge and experience.

¹ For purposes of this document the term “biopharmaceutical sector” includes Companies, regardless of ownership status, that research/discover/develop, manufacture, market, supply ingredients (including components/raw materials of chemical, organic, or synthetic nature), distribute, or serve as an intermediary for pharmaceutical and/or biologic products, including vaccines. Such products are also referred to in these Principles as “medicines.”

5. Companies and Stakeholders commit to meaningful patient organization engagement in the development of ethical principles and decision-making processes.
6. Companies have an obligation and responsibility to provide objective, accurate, balanced, and evidence based, scientifically sound information about their medicines to healthcare professionals in order to establish a clear understanding of the appropriate use of these medicines. Industry relationships with healthcare professionals must support, and be consistent with, the professional responsibilities healthcare professionals have towards their patients.
7. Companies should promote, sell and distribute their medicines in a manner that is ethical, objective, balanced and accountable, and in accordance with all relevant and applicable laws and regulations. Information in promotional materials must support proper assessment of the benefits and risks of the product and its proper use.
8. Companies are committed to education and training on the safe, efficacious, appropriate, and effective use of their medicines.
9. Companies are accountable for complying with relevant codes of ethical business practices. They should also ensure that internal structures and procedures (including adequate training of employees) are created to ensure responsible and ethical activities.
10. Companies will comply with relevant standards regarding the development, production, processing, distribution, commercialization, and safety of medicines.
11. Companies undertake to adhere to relevant local and regional industry ethics codes in both the spirit and the letter.
12. Companies should adopt and utilize ethical conduct standards and principles in their strategies and decision making to foster sustained business success and stakeholder trust.
13. Companies will respect the independence of patient organizations and healthcare professionals.
14. Companies should ensure that all relevant personnel and agents acting on their behalf are appropriately trained in the requirements of local and regional industry ethics codes and also comply with these Principles and all applicable laws and regulations.
15. Companies will respect patient data and privacy. This includes individual patient as well as collective privacy in a larger population.
16. Companies and all Stakeholders should embrace the responsible development and use of data and technology, including artificial intelligence.

Through the promotion of these Principles, Companies seek to ensure that ethical practices are established.

I. Interactions with Healthcare Professionals

- A. Interactions between Companies and healthcare professionals provide valuable scientific, clinical, product, and policy information about medicines that may lead to improved patient care.
- B. Appropriate marketing helps to ensure that medicines are used correctly for maximum patient benefit. Ethical company relationships with healthcare professionals are critical to achieving these goals because they enable Companies to:
 - 1. Inform healthcare professionals about the benefits and risks of medicines to help advance appropriate patient use;
 - 2. Provide accurate and current scientific and educational information;
 - 3. Support medical research and education; and
 - 4. Obtain feedback and advice about products through consultation with medical experts.
- C. All interactions with healthcare professionals are to be conducted in a transparent, open, and professional and ethical manner.
 - 1. Companies must not improperly influence Healthcare professionals.
 - 2. Nothing should be offered or provided by a Company in a manner that could inappropriately influence a healthcare professional's prescribing practices.
 - 3. Companies' education and promotional activities should encourage the appropriate use of medicines by presenting them objectively and without exaggerating their properties, in a fair, balanced and scientifically accurate manner, and should be in compliance with the provisions prescribed by these Principles and applicable local and regional industry codes of ethics.
 - 4. Relationships between Company personnel and healthcare professionals should encourage the development of medical and prescribing practices committed to patients' well-being and be based on truthful, accurate, and updated scientific evidence.

II. Promotional Information and Activities

- A. No medicines shall be promoted for use in a specific economy until the requisite approval for marketing for such use has been given in that economy. Promotion should be consistent with locally approved product information, advertisement and competition laws.
 - 1. It is understood that local laws and regulations usually dictate the format and content of the product information communicated on labeling, packaging, leaflets, data sheets and in all promotional material.
 - 2. Companies commit that pertinent, accurate and appropriate information will be made available to all healthcare professionals in all economies, as required and permitted by applicable laws and regulations.

- B. Promotional information should be clear, legible, scientifically and clinically accurate, balanced, fair, objective and sufficiently complete to enable healthcare professionals to form their own opinion of the therapeutic value of the medicines concerned.
 - 1. Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It should not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.
 - 2. Promotional information should be capable of substantiation either by reference to the approved labeling or by scientific evidence. Such evidence should be made available on request to healthcare professionals. Companies should deal objectively with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry.
 - 3. Companies are responsible for compliance with applicable laws and regulations, including intellectual property laws, and local and regional industry codes of ethics.
 - 4. Clinical assessments, post marketing surveillance and experience programmes and post authorization studies must not be disguised promotion. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose.
 - 5. Materials sponsored by a Company relating to medicines and their uses, whether promotional in nature or not, should clearly indicate by whom they have been sponsored.

III. Safety of Medicines

- A. Medicines provided by Companies will conform to the highest standards of quality, safety and efficacy as determined by regulatory authorities in each economy in which they operate.
- B. Companies will report adverse events or adverse drug reactions to regulatory authorities, subject to applicable laws and regulations.
- C. Maintaining ethical oversight and transparent reporting of medicine safety through pharmacovigilance will remain a priority for Companies, in alignment with applicable local laws and regulatory frameworks.

IV. Symposia and Congresses

- A. The purpose and focus of all symposia, congresses and other promotional or non- promotional, scientific, or professional meetings (an “Event”) for healthcare professionals organized or sponsored by a Company should be to inform healthcare professionals about products and/or to provide accurate and balanced scientific or educational information.
- B. Company relationships with healthcare professionals are regulated by multiple entities and intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical education.
- C. Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, supply, administer, or promote any medicine.
- D. All Events should be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. Companies should avoid using extravagant venues or resorts.

- E. Hospitality should be limited to refreshments and/or meals incidental to the main purpose of the Event and should only be provided:
 - 1. To participants of the Event and not their guests; and
 - 2. Is moderate and reasonable as judged by local standards.
- F. Companies should not pay any costs associated with individuals accompanying invited healthcare professionals.

V. Informational Presentations by Company Representatives

- A. In order to provide important scientific information and to respect healthcare professionals' abilities to manage their schedules and provide patient care, Company representatives may take the opportunity to present information during healthcare professionals' working day, including mealtimes, in accordance with applicable laws and regulations.
 - 1. In connection with such presentations or discussions, it is appropriate for occasional modest meals to be offered as a business necessity to the healthcare professional as well as members of their staff attending presentations, so long as the presentations provide scientific or educational value and the meals (a) are reasonable as judged by local standards; (b) are not part of an entertainment or recreational event; and (c) are provided in a manner conducive to informational communication.
 - 2. Inclusion of a healthcare professional's spouse or other guest in a meal accompanying an informational presentation made by or on behalf of a Company is not appropriate. Offering "take-out" meals or meals to be eaten without a Company representative being present is not appropriate.

VI. Entertainment

- A. Company interactions are professional in nature and are intended to facilitate the exchange of medical or scientific information that will benefit patient care.
 - 1. To ensure the appropriate focus on education and informational exchange and to avoid the appearance of impropriety, Companies should not provide any form of entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any healthcare professional. Such entertainment or recreational benefits should not be offered, regardless of (1) the value of the items; (2) whether the Company engages the healthcare professional as a speaker or consultant, or (3) whether the entertainment or recreation is secondary to an educational purpose.
 - 2. No standalone entertainment or other leisure or social activities should be provided or paid for by Companies.

VII. Gifts, Promotional Aids, and Educational Items

- A. Gifts for the personal benefit (such as sporting or entertainment tickets, electronic items, social curtesy gifts, etc.) of healthcare professionals (either directly or through clinics and institutions) are prohibited. Providing of cash, cash equivalents or personal services is also prohibited. For these purposes, personal services are any type of service unrelated to the healthcare professional's profession and that confer a personal benefit to the healthcare professional.

- B. A promotional aid is a non-monetary item given for a promotional purpose (common examples include sticky notes, diaries, and calendars, but can include a vast array of items that have no educational value). Providing or offering promotional aids to healthcare professionals in relation to the promotion of a prescription medicine is prohibited.
- C. It is appropriate 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.

VIII. Support for Continuing Medical Education

- A. Continuing medical education (CME), also known as independent medical education (IME), helps physicians and other medical professionals to obtain information and insights that can contribute to the improvement of patient care and medical practice.
 - 1. Companies should develop objective criteria for making CME grant decisions to ensure that programs funded are bona fide, independently developed and quality educational programs and that financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment.
- B. Grants, scholarships, subsidies, support, consulting contracts, educational or practice related items should not be provided or offered to a healthcare professional in exchange for recommending and prescribing medicines, or otherwise in a manner that would interfere with the ethics and the independence of a healthcare professional's prescribing practices. Companies should have a reasonable expectation that the grant is for the purpose of supporting legitimate education, scientific, or medical research.

IX. Samples

- A. Samples can be an important tool for healthcare professionals to help assess efficacy and tolerability for individual patients and should be used in adherence to the local laws and industry code of ethical conduct/marketing practice.
- B. In accordance with local laws and regulations, samples of medicines supplied at no charge may be provided to healthcare professionals in order to enhance patient care. Samples must not be resold or otherwise misused.
 - 1. Companies should have adequate systems of control and accountability for samples provided to healthcare professionals including how to look after such samples while they are in possession of medical representatives.
 - 2. Samples should not be used as payment for services, return for favorable treatment, or other inappropriate inducements.

X. Consultant and Speaker Arrangements

- A. Consulting arrangements with healthcare professionals allow companies to obtain information or advice from medical experts on such topics as the marketplace, products, therapeutic areas and the needs of patients. Companies use this advice to inform their efforts to ensure that the medicines they develop, produce and/or market meet the needs of patients. In addition, healthcare professionals participate in Company- sponsored speaking programs in order to help educate and inform other healthcare professionals about the benefits, risks, and appropriate uses of medicines.

1. Companies should continue to ensure that consultant and speaking arrangements are neither inducements nor rewards for prescribing or recommending a particular medicine or course of treatment.
 2. It is appropriate for consultants and speakers who provide services to be offered reasonable compensation for those services and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Any compensation or reimbursement made in conjunction with a consulting or speaking arrangement should be reasonable and based on fair market value.
 3. Consulting or advisory arrangements lacking a bona fide business purpose should not be used to justify compensating healthcare professionals for their time or their travel, lodging, and other out-of-pocket expenses.
- B. The following factors support the existence of a bona fide consulting or speaking arrangement (not all factors may be relevant to any particular arrangement):
1. A written contract specifies the nature of the services to be provided and the basis for payment of those services;
 2. A legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
 3. The criteria for selecting consultants and speakers are directly related to the identified purpose, and the persons responsible for selecting the consultants and speakers have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;
 4. The number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;
 5. The retaining Company maintains records concerning, and makes appropriate use of, the services provided; and
 6. The venue and circumstances of any meeting with consultants or speakers should be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. Companies should avoid using extravagant venues or resorts.

XI. Compliance Procedures and Responsibilities

- A. It is the responsibility of Companies to ensure that internal compliance procedures exist that facilitate compliance with these Principles and the spirit they embody. These procedures should be documented and provided to employees to further enhance compliance.

XII. Conduct and Training of Company Representatives

- A. Company representatives play an important role in delivering accurate, up-to-date information to healthcare professionals about the approved indications, benefits, and risks of medicines. These representatives often serve as the primary point of contact between the Companies who research, develop, manufacture and market medicines and the healthcare professionals who prescribe them. As such, Company representatives must act with the highest degree of professionalism and integrity.

1. Companies should ensure that all representatives who are employed by or acting on behalf of the Companies, and who visit healthcare professionals, receive training about the applicable laws, regulations and industry codes of ethics that govern the representatives' interactions with healthcare professionals. In addition, Companies should train their representatives to ensure that they have sufficient knowledge of general science and product-specific information to provide accurate, up-to-date information, consistent with applicable laws and regulations.
2. Companies should provide updated or additional training in all of the areas needed for their representatives who visit healthcare professionals. Companies should also assess their representatives periodically to ensure that they comply with relevant Company policies and standards of conduct.
3. Companies should take appropriate action when representatives fail to comply with relevant Company policies that are consistent with these Principles and local industry codes of ethics.

XIII. Public Sector Relationships and Procurement

- A. The decision-making process by Companies and Governments during and including the government procurement process, through bidding or any other procedure of government procurement, must be professional and ethical. There should be no attempt to exert inappropriate influence.
- B. Companies must provide accurate and balanced information to the Government.
- C. Companies and government officials should ensure that their relationships and fee-for-service arrangements comply with government ethics rules or procedures.

XIV. Clinical Trials

- A. All clinical trials (phases I to IV) and scientific research involving patients sponsored or supported by companies will be conducted with the intent to develop bona fide scientific knowledge that will benefit patients and advance science and medicine. Companies must ensure transparency and accountability in the presentation of research and publication of study results.
- B. Clinical trials should not be used as inappropriate inducements for past or future sales.
- C. Clinical trials should be undertaken in an ethical manner, without undue influence and sensitive to their impact on the patient community.

XV. Company Donations for Charitable Purposes

- A. As a demonstration of good corporate citizenship, Companies recognize their responsibility to support worthwhile activities both within and outside our communities.
 1. Donations including donations in kind, may be provided to organizations and institutions involved in promoting activities such as artistic, charitable, cultural, community, educational, humanitarian, health, philanthropic, and sporting activities in accordance with applicable laws and regulations.
 2. Companies should ensure that such support is not undertaken or directed solely for product promotional reasons.

3. Funding and donations in-kind should be directed to organizations and documented in a manner that outlines the nature of the donation provided.
4. Acknowledgement by the recipient organization of such support should be restricted to appropriate recognition of support.
5. Companies should ensure that there are no incentives to prescribe, recommend, purchase, supply or administer a product based on financial support and that nothing should be offered or provided which would interfere with the independence of a healthcare professional's prescribing or dispensing practices.

XVI. Patient Organizations

- A. Companies recognize that patients, their families, and caregivers are at the core of the mission of biopharmaceutical industry. Companies should observe clear and ethical boundaries when interacting with patients and caregivers, individually or as part of patient organizations.
- B. Companies should respect the autonomy and independence of patient organizations and should not influence their policy or advocacy decisions or activities. No Company should require that it be the sole funder of a patient organization or any of its programs. Patient organizations are encouraged to seek financial and non-financial support from a wide variety of private and public sources.
- C. Companies that provide financial support or in-kind contribution to patient organizations should have in place written documentation setting out the nature of support, including the purpose of any activity and its funding.
- D. Companies should ensure patient organizations are engaged in a meaningful manner in discussions and decision making regarding ethical standards and Principles.

XVII. Patient Privacy

- A. Companies should respect patient privacy rights, regulations, and legislation, and should appropriately manage and protect personal information.

XVIII. Health Data and Technology

- A. Companies and Stakeholders should embrace the responsible development and use of data and technology. Collection and use of health data and utilizing health technologies, including artificial intelligence, should advance health while respecting patients. Measures should be taken to describe and make available when and how health data is used. Health technologies should be designed and deployed with human control, oversight, and transparency, appropriate to the nature of the technology. This includes detailing how the technology is used, the goals and assumptions driving the technology, and its limitations.
- B. Stakeholders share responsibility to steward health data and technology, including continuous validation to uphold quality and responsible use and sharing of data. Ongoing collaboration will help ensure open communication and continuous feedback to foster and guide alignment while improving patient care and public health.

XIX. Adherence to Principles

- A. All Companies and Stakeholders should adopt procedures to assure adherence to these Principles and local and regional industry codes of ethics.
- B. Companies and Stakeholders should ensure that patient organizations have the support and ability to participate in the creation and review of these Principles.

Implementation

In order to promote an ethical commercial environment, cooperation among multiple Stakeholders is required. Therefore, it is recommended that Companies and all Stakeholders in APEC economies engage in the following activities:

Companies and industry associations should:

- Develop, measure, and implement codes of ethics consistent with the Principles set out above. Industry associations should consider publicly acknowledging members that have adopted industry codes, among other steps to encourage adoption of industry codes.
- Make available training regarding industry codes of ethics to healthcare professionals and healthcare professional students in collaboration with recognized authorities.
- Contribute to and participate in capacity building, particularly for small and medium sized enterprises (SMEs).
- Work together to ensure that the above Principles and their industry codes of ethics remain relevant and effective to address new business arrangements that may emerge.
- Encourage industry regulators and/or anti-corruption enforcement authorities to support the above Principles and local industry codes of ethics, where appropriate.
- Work to advance Consensus Frameworks and other collective action initiatives consistent with the [APEC Guide to Facilitate Multi-Stakeholder Ethical Collaborations in the Medical Device and Biopharmaceutical Sectors](#).

Healthcare Professional Organizations should:

- Develop and implement codes of ethics consistent with these Principles.
- Disseminate these policies to their members and facilitate training, education, and metrics on their use and implementation.
- Work to advance Consensus Frameworks and other collective action initiatives consistent with the [APEC Guide to Facilitate Multi-Stakeholder Ethical Collaborations in the Medical Device and Biopharmaceutical Sectors](#).

Patient Organizations should:

- Develop and implement codes of ethics directed towards patient organizations that are, at a minimum, consistent with the above Principles.
- Disseminate these policies to their members and facilitate training and education, including capacity building, as well as metrics on their use and implementation.

- Work to advance Consensus Frameworks and other collective action initiatives consistent with the [APEC Guide to Facilitate Multi-Stakeholder Ethical Collaborations in the Medical Device and Biopharmaceutical Sectors](#).

Third-Party Intermediaries should:

- Respect these Principles and develop and implement codes of ethics consistent with the above Principles.
- Ensure interactions on behalf of Companies adhere to applicable international and local laws, regulations, industry codes, standards, and ethical principles.
- Work to advance Consensus Frameworks and other collective action initiatives consistent with the [APEC Guide to Facilitate Multi-Stakeholder Ethical Collaborations in the Medical Device and Biopharmaceutical Sectors](#).

APEC Economies should:

- Develop and make known clear, accountable, and comprehensive policies on procurement processes and procedures.
- Encourage industry regulators and/or anti-corruption enforcement authorities to promote the above Principles and local industry codes of ethics, where appropriate.
- Encourage Stakeholders to adhere to the above Principles and Companies to adopt and implement local industry codes of ethics consistent with these Principles.
- Formulate and promote clear laws and regulations that are objectively applied.
- Work to advance Consensus Frameworks and other collective action initiatives consistent with the [APEC Guide to Facilitate Multi-Stakeholder Ethical Collaborations in the Medical Device and Biopharmaceutical Sectors](#).

Appendix

For the purpose of these Principles, the following definitions are provided:

"Congress" means an event sponsored and organized by a society, college, university, or other non-Company entity for the purpose of providing medical and/or scientific information.

"Consultant" means an external, independent healthcare professional, scientist, patient association/ patient representative, public or private payer retained individually or through an entity (e.g. university, hospital, or research organization) to provide advice, information or other services.

"Healthcare Professional" means a provider of medical or health services and any other person or organization that furnishes, bills, or is paid for health care in the normal course of business, including but not limited to physicians, nurses, or pharmacists and their staff.

"Patient Organization" means a not-for-profit institution that primarily represents the interests and needs of patients, their families and/or caregivers. Patient Organizations may be comprised of volunteers and/or professional staff; they may or may not be formally constituted entities. Patient Organizations may be described as patient organizations, patient advocacy groups, or healthcare consumer organizations depending on the economy or region.

"Representative" means a person calling on healthcare professionals and/or their staff on behalf of a Company regarding the promotion or discussion of medicines.