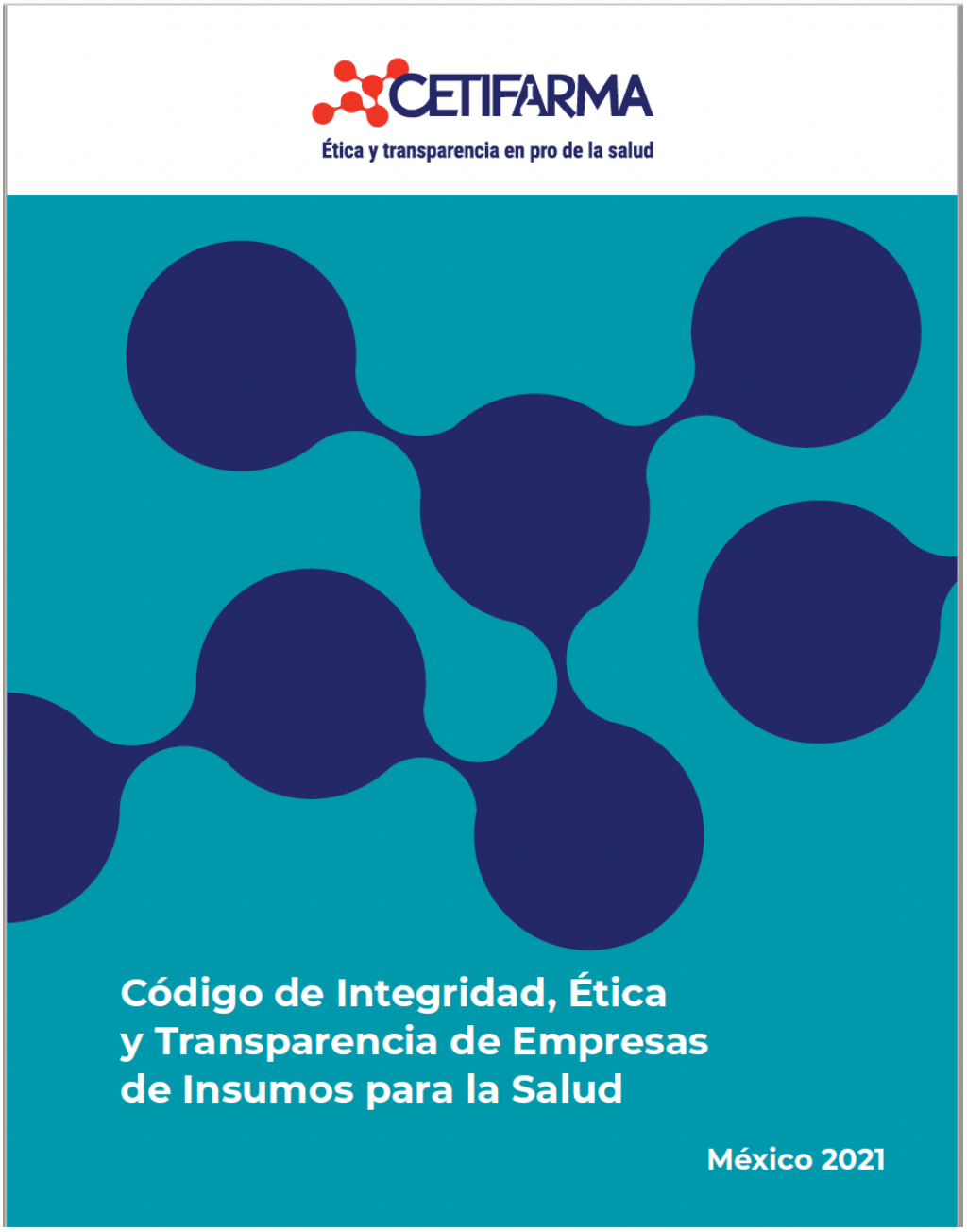
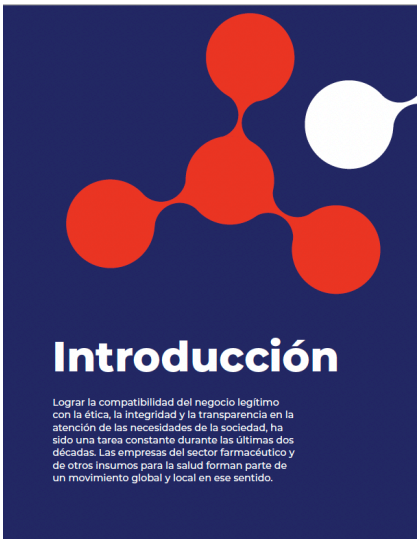


Code of Integrity, Ethics and Transparency for Healthcare Supply Companies

Mexico 2021

Contents



Introduction

The pharmaceutical companies and other healthcare suppliers have become part of a global and local movement that pursues the compatibility of a legitimate business with ethics, integrity, and transparency while meeting society´s needs.

Within the health sector different international agencies have developed criteria and strategies to advance in issues related to ethics, integrity, and transparency[1].

At the national level the institutions that have worked in these areas are The General Health Council (Consejo de Salubridad General, CSG); the Ministry of Health (Secretaría de Salud); the Federal Commission for Protection against Sanitary Risks (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS); the Committee of Ethics and Transparency in the interaction of Medical Professionals and-Pharma Industry, of the National Academy of Medicine (Comité de Ética y Transparencia en la Relación Médico-Industria de la Academia Nacional de Medicina, CETREMI); the National Bioethics Commission (Comisión Nacional de Bioética, CONBIOÉTICA); the Public Administration Ministry (Secretaría de la Función Pública, SPF); the National Chamber of the Pharmaceutical Industry established in Mexico (Cámara Nacional de la Industria Farmacéutica establecida en México, CANIFARMA); and the Council of Ethics and Transparency of the Pharmaceutical Industry (Consejo de Ética y Transparencia de la Industria Farmacéutica, CETIFARMA).

This global trend has generated guidelines and materialized it´s efforts in the establishment and application of codes of ethics and good practices of the pharmaceutical industry. These codes regulate at the regional and national levels the interactions of the pharma sector with healthcare professionals, healthcare systems, medical associations, healthcare service providers and patient organizations. In other countries, laws with similar regulations have been enacted. In all cases, the objective has been to promote business practices within an ethical, integrity and transparency framework, to improve the healthcare services to benefit the patients.

[1] The institutions whose concepts have guided CETIFARMA´s are an essential part of the Council's documentary background and are available for consultation on its website, which corresponds to a universally accepted conduct of transparency.

At the time, the pharmaceutical industry established in Mexico took on this challenge with the development of a self-regulating system oriented towards the prevention of unethical conducts and transparency., The former, was understood as a system created by an organization to channel and promote its corporate conduct and activities, based on eminently preventive rules, the supervision of their implementation and their compliance. This involved both the organizations and in their interactions with third parties, through a self-regulation system that is complementary to the provisions of the regulatory authorities. The ethical bases of self-regulation in a business context are based on truthfulness, autonomy, integrity and transparency.

The **self-regulation system** has the following **components**:

1. The voluntary decision, without external pressures, on the part of an industry or profession to design, establish and comply with a system of ethical and integrity rules and provisions to regulate their activities, their interactions, and their conducts.
2. The construction of a system of norms and provisions in a Code of Integrity, Ethics and Good Practices based on the applicable legal framework and on the principles and values adopted by the industry, the companies that comprise it and by those who collaborate within each one of them.
3. A monitoring system with a preventive approach that allows tracking the compliance with the rules and regulations defined in the Code.
4. A body responsible for the administration, promotion, monitoring and evaluation of compliance with the Code. As well as of its periodic updating, to maintain a process of continuous reinforcement of the self-regulating system.
5. A system of ethics with consequences, which:
    a. Recognizes and encourages companies that prevent improper practices, by complying with the norms and provisions of the Code. That identifies and disseminates good practices that help form habits, that drive the compliance culture by conviction.
    b. Motivates transparency in the actions and interactions of companies adhered to the self-regulation model, as evidence of their integrity and legitimacy.
    c. Establishes a denunciation and complaint system that guides, conciliates and, ultimately, sanctions the breaches of the Code.

CANIFARMA created CETIFARMA in 2005 as the body responsible for promoting ethics and transparency in the sector; for the design and establishment of deontological instruments (codes); and to monitor its compliance by companies adhering to them.

Fifteen years after the beginning of this journey, the results have allowed the development of a platform in favor of the integrity, ethics, and transparency of pharmaceutical companies and its dissemination to other related industries.

Evidence of this process is the following:

1. Creation of CETIFARMA in 2005, with the purpose of strengthening the development of a socially responsible, integral, and transparent pharmaceutical industry. Industries which are conscientious of behaviors that jeopardize compliance with ethical principles, to contribute to the welfare of society, to protect the environment and the safety of the patient.

CETIFARMA governing body includes 11 people, eight of which are independent Counselors who do not have any interests in the pharma and health care industries who have a multidisciplinary profile and who act *pro bono*. And, three members of CANIFARMA.

2. Establishment of a self-regulation model based on three deontological instruments: *Code of Ethics and Transparency of the Pharmaceutical Industry established in Mexico* (Código de Ética y Transparencia de la Industria Farmacéutica establecida en México, 2005); Code of Good Promotional Practices (Código de Buenas Prácticas de Promoción, 2006); and the Code of Good Practices in the Interaction of the Pharmaceutical Industry with Patient Organizations (Código de Buenas Prácticas de Interacción de la Industria Farmacéutica con Organizaciones de Pacientes, 2009), all of which are updated periodically. These instruments are inspired by similar international initiatives[2].

3. Integration of CETIFARMA (April of 2007) as a permanent member of Mexico's General Health Council (CSG), a constitutional body of the Mexican State which is the highest health authority and is headed by the president of the republic. The CSG issues national health provisions for the country; mandatory for all the public and private organizations that constitute the National Health System (Sistema Nacional de Salud), including the federal, state, and municipal administrative authorities.

4. Reinforcement of the self-regulation system of the pharmaceutical industry, in October of 2007, with the support of the General Health Council a *Commitment to Transparency in the relationship between doctors and healthcare institutions and the pharmaceutical industry* (Compromiso por la Transparencia en la relación entre los médicos e instituciones de atención a la salud y la industria farmacéutica) was signed.

In 2008 the Ministry of Health issued an *Agreement that establishes the guidelines to be observed in public establishments that provide health care services to regulate their relationship with manufacturers and distributors of medicines and other healthcare suppliers, derived from the promotion of products or the performance of academic, research or scientific activities* (Acuerdo que establece los lineamientos que deberán observarse en los establecimientos públicos que presten servicios de atención médica para regular su relación con los fabricantes y distribuidores de medicamentos y otros insumos para la salud, derivada de la promoción de productos o la realización de actividades académicas, de investigación o científicas), published in the Official Gazette of the Federation, 12 August of 2008).

5. Another contribution to the self-regulation system has been the *Self-regulation agreement for healthcare supplies and advertising ethics* (Convenio de concertación en materia de autorregulación de insumos para la salud y ética publicitaria), signed in 2012 by CANIFARMA and

[2] Ibidem.

CETIFARMA with Mexico's Federal Commission for the Protection against Sanitary Risks (COFEPRIS) and updated in 2018.

6. The General Administrative Responsibilities Law (La Ley General de Responsabilidades Administrativas, LGRA), published July 19, 2017, and the Code of Ethics for Public Servants of the Federal Government, published in the Official Gazette of the Federation (Diario Oficial de la Federación, DOF) on February 5, 2019, reinforce the framework of action between healthcare companies with public servants.

7. Participation, together with CANIFARMA, in the Business Integrity Project (Proyecto de Integridad Empresarial) jointly promoted by the United Nations Development Program (UNDP, Mexican Chapter), the Liaison and Partnership Office of the United Nations Office on Drugs and Crime (UNODC), the United States Agency for International Development (USAID) and Mexico's Ministry of Public Administration (SFP).

The purposes of these instruments have coincided in promoting practices of integrity and accountability, in preventing conflicts of interest and in avoiding corruption practices.

This framework of self-regulation includes four instruments for its operation:

8. A system of complaints and sanctions for breaches of the codes of ethics, transparency, and good practices of the pharmaceutical industry (2005).

9. A program for the evaluation and accreditation of transparent practices of companies. It recognizes compliance with codes of ethics, transparency, and good practices (2006). This evaluation is carried out by an independent agency from the industry and CETIFARMA, which has national and international recognition in the subject, Gestión Social y Cooperación, A.C. (GESOC).

10. A report of adherent companies to the CETIFARMA concerning their compliance with the obligations regarding scientific and educational events, medical samples, adverse effects, protection of the environment and compliance officers, which constitutes a transparency exercise towards the sector.

11. A Compliance Network integrated by those responsible of this function in each of the pharmaceutical companies (2007), which promotes and monitors compliance with the codes in their companies and with the third parties with which they interact,

The consolidation of the self-regulation system of the pharmaceutical industry, generated the trust and conditions for other service providers that sought to adhere. Manufacturing and marketing companies of infant formulas, assembled in the respective Commission of the National Chamber of Industrialized Milk (Cámara Nacional de Industriales de la Leche, CFFI-CANILEC), joined the self-regulation system with the signature, in August 2016, of the *Code of Ethics, Transparency and Good Practices of Marketing and Advertising of Human Mother's Milk Substitutes for Infants* (Código de Ética, Transparencia y Buenas Prácticas de Comercialización y Publicidad de los Sucedáneos de la Leche Materna o Humana para Lactantes), and their adhesion to CETIFARMA and its mechanisms for monitoring the application of the codes.

In 2018 the scope of the self-regulation system was broadened at the request of two more industries related to the field of healthcare: Medical Devices and other healthcare suppliers the (Dispositivos Médicos y Otros Insumos para la Salud), already part of CANIFARMA, and the Alliance of Contract Research Organizations of Mexico (Alianza de Organizaciones de Investigación por Contrato de México, ACROM).

The fact that three industries and a service provider closely linked to the field of healthcare, hereafter identified in this Code as **Healthcare Supply Companies (HSC)**, coincide in their interest and decision to share the same system of self-regulation suggests a process of change towards a culture of ethics and integrity that is beginning to permeate the Mexican healthcare business environment.

The Code of Integrity, Ethics and Transparency of Healthcare Supply Companies (Código de Integridad, Ética y Transparencia de Empresas de Insumos para la Salud, CIETEMIS), hereinafter referred to as the Code, is constituted of two components: a set of transversal provisions that apply to all healthcare supply companies adhered to the Code (principles, values, conducts and responsibilities); and specific provisions for each group of companies in particular, integrated in the chapters of Good Practices, for an easy reference.

The purpose is that, based on coincidences and convictions, healthcare supply companies consolidate as a sector, with ethical conducts and practices, integrity, and transparency as the cornerstones of their activities. As well as to foster the promotion of these behaviors in all areas in which they participate for the benefit of people's health, health safety and business legitimacy.

In the Code the term *compliance* has a broader scope since it also implies *prevention* via the establishment of clear and robust policies and procedures, *responsibility,* with detection, audit and control mechanism, and compliance, as the ability to generate evidence of the observance of the provisions and the capacity to identify possible deviations in order to control and, if necessary, rectify them. Compliance involves the highest level of a company's leadership whose role is to make it possible for its personnel to adopt the Code and its observance.

Four aspects guided the codes updating and their integration into one:

- Healthcare supplier companies are centered on people and their healthcare needs, working with a humane approach.
- The company's determination to position and reinforce integrity as the core of their internal operations and external interactions and to intensify their actions against corruption.
- To promote an ethically sustainable development of healthcare supplies companies, that considers "ethics with consequences", as mentioned before.
- To advance the transparency process by establishing the terms for gradual disclosure of information on HSC interactions with third parties in the healthcare field. This completes the virtuous circle of transparency: internal and external transparency of the companies.

In specific aspects, the HSC established in Mexico recognize in this Code the efforts of organizations that support the needs and expectations of patients, as well as the potential of joining efforts for the benefit of health.

Relevant aspects of the Codes update

To update the provisions for good practices of interaction with patient organizations (PO), the following documents were taken as reference:

- ✧ National regulatory provisions, and WHO recommendations.
- ✧ The codes of the European Federation of Pharmaceutical Industries and Associations (EFPIA), Germany, Spain, and Ireland.
- ✧ The European Charter on Patients' Rights of the Active Citizens' Network[3].
- ✧ The World Medical Association's Declaration of Lisbon[4].

[3] Which includes of patient organizations from Germany, Belgium, Portugal, Spain, Greece, Ireland, Denmark, the Netherlands, Austria and the United Kingdom.

[4] Adopted by the 34th World Medical Assembly, Lisbon, Portugal, September/October 1981; amended by the 47th General Assembly, Bali, Indonesia, September 1995; revised by the 171st Council Session, Santiago, Chile, October 2005; and, reaffirmed by the 200th Council Session of the World Medical Association, Oslo, Norway, April 2015.

In the corresponding chapter, adherents to this Code ratify their commitment to ensure that their interaction with the PO is constructive, legitimate, honest and transparent for the benefit of all, especially the patients.

The medical devices and healthcare supply companies recognize that throughout the useful life their products they have direct or indirect interactions with the people who supply them; with those who operate and maintain the equipment, whether or not they are healthcare professionals; and, with the patients, their relatives and caregivers. The companies are aware that these interactions must be conducted with integrity, ethics, and transparency to protect the patient's safety. As well as to prevent any undue influence in the selection of medical technologies by health institutions or in the treatments prescribed by healthcare professionals.

In the integration of the Chapter on Good Practices of the Medical Devices Companies, the following documents were consulted:

- ✧ Healthcare Supplies Regulation (Reglamento de Insumos para la Salud) issued by the Ministry of Health, last amended on March 14, 2014.
- ✧ Official Mexican Standard (Norma Oficial Mexicana) NOM-240-SSA1-2012, Implementation and operation of techno-vigilance (Instalación y operación de la tecnovigilancia), Ministry of Health; published in the Official Gazette of the Federation (DOF), on October 30, 2012, first section).
- ✧ Code of Ethics of the Chamber of Medical Devices and Healthcare Supplies, National Association of Businessmen of Colombia (Código de Ética de la Cámara de Dispositivos Médicos e Insumos para la Salud, Asociación Nacional de Empresarios de Colombia).
- ✧ Code of Interaction with Health Care Professionals 2017, Mexican Association of Innovative Medical Devices Industries (Código de Interacción con los Profesionales del Cuidado de la Salud 2017, Asociación Mexicana de Industrias Innovadoras de Dispositivos Médicos).
- ✧ Principles and Ethical Codes of the Medical Devices Sector of APEC, Kuala Lumpur, Malaysia, May 21, 2011.

The contract research organizations (CRO), grouped in Mexico's Alliance of CRO (ACROM) recognize that integrity in research with human beings has been under scrutiny for several decades. This has led to emergence of multiple national and international guidelines, regulations, and provisions, which seek to establish the highest ethical and scientific standards. As well as self-control measures to achieve greater transparency and accountability in clinical research activities in general, and in particular the research oriented to the development of new drugs, The Chapter on Good Practices of Contract Research Organizations (CRO) establishes standards and self-monitoring measures in the operation of CRO.

Healthcare supply companies that subscribe to this Code join their will to promote integrity, ethics and transparency as pillars of their business activity in all areas.

Mexico City, 2021.

Chapter I.
General Provisions

Article 1. Objectives of the Code

1.1 To be the basis of the activities of the healthcare supply companies (HSC)[5] established in Mexico. Activities aimed to the development promotion of an ethical culture and entrepreneurial integrity, based on a self-regulation system, a commitment to transparency that encourages principles and values and legitimate businesses practices with accountability. Behaviors oriented to fight corruption, and promote environmental responsibilities, responsible with the for the benefit of healthcare, the safety of patients and the welfare of society.

1.2 Promote the ethically sustainable development of HSC, with clear and fair rules, that legitimize and facilitate free market competition, avoiding practices of abuse, corruption, unfair competition, public image battles and misleading information.

1.3 Strengthen the relationship of HSC with society, authorities, and related national and international organizations based ethical behaviors that generate trust, assert their image, consolidate their acceptance, and recognize the reciprocal need among all of them.

1.4 Work based on ethical and free market parameters that promote harmony and fair benefits for all HSC, its shareholders, executives, and staff, as well as its customers, suppliers, associated third parties, and society.

1.5 Promote congruence between behaviors and attitudes of the Adherents, including their staff, customers, suppliers and associated third parties, and the ethics and integrity culture endorsed by this Code.

[5] Companies whose field of action is the generation and development of conditions in favor of people's health, through research, design, manufacturing, marketing and distribution of pharmaceutical products, medical devices and other supplies for healthcare. They coincide in the practice of legitimate business based on integrity, ethics and transparency, which they endorse with their adherence to the Code of Ethics and Transparency of Healthcare Supply Companies.

1.6 Define the principles of ethical action that will govern the relations of the companies adhering to this Code, with health professionals, institutions, doctors' associations, and patient organizations to ensure that promotional activities, support for educational programs and scientific events, and conduct in clinical trials do not unduly influence the decisions of institutions and the health professionals.

1.7 Establish ethical promotion standards for pharmaceutical products, medical devices, other healthcare supplies, chemical products, diagnosis systems, and contracted research services, to strengthen transparent interactions between companies and healthcare professionals. The latter without limiting the exchange of truthful medical and scientific information, or obstructing the organization of educational and informational events, which are necessary and must be carried out in compliance with the provisions of this Code.

1.8 Encourage the development of environment responsible companies and, above all, that actively promote sanitary safety.

1.9 Promote the identity and the sense of belonging to HSC based on their integrity and transparency practices for the benefit of people's health.

Article 2. Adhesions

An Adherent will be understood as a HSC and any other individual or moral persons, that voluntarily accept to regulate their actions in accordance with the provisions of this Code and other deontological instruments issued by the CETIFARMA.

The companies, for the sole fact of belonging to CANIFARMA, AMIIF (Mexico's Association of Pharmaceutical Research and Development Industries), ANAFAM (Mexico's National Association of Pharmaceutical Products) or the ACROM (Mexico's Association of CRO) acquire the status of Adherents to the Code of Integrity, Ethics and Transparency of Healthcare Supply Companies (i.e. The Code), which never the less must be formalized in writing, as part of its process of affiliation to the corresponding chamber or association.

All Adherents have the commitment to comply with the provisions established in this Code and to include them in their internal regulations.

Individuals and moral persons other than those mentioned above, who are interested in adhering to the Code and other self-regulation instruments, may do so through the procedure established by CETIFARMA.

The validity of the adhesion will continue if the Code is not modified. When the Code is updated, all Adherents must ratify their adherence in writing before CETIFARMA, within a period not exceeding 60 natural days from the beginning of its validity.

Article 3. Scope

For the purpose of this Code, healthcare supply companies include the pharmaceutical industry medical device and other healthcare suppliers, organized in the National Chamber of the Pharmaceutical Industry, the National Association of Drug Manufacturers and the Mexican Association of Pharmaceutical Research Industries (CANIFARMA, ANAFAM and AMIIF,

respectively); companies providing contract research services, associated in the Alliance of Contract Research Organizations of Mexico (ACROM); and other companies providing services to the pharmaceutical industry.

HSC will inform the provisions of this Code to all areas of their internal organizations and to their associated third parties, when they act in the name and on behalf of the company.

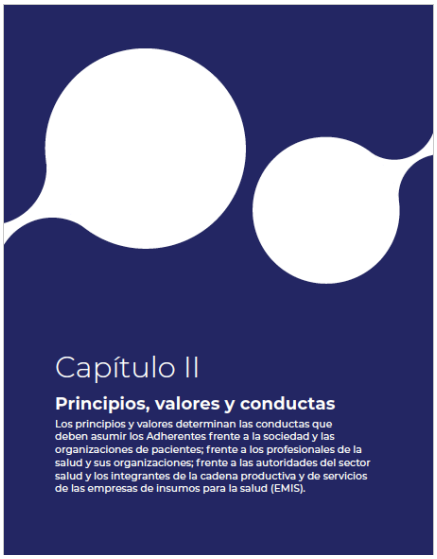
The Code contains provisions on ethics, integrity, transparency, prevention of conflicts of interest and anti-corruption measures that must be incorporated into the business practices of the HSC.

Article 4. Responsibilities in the application of the Code

4.1 The application of the Code is an obligation of all Adherents. Monitoring of its compliance is a shared responsibility of those responsible of compliance in each company and CETIFARMA. It is an activity that the latter performs in a context of respect, professionalism, and impartiality.

4.2 CETIFARMA is the only authorized body to interpret and clarify the scope of the Code´s provisions, or to clarify any doubts related to its application.

4.3 In order to promote the application and monitoring of compliance with the provisions of the Code, CETIFARMA will provide advisory and training services to the Adherents that require it.



Chapter II.
Principles, values, and behaviors

The principles and values that determine the behaviors that the Adherents must assume before society and patient organizations; healthcare professionals and their organizations; the authorities of the health sector and before the members of the productive chain and services of the healthcare supply companies (HSC)

Article 5. Ethical principles

Adherents assume the following principles as basic responsibilities before society:

5.1 Patient's centrality as the final objective of HSC

To contribute to the safe use and to the quality of people's healthcare, HSC must provide information to healthcare professionals involved in the prevention, prescription, supply, dispensing and sanitary surveillance of their products.

They will promote the respect for the rights of patients, their needs, and preferences, taking their opinion into account.

5.2 Responsibility with the life and the health of people

Ensure that healthcare supplies and the development of clinical trials effectively serve to preserve and improve people's quality of life. Particular attention must be paid to their safety, the quality and therapeutic efficacy of their products, as well as the availability of sufficient stocks in the market.

5.3 Solidarity commitment with society and the development of the country

Perform activities that provide a service to society, as well as a positive impact with its products by improving the population´s health. Contribute with the public healthcare policies and programs and meet the authority's requirements in sanitary emergency situations and natural disasters.

Provide quality employment and specialization opportunities to contribute to the formation of intellectual capital, the development of high value-added processes, as well as being an example of companies committed to sanitary and environmental safety.

5.4 Commitment to integrity and transparency in the marketplace and with society

It is the responsibility of the HSC to provide objective and truthful information, and exact instructions on the use and benefits of its products, without the intention of deceiving or confusing healthcare professionals or consumers. It is also their responsibility to ensure that third party associates acting on their behalf comply with this principle.

5.5 Responsibility for the viability and strength of HSC

Strengthen the credibility of the HSC, by creating conditions for all the actors in the health field with whom they interact -governments, institutions, healthcare professionals, medical societies, patient organizations, suppliers, third-party associates, distributors, and media- to promote integrity in their actions, for the benefit of Mexican society.

Article 6. Principles for action

6.1 Compliance with the Code

The companies that are part of the HSC are responsible for the observance and compliance with the spirit and the provisions established in this Code. To achieve this, they must ensure that their personnel at all levels are aware of and comply with the ethical precepts established in the code. Likewise, they shall ensure that these precepts are communicated to third party associates acting on behalf of the company.

They will also inform healthcare institutions and professionals, medical associations, and patient organizations about the provisions of the Code that govern the interactions with each one of them.

6.2 Healthy market practices and adherence to the law

The conduct of HSC, as well as that of its members and third parties acting on their behalf, must be in accordance with the guidelines of this Code and the corresponding laws, regulations, general and specific provisions. For these reasons they must have a broad knowledge of the legislation applicable to the sector, of complementary issues in administrative, commercial, economic, environmental, transparency and anti-corruption areas, among others; as well as of the guidelines and/or general national or international agreements on bioethics and biosafety.

The Adherents to the Code, and the administrative bodies of the chambers and associations, must establish procedures and the necessary means of control to verify that their members comply with the provisions stated in this principle.

6.3 Integrity and professional conduct as part of HSC culture

It is the responsibility of the HSC and their members to act with integrity because their behaviors not only affect the company's reputation and that of the associated third parties, but

also that of the sector as a whole and may put at risk the well-being of the people who consume their products and services.

Adherents will promote among the different chambers and associations that carry out activities with the sector, the supervision of their operations so that they are carried out in accordance with healthy market practices, and this Code.

6.4 Patient's satisfaction as a means to build trust

Companies in the sector must generate trust among their users, through integral and transparent actions that facilitate the access and availability to their products and services.

This principle requires that the chambers, associations, and Adherents have mechanisms and procedures that ensure the transparency of the activities of their members.

6.5 Identify conflicts of interest

A conflict of interest shall be understood as the circumstance that endangers the autonomy of a decision or action of healthcare professionals, public servants, HSC managers or employees and/or third parties, by giving priority to a personal, group or company benefit, over the patients benefits and society as a whole.

Adherents will avoid conducts likely to generate conflicts of interest and, where appropriate, should disclose any personal or family relationship that could imply benefits or undue advantages over clients, authorities, healthcare institutions and professionals, medical societies, associated third parties and of patient and/or altruistic organizations.

HSC should establish control mechanisms to identify and avoid conflicts of interest both among their internal areas and in their external interactions.

6.6 Informing for transparency

To a large extent trust in the HSC depends on the authenticity, opportunity, sufficiency, clarity, and easy access to the information that is made public. All information related to the products and services provided by the HSC, as well as the one corresponding to the different interactions they have with healthcare professionals and institutions, patient organizations and medical associations, must comply with the mentioned attributes.

The chambers and associations related to HSC must have adequate information systems to comply with this principle.

6.7 Respect the confidentiality of information

This principle is oriented towards safeguarding confidential information that the members of the sector possess due to their research, trade, and operations in Mexico and around the world. This information may only be shared with the competent authorities and entities, when appropriate. If the owner of the information has made it public *motu proprio* by any means, it will cease to be confidential.

Within the framework of privacy and personal data protection, in accordance with applicable laws, HSC are responsible for protecting and keeping the due confidentiality of any

information they manage of an identified or identifiable physical person. Sensitive personal data that may affect its owner or whose improper use may give rise to discrimination or entail a serious risk to the owner; among others, personal data that may reveal aspects of racial or ethnic origin, present and future health status, genetic information, religion and sexual preference.

The chambers and associations of HSC commit to having adequate control systems to prevent the inappropriate use of this type of information.

6.8 Promote responsible prescription and combat self-prescription

Adherents shall contribute with national authorities and international organizations in promoting the appropriate use of medicines, medical devices, and other healthcare supplies, as well as in discouraging the practice of self-prescription among the public.

Chambers, associations, and companies should use all means at their disposal to promote respect for medical prescription and warn about the risks of prescription by employees of pharmacies or among consumers. HSC will insist on the recommendation to consult a healthcare professional even for the purchase of over-the-counter products.

6.9 Compete with loyalty

Participate in the market with fair competition terms, applying the strictest respect for industrial and intellectual property rights, as well as all the rights of the other members of the HSC.

Members of the HSC will ensure that the competition of products and services is carried out with integrity and transparency, avoiding corruption practices and/or denigrating their competitors.

6.10 Promote scientific research and studies for the generation of knowledge.

Scientific research and clinical studies sponsored by HSC will be conducted for the purpose of developing products and disseminating knowledge for the benefit of patients and the advancement of science and medicine.

Adherents to the Code are obliged to transparent the results of the clinical trials sponsored or contracted by them, whether positive or negative.

Article 7. Corporate values

In accordance with the preceding principles, the entrepreneurial values that follow have been identified as substantive elements of the behavior of HSC members and all other stakeholders involved in their activities. These elements are based on ethics, integrity, and the prevention of corruption practices:

7.1 Integrity

Proceed with the highest standards of ethical and legal conduct, so that in practice these are reflected in transparency, honesty, and consistency between what companies say and do.

7.2 Transparency

Promote access to information in the main interactions of HSC, to generate trust, credibility and legitimacy, with evidence of corporate practices based on ethics, integrity and fair competition of legitimate business.

7.5 Security of the patient

Promote research and activities aimed at reducing the risk associated with the use of medicines, medical devices, and other healthcare, particularly promoting the timely practice of pharmacovigilance and techno vigilance among healthcare professionals, for the benefit of patients.

7.4 Proactive responsibility

Identify risk areas of potential non-compliance with the Code and laws, and determine appropriate measures to prevent, avoid and correct them. to Foresee the effects of non-compliance actions and assume the consequences, always considering the improvement of people's health and the trust in HSC as a sector.

7.5 Shared responsibility

Collaboration with the National Health System to contribute to people’s health with quality, opportunity, and accessibility.

7.6 Common good

The final purpose of the HSC actions is the benefit of people and society.

7.7 Subsidiarity

Development of an ethical culture among HSC and interacting third parties.

7.8 Legality

Comply with the legal and normative framework in an unrestricted manner.

7.9 Honesty

Ensure adherence to the principles and values established in the Code of Integrity, Ethics and Transparency of the HSC and promote rectitude and congruence in the interactions of companies with the different actors within their field of operation.

7.10 Justice

Support and respect fair business practices and free competition, in accordance with legal and ethical principles.

7.11 Ethical sustainability

Assume integrity and ethics as the guiding principles of the strategy for legitimate business and of each of the activities and interactions undertaken by the HSC. Encourage behaviors of increasing compliance, based on a cultural platform of principles and values within companies.

7.12 Leadership

Encourage the development of HSC´s entrepreneurial practices with ethical sustainability, based on consistency, the pursuit of excellence, the continuous change for improvement and the proper articulation of legitimate business with integrity, in order to provide high-quality products and services for the benefit of people's health.

Article 8. Adherent's conducts

8.1 Conducts that must be followed as companies.

8.1.1 Distinguish themselves in the entrepreneurial field for their exemplary performance, high level of professionalism, honesty, integrity and transparency in their business interactions and operations, and by complying with the principles and values of each company and those of this Code.

8.1.2 Respect and analyze differences of criteria, interests, and entrepreneurial perspectives, as well as between their associations and chambers to reach common positions through dialogue.

8.1.3 Maintain an impartial criterion when issuing opinions on matters related to the sector.

8.1.4 Respect the dignity and human rights of its personnel, other Adherents and third parties involved, without distinction of any kind, with emphasis on the protection of personal data, under the terms of the corresponding law.

8.1.5 Do not offer, grant or promise, directly or indirectly via third parties acting on their behalf or representation, gifts, bonuses, commissions, premiums, financial or in-kind advantages; incentives, considerations or any other tangible benefit to any person or public or private entity, national or international, that are against the laws, international agreements and provisions of the approved codes, in exchange for favoring its own business.

In compliance with the General Administrative Responsibilities Law, Adherents shall refrain from influencing, by any means, the actions, or omissions of a public servant for the benefit of their own business. This includes healthcare professionals, administrative personnel or any other public servant involved in the cycle of prescription, acquisition, distribution, dispensing and administration of medicines, medical devices and other healthcare suppliers, as well as those who participate in the selection and approval of research services.

8.1.6 Promote the development and continuous improvement of the company's personnel.

8.1.7 Maintain good relations with other Adherents, always promoting mutual support to dignify the business activity of the HSC. Likewise, to encourage relations based on ethics and integrity with third parties within the field of action.

8.1.8 Refrain from making unfounded comments about other Adherents, which may damage their reputation, good name, business credit, moral quality and prestige of their staff or of HSC in general.

8.1.9 Contribute to the ethically sustainable growth and development of HSC in the country.

8.1.10 Contribute with the National Healthcare System in the establishment of priority public health activities for the benefit of the population.

8.1.11 Help strengthen the chambers and associations that represent the Adherents, duly fulfilling the corresponding obligations.

8.1.12 Act with social responsibility for the benefit of the health of individuals and society, as well as the legitimate interests of the HSC and its members.

8.1.13 Produce, distribute or market medicines, medical devices, and other healthcare supplies with the highest standards of quality, safety, and efficacy, both for the domestic and the export markets. This provision applies in similar terms to the clinical research services provided by the Adherents directly or through third parties.

8.1.14 Strictly comply with the standards of good sanitary manufacturing practices, verify the quality of the supplies used, and respect the conditions of the sanitary registers of the products.

8.1.15 Inform the health authorities, healthcare professionals and consumers with truthfulness and objectivity, about the characteristics of their products. Always considering that the respective commercial, scientific, and technical information, is in accordance with the applicable legislation, the provisions of the Code and other present and future deontological instruments issued by CETIFARMA.

8.1.16 Act with transparency in the value transfers that companies make to social organizations, public or private institutions, particularly in situations of natural disaster or sanitary emergencies.

8.1.17 Contribute with ethical and integrity criteria in the training of technicians and professionals related to the field of HSC.

8.1.18 Promote the development of the HSC as green companies that foster the sanitary security of the population and take care of the environment in favor of its sustainability.

8.2 Industrial and intellectual property rights.

Scrupulously respect the rights of the industrial and intellectual property holders, the signed agreements on patents and trademarks, and each one of the provisions contained in the Federal Author's Rights Law (Ley Federal del Derecho de Autor), the Industrial Property Law (Ley Federal de Protección a la Propiedad Industrial), and all other applicable obligations.

To prevent or avoid abuse and corruption, companies will adopt the necessary measures so that their personnel comply with the above provisions,

8.3 Secrecy and confidentiality.

8.3.1 Observe the confidentiality requirements in relation to any product, equipment, device, service, technology, technical assistance, procedures, market information, sales strategies or price lists and advertising campaigns, whose access, disclosure, and use are restricted, classified as confidential information or are protected by patents, trademarks, industrial secret,

copyrights or any right or privilege, in accordance with the applicable legislation or agreements signed.

8.3.2 Keep confidentiality of the information and issues brought to the attention or analysis of CETIFARMA.

8.4 Sales to the public sector.

8.4.1 Act with integrity and transparency to comply thoroughly and loyally with the provisions of the Acquisitions, Leasing and Services of the Public Sector Law, the Federal Law of Economic Competition, and the General Law of Administrative Responsibilities and all other applicable protocols and other regulatory provisions.

8.4.2 In a process involving a bidding or any other public procurement procedure, Adherents shall refrain from any action that could be interpreted as a conflict of interest, obstruction or attempt to unduly influence the decisions or obtain confidential information from the public servants involved. Similarly, Adherents must point out any error or omission in the procurement procedures in which they participate, which could mean a breach of the legal provisions, even when such error or omission could benefit their own business.

8.5 Information and advertising.

8.5.1 In the terms of the law and this Code provide truthful, complete, and timely information, when using information media. Avoid taking undue advantage of clients or consumers, of any product, person, company, trade name or symbol, especially in situations of natural disasters or sanitary emergencies.

8.5.2 In the terms approved by the health authority and this Code explain objectively and truthfully the characteristics, functions, advantages or disadvantages of the products or services they provide.

8.5.3 Do not denigrate competitors or spread incorrect, distorted, or exaggerated data about their activities and products.

8.5.4 Strictly comply with the legal provisions regarding advertising, taking special care that messages in mass media or social networks do not cause confusion in consumers or induce misunderstandings.

8.6 Free competition and concurrence

8.6.1 Refrain from engaging in practices that limit, damage or impede free competition and concurrence in the production, processing, distribution and/or marketing of pharmaceutical products, medical devices and other healthcare supplies, as well as in the clinical research HSC develop.

8.6.2 Avoid colluding with other competitors to manipulate or elevate prices; as well as agreeing in the segmentation of markets, territories or customers; the restriction or conditioning of production; the closure or obstruction of distribution or commercialization channels; or the exclusion of products at the sale points.

8.7 Medical prescription

8.7.1 Contribute with the National Health System and the World Health Organization (WHO) in the promotion of the appropriate use of medicines and in fighting the improper practices that occur between the users and the dispensing system.

8.7.2 Adherents will promote respect for medical prescription through their distributors or associated third parties, including the restriction to offer incentives to the people in the sale points to encourage substitution of medicines, for their own.

8.8 Donations

8.8.1 Donations will be a part of the social responsibility actions of the companies and will be disclosed in accordance with the provisions of Article 27 of this Code.

Adherents may grant humanitarian donations, but not use them to evade responsibilities or as an undue incentive for the recommendation, prescription, purchase, supply, sale, administration, or promotion of the products of the donor company. Each company shall inform its personnel of this provision and the guidelines to be followed regarding donations.

8.8.2 Donations for social programs are defined as the free delivery of products, goods or services, and financial support, made by Healthcare Supply Companies which are accredited by the Ministry of Finance and Public Credit (Secretaría de Hacienda y Crédito Público, SHCP) and registered as authorized donors, Donations are made to: medical societies, patient associations, research centers, clinics and/or hospitals, charitable and private assistance institutions or civil society organizations, for the purpose of supporting social and altruistic projects. They also occur in cases of natural disasters or health emergencies, and to collaborate in improving the health of the population.

Companies shall make their donations in accordance with the provisions of the corresponding legislation and this Code.

It is forbidden to make any donation with the purpose of influencing the decisions of doctors, healthcare professionals and/or related officials, to favor the donor company's business.

8.8.3 Companies must establish policies for the evaluation, approval, and allocation of donations in accordance with the provisions of the National Anticorruption System (Sistema Nacional Anticorrupción). Donations will not be granted to individuals.

8.8.4 In accordance with the provisions of the National Anticorruption System donations will be formalized in writing, specifying commitments, their scope, validity, and accountability of the beneficiary,

8.8.5 For no reason, companies may companies condition the granting of donations to the recommendation of use or acquisition of medicines, medical devices, other healthcare supplies, or for the participation in clinical studies.

8.9 Environment and sanitary security.

Observe the universally accepted ethical principles of environmental sustainability and comply with the legal provisions regarding ecological preservation and improvement, sanitary security and the final disposal of packaging and waste products in the possession of final consumers in their homes.

When appropriate, support the initiatives of the chambers and associations of the HSC, in the promotion and development of green companies with social responsibility and committed to sanitary security.

8.10 Anti-bribery policies

Establish policies that expressly prohibit all forms of bribery in entrepreneurial activities carried out directly or through third parties or any other intermediary, in accordance with the provisions of the National Anticorruption System laws.

8.11 Political contributions

In accordance with the provisions of the law, HSC shall not make, by any means or third parties, contributions to political parties, individuals or organizations involved in politics.

8.12 Due diligence

The HSC should establish robust policies for the application of due diligence procedures in the selection of personnel, particularly in high-risk areas of the company; associated third parties; suppliers; or any other intermediary that they intend to hire.

8.13 Other chambers and associations

Strive for related chambers and business associations to establish and comply with transparency and integrity policies and programs as well as adequate means of control to verify that their members adjust their corporate behavior and that of their personnel to ethical principles and values.

Article 9. Cooperation between Adherents and CETIFARMA

9.1 Adherents will be able to participate with CETIFARMA in the study of topics of interest and/or contingency situations for the sector; in the development of new deontological instruments and dissemination materials; and in the identification of actions aimed at strengthening compliance with this Code.

9.2 Adherents agree to share experiences on the application of the Code, the development of their own ethical and integrity policies, case studies, among others, if they do not contain confidential, protected, restricted information, or personal data and are intended to support the training of HSC personnel.

Shared information will be for the exclusive use of the Adherents, who will respect the intellectual and property rights that may apply.

9.3 Adherents will promote activities that allow HSC professionals and technicians to acquire the most advanced theoretical and practical knowledge in the field of integrity, ethics, and transparency.

9.4 Adherents who participate in teaching activities should promote the following topics for the benefit of the new healthcare professionals and of HSC themselves:

9.4.1 The strategic role of self-regulation in the pharmaceutical industry and in other healthcare supply companies.

9.4.2 Business practices based on integrity, loyalty, and free competition, compliance with the law and the deontological provisions of the self-regulation system.

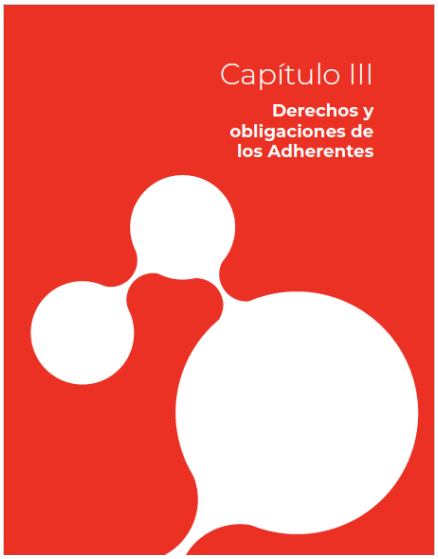
9.4.3 Commitment to a culture of ethics, integrity, and transparency, as the center of the management and the activities and research the companies carry out directly or with third parties.

9.4.4 Integrity practices to prevent risks, avoid acts of corruption or conflicts of interest.

9.4.5 Commitment to sanitary security and environmental sustainability.

9.4.6 Respect for intellectual property in the information to be publicized.

9.5 Adherents that might participate in teaching activities or in the formulation of study plans, will ensure that the new generations receive complete information about the different aspects of the pharmaceutical industry and other healthcare supplies companies, as well as business ethics and integrity.



Chapter III.
Adherent's rights and obligations

Article 10. Rights

All Adherents shall have the right to:

10.1 Receive advice from CETIFARMA on issues related to the application and compliance with the Code provisions, and other deontological instruments issued by it and/or by other related organizations.

10.2 Participate in the training activities developed by CETIFARMA.

10.3 Request from CETIFARMA the provision of training activities on ethics, integrity and transparency applied to the business field.

10.4 Propose the study of topics of interest for the healthcare supply companies.

10.5 Be recognized for compliance with standards of conduct and good practices in conducting their business, in accordance with the provisions of this Code and other deontological instruments that CETIFARMA has issued or will issue in the future.

10.6 Present complaints against any Adherent that fails to comply with the provisions of this Code and other self-regulation instruments issued by CETIFARMA.

10.7 Request guidance and support from CETIFARMA regarding third-party behaviors that affect healthcare supply companies in the compliance of this Code.

10.8 When appropriate, request the mediation of CETIFARMA in disputes between Adherents.

10.9 As part of a dispute process, request the testimony of another Adherent to confirm, explain or clarify the evidence presented to CETIFARMA.

10.10 Suggest amendments to this Code and other deontological instruments issued by CETIFARMA, for their updating, better understanding and due application.

Article 11. Obligations

All Adherents to the Code are required to:

11.1 Strictly comply with the prevailing laws, rules, official regulations and general legal provisions that are applicable.

11.2 Strictly comply with the rules of conduct and provisions established in this Code and in other deontological instruments issued by CETIFARMA. Monitor Code compliance within each company and provide information of the rules of conduct and deontological provisions to suppliers, associated third parties and any other person or entity with which they interact.

11.3 Establish a corporate integrity program that includes, but is not limited to:

- ✧ The provisions of this Code and the internal policies and procedures established to comply.
- ✧ Specially designed procedures to avoid any form of bribery in their entrepreneurial activities.
- ✧ The components of the integrity policy established in Article 25 of the General Administrative Responsibilities Law.
- ✧ Permanent mechanisms for monitoring and evaluating the application of the program.
- ✧ Means for training and the dissemination of information of the integrity program oriented to their personnel, as well as suppliers, associated third parties and others with whom they interact.
- ✧ Secure mechanisms to manage internal complaints and breaches of the integrity program and this Code, which should include methods to protect complainants.
- ✧ Procedures to perform due diligence in the employment of personnel, associated third parties, suppliers, or any other intermediary.

11.4 Promote the integral training and continuous preparation of the personnel of each company to ensure they comprehend the Code´s provisions, the integrity program and other deontological instruments signed by the Adherents.

11.5 Designate a Compliance Officer to steer and monitor the application of the provisions of this Code, other approved deontological instruments, and the company's integrity program. and to implement the preventive and corrective measures that may apply. As well as to collaborate with CETIFARMA in the verification measures it applies.,

Companies will notify CETIFARMA the name of their compliance officer and in the case of any change they will keep this information updated.

11.6 Support CETIFARMA by regularly contributing to the performance of its duties.

11.7 Comply promptly with the submission to CETIFARMA of the reports specified in this Code and provide any other information that is required on different aspects of compliance.

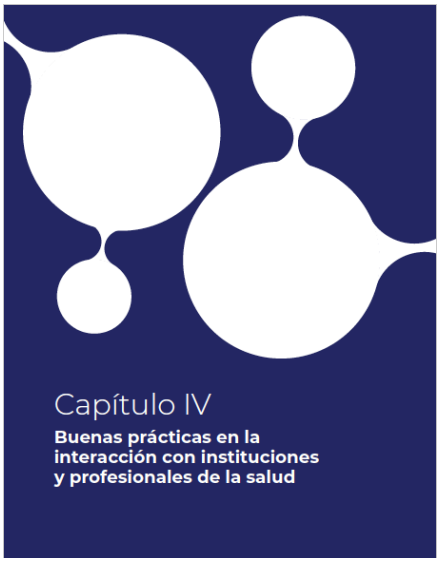
11.8 Reveal and provide information to CETIFARMA of Adherent´s practices that may affect the health of consumers, the trust or image of the HSC.

11.9 Base the complaints and denunciations presented to CETIFARMA must be honest, truthful, and objective, providing all the pertinent information of the case. Depending on the situation, including any related legal appeals lodged before the jurisdictional authorities.

11.10 Inform CETIFARMA about any deviations or internal breaches of the Code, the integrity program, or any other deontological instruments. Provide all the information regarding the measures adopted to correct them and avoid recurrence, respecting at all times the confidentiality of the personal data.

11.11 In case of non-compliance or contravention of the Code and other approved deontological instruments, to abide by the preventive and corrective measures and sanctions, if any, determined by CETIFARMA.

11.12 Keep confidentiality about information and matters in knowledge of CETIFARMA.



Chapter IV.
Good practices in the interaction with healthcare institutions and professionals

Article 12. General guideline

In their interactions with institutions, healthcare professionals and their organizations, including physicians, nurses, pharmacists and professionals who administer, prescribe, supply, purchase or recommend medicines, medical devices and other healthcare supplies, or perform clinical trials, Adherents shall comply with the principles of ethics, transparency and integrity established in this Code; with the applicable laws and regulations; and with the recommendations of the Committee of Ethics and Transparency in the Medical-Industry Relationship, of the National Academy of Medicine.

Adherents must ensure that interactions are appropriate and are perceived as such considering, but not limited to, the following general guidelines:

12.1 Patients centrality and the advancement of medicine.

Adherents' interactions with healthcare professionals and other stakeholders have the central objective of benefiting patients and improving the practice of medicine. Interactions should focus on providing truthful and scientific information, supporting medical research and certified quality continuing medical education, all supported by principles of integrity and transparency.

12.2 Primacy of the patient-healthcare professional relationship

Consider patient centrality as a superior commitment of the companies and the sector. The relationships of Adherents' personnel with healthcare professionals must support the development of a medical practice committed to the well-being and safety of their patients, based on truthful accurate information, and proven and updated scientific evidence. In their interaction with healthcare professionals, personnel from the HSC will promote the appropriate use of medicines, medical devices, and other healthcare. All of which must have the corresponding sanitary authorization.

12.3 Social responsibility and complementarity

Protecting health and facilitating the access of all society to quality healthcare services are fundamental responsibilities of the National Health System; to comply with the former, all institutions of the sector, the HSC, the healthcare professionals, the pharmacies, the patients, and their organizations must work together.

Adherents are committed to apply good marketing practices, to secure the availability and access to medicines, medical devices and other healthcare supplies, to conduct of clinical trials to contribute to the promotion, prevention, treatment and rehabilitation of people.

This implies working in coordination with the authorities to strengthen the patients and healthcare professionals' autonomy and decision-making capacity by ensuring that the products, services and information provided by the HSC contribute to generate a greater confidence in companies, and on the competition between them.

12.4 Transparency

12.4.1 Adherents from the HSC will make transparent their interactions with institutions and healthcare professionals and their organizations, in the terms established in Article 27 of this Code. In accordance with the Federal Law for the Protection of Personal Data Held by Private Parties (Ley Federal de Protección de Datos Personales en Posesión de los Particulares), HSC must safeguard all personal data and information classified as confidential or reserved.

12.4.2 All activities of promotional nature must make explicit its objectives and nature, avoiding misunderstandings or deceits. In these activities HSC must comply with the applicable laws and the provisions of this Code.

12.4.3 Adherents shall clearly indicate the sponsorship of any material on medicines, medical devices and other healthcare supplies, as well as their uses.

12.4.4 Clinical trials, controls, after-sales experience programs, and post-sanitary authorization studies will not be considered promotional activities; they will be carried out with clearly established scientific or educational objectives and adhere to universal ethical principles.

12.4.5 Any Adherent who directly or indirectly funds, performs, or coordinates the publication of promotional material in any media, whether printed, in audio or digital format, must expressly state it and may not present it as an independent editorial matter. In the case of advertising materials, these will have to adhere to the provisions of the General Health Law and its Regulations on Advertising (Ley General de Salud y su Reglamento en Materia de Publicidad), and the name of the company will be clearly displayed.

12.4.6 The interaction of Adherents with the personnel of regulatory agencies shall strictly adhere to the applicable laws and regulations, particularly to the General Administrative Responsibilities Law), and to the principles established in this Code. Adherents shall refrain from unduly influencing the decisions of such agencies to hinder or expedite their actions for their own benefit.

12.4.7 Under all circumstances, HSC must observe the applicable laws, regulations, and deontological codes. Companies have the responsibility of verifying local requirements before preparing materials or carrying out promotional activities, and to ensure that they also comply with their own ethical requirements.

Article 13. Provisions regarding medical information, medical devices, and other healthcare supplies

13.1 The medical, scientific and compliance information areas of the Adherents shall ensure that the information provided to the healthcare professionals is accurate, balanced, honest, objective and sufficiently complete to enable the recipient to judge for him/herself the therapeutic value of the medicine, medical device, or any other healthcare supplies.

Adherents have the undeniable scientific and ethical responsibility for the contents of the information that they prepare and disseminate by themselves or through third parties and must ensure compliance of the provisions of this Code at all times.

13.2 All information on pharmaceutical products, medical devices, and other healthcare, that is disseminated by the Adherents themselves or via third parties must be accurate, verifiable, current, rigorously scientific, and consistent with the prevailing legal and regulatory standards. Ambiguities or exaggerations must be avoided.

13.3 Information of pharmaceutical products, medical devices and other healthcare supplies should be based on a scientific evaluation and the corresponding empirical evidence. The information should not lead to confusion due to distortion, unjustified reiterations, omission, or any other cause.

When requested by healthcare professionals and health institutions this information will be provided by the HSC.

13.4 Scientific information not contained in the Prescribing Information, (Información para Prescribir, IPP) approved or authorized by the sanitary registry, can only be presented to strictly scientific audiences. Direct promotion or via third parties of locally unauthorized uses must be avoided.

13.5 All graphic material must be presented in a way that offers a clear and truthful vision of the topics that are treated, it must be didactic and understandable. It should not lead to confusion regarding the nature of the product in question and should not include statements or comparisons that are not scientifically proven.

13.6 Information on prescription medicines, medical devices and health care supplies intended for healthcare professionals shall comply with the provisions of the General Health Law, its regulations and official standards, as well as with the approved Prescribing Information, and it should clearly identify the sponsoring company.

13.7 Companies should consider that the digital media by which they disseminate information and promote prescription medicines, medical devices and healthcare supplies have measures to ensure that it is only accessible to healthcare professionals.

Information presented on restricted access electronic pages should include a warning indicating that it is intended only for healthcare professionals authorized to prescribe.

13.8 Information and statements about adverse reactions should reflect the available evidence or be able to substantiate them with clinical experience. It cannot be affirmed that a product has no adverse reactions or side effects.

13.9 When the promotional material refers to published studies, they must be faithfully reproduced or offer a clear reference that allows easy access to them. Faithful reproduction must be understood as one that objectively reflects the meaning and content of the original source, without adding or excluding any information that could lead to error or confusion of the recipient.

13.10 When using comparisons of the efficacy, safety, or other properties of different active ingredients as an advertising tool, information regarding the statistical significance of the results must not be omitted.

Statistics or conclusions shall not be mixed or compared, nor the data from studies carried out with different methodologies, unless they come from systematic reviews or meta-analysis in which homogeneity criteria are expressed. Adaptations that may introduce biases and induce to confusion are not acceptable. Studies from accredited and reliable sources of information may be submitted, clarifying the methodology used.

13.11 Exaggerated claims that lead to believe that a medicine, medicinal substance, medical device, or healthcare supply has any special property that is not contained in the corresponding authorization should not be made.

13.12 The term "new molecule" cannot be used to describe a drug or medicine that has been available or has been promoted for more than two years in the country.

13.13 The brands of products of other companies can only be cited, indicating unequivocally that they are their property.

13.14 The information or printed documentation addressed to patients to facilitate the use of certain medications with complexities in their dosage, route of administration, etc., must be delivered to healthcare professionals who will determine their final use. This type of information will not have a promotional nature.

Article 14. Provisions regarding promotional activities

The ethical promotion of medicines, medical devices and other healthcare supplies contributes to the patients' healthcare and helps ensure that healthcare professionals have access to up-to-date information to substantiate their therapeutic decisions; that patients have access to the products they need; and that these products are prescribed and used in a way that provides maximum benefit to the individuals.

Promotional activities may be complementary but must always be compatible with the national sanitary policy and congruent with the corresponding regulations and standards.

14.1 The promotion of medicines, medical devices, and other healthcare supplies among health professionals, as well as the information authorized to be disseminated among the public, will be limited to products registered and approved by the Mexican authorities, in compliance with the General Health Law, its regulations and corresponding norms.

14.2 The promotion of prescription drugs, medical devices, and other healthcare supplies shall be directed only to health professionals, it shall adhere to the provisions of numeral 13.6 and in no case may it be presented as a scientific or educational activity under the terms of Article 18 of the present Chapter.

14.3 Promotional material, including advertising in print, audiovisual or electronic media, should be understandable and consistent with the information contained in the sanitary registration and with the provisions of this Code.

14.4 Specific information shall be provided regarding the benefits, contraindications, side effects and major adverse reactions related to the use of medicines, medical devices, and healthcare supplies, avoiding exaggerations or statements that may mislead or confuse.

14.5 All the activities or promotional materials must respect the nature of the product and the characteristics of the recipients, without causing offenses or undermining the confidence in the HSC.

14.6 The promotional material must not imitate the products, messages, presentation, or general designs adopted by other companies, in a way that may lead to deceit, be misleading or confusing, or lead to unfair competition practices.

14.7 Material relating to medicines, medical devices and healthcare supplies and their uses, whether it is promotional or not in its nature, should clearly indicate the name of the sponsoring company.

14.8 Quotations drawn from medical and scientific literature or personal communications should accurately reflect the opinion of its author.

14.9 Under no circumstances may promotional materials be distributed before having their final version reviewed and authorized by the medical area and the compliance committee, or their equivalent figures.

14.10 The promotional material that is intended to be disseminated, through telephone messages and electronic communications, must have the explicit approval of the competent authority and the acceptance of the recipients to receive it.

14.11 The incorporation of the data of a healthcare professional to the lists of addresses for the sending or the delivery of promotional material by any means, must have their explicit authorization. When they request to be excluded from these lists, their request must be fulfilled.

The administration and protection of this information must comply with the legal provisions on privacy included in Federal Law on Protection of Personal Data Held by Private Parties.

14.12 In compliance with the provisions of the Commitment to Transparency and the Agreement of the Ministry of Health of August 2008, HSC shall under no circumstances accept open or

disguised conditioning to carry out their promotional activities or to allow the access of their medical representatives to public or private health institutions.

14.13 No gifts, bonuses, monetary or in-kind advantages, incentives or considerations of any nature may be offered or promised to healthcare professionals, administrative personnel or government employees involved in the cycle of prescription, acquisition, distribution, dispensation, administration of medicines and other healthcare supplies. The only exception is in the case of promotional items related to the practice of medicine or pharmacy, and these must be of limited value, i.e., not exceeding ten daily units of measurement (Unidad de Medida y Actualización, UMA), according to the economic reference established by the National Institute of Statistics and Geography (Instituto Nacional de Estadística y Geografía, INEGI) each year.

Article 15. Promoting the proper use of medicines, medical devices, and other healthcare supplies

15.1 As part of their commitment to people's health HSC shall promote, directly, indirectly and, where appropriate, in support of the authorities, campaigns directed to the consumer public to promote a culture of rational and appropriate use of their products. Emphasizing the need to consult healthcare professionals authorized to prescribe, to respect the medical prescriptions, the provisions established for patient safety and to adhere to treatment. HSC should be attentive to specific provisions issued by WHO, such as the Global Action Plan to Combat Antimicrobial Resistance.

15.2 HSC should promote actions and support initiatives aimed at discouraging consumers' self-prescription.

15.3 Encourage and support actions aimed at respecting medical prescription and the prescription of healthcare professionals, so that the medicines, medical devices, or any other health supplies are consumed or used during the appropriate time, under the required conditions and in the correct dosage.

15.4 HSC and their associated third parties will adopt the necessary measures to respect the prescription of the healthcare professional and may not offer incentives or benefits to replace it.

15.5 In the terms of the applicable law inform individuals of the properties of the prescribed product, including its contraindications, possible adverse effects, the importance of concluding the treatment recommended by the health professional and the risks of substituting or modifying it without the knowledge and supervision of the prescriber.

15.6 HSC must have a person in charge of pharmacovigilance or techno vigilance, to collect the data provided by the healthcare professionals, medical representatives, points of sale and consumers, and analyze all the information related to doubts and adverse effects of the products that they commercialize.

In the case of medicines HSC will promote the collaboration of the prescribers with the Permanent Pharmacovigilance Program of the National Pharmacovigilance Center (Programa Permanente de Farmacovigilancia del Centro Nacional de Farmacovigilancia, CNFV). In the case of

medical devices, they will collaborate with the Executive Direction of Pharmacopoeia and Pharmacovigilance (Dirección Ejecutiva de Farmacopea y Farmacovigilancia), using the Online Notification System of Adverse Incidents of Medical Devices (Sistema de Notificación en Línea de Incidentes Adversos de Dispositivos Médicos).

According to the case, they will also inform health authorities, healthcare institutions and professionals.

15.7 In the first quarter of each year, the HSC companies must submit to CETIFARMA an annual report of the adverse reactions to their products, reported during the previous year to the health authority. For this purpose, CETIFARMA has established a format, and the companies will safeguard their sources and records.

Article 16. Medical samples, medical devices, and other healthcare supplies

In addition to complying with the provisions of the applicable legal framework[6], the Adherents must comply with the following:

16.1 In the case of prescription medicines, samples shall be provided directly, free of charge and in reasonable quantities to healthcare professionals authorized to prescribe, to familiarize them with the products and, if necessary, to support the patient in the initiation of their treatment.

16.2 Samples must not be offered, provided to induce or incentivize prescription practices, or as compensation for the provision of a service.

16.3 Samples should not be provided to healthcare professionals with a purpose other than their free distribution among patients, they should not be marketed in any way and must have a readily visible "not for sale" stamp.

Any breach of this provision must be notified in a timely manner to CETIFARMA who will proceed in accordance with the provisions of this Code.

16.4 In accordance with the Agreement of the Ministry of Health of August 12, 2008, (Acuerdo de la Secretaría de Salud)[7] the delivery of samples to public institutions that provide healthcare services will be subject to the provisions determined by each of them,

16.5 According to what is defined in the international agreements and the provisions of the Regulation of Health Supplies (Reglamento de Insumos para la Salud), the samples of medicines containing psychotropic or narcotic substances are prohibited[8].

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[6] Mexico's General Health Law; Regulation of the General Health Law on advertising (Reglamento de la Ley General de Salud en materia de Publicidad), DOF February 14, 2014; and Official Mexican Standard (Norma Oficial Mexicana, NOM) 072-SSA1-2012, Labeling of medicines and herbal remedies, section 4.1 Definitions, numeral 4.4.31.

[7] "Agreement that establishes the guidelines to be observed in public institutions that provide medical care services. It regulates their interaction with the manufacturers and distributors of medicines and other healthcare supplies, in relation to the promotion of products, academic, research or scientific activities." (August 12, 2008).

[8] Article 57 of the Regulation of Health Supplies.

16.6 Companies will keep a strict and permanent control of the handling of medicine samples, from their production, storage, delivery to the regional coordinators or equivalent figures, distribution to the medical representatives and of their delivery to the healthcare professionals. It is the responsibility of companies to maintain this control and to ensure that medical samples are given exclusively to healthcare professionals authorized to prescribe, whether in clinics, educational events or in any other circumstance.

In the case of medical devices and other healthcare supplies, the Adherents will keep a record of their production, delivery to the healthcare professionals and use of the samples, as well as of the final disposal of the samples that are subject to recovery.

16.7 Companies will provide a report to CETIFARMA with the measures and procedures adopted to comply with the control of medical samples, medical devices, and other healthcare supplies, using the format determined by CETIFARMA. When, for any reason, the company modifies its procedures, it will send an up-date to CETIFARMA.

Any deviation identified by the company must be reported immediately to the health authority and CETIFARMA, with the purpose of readily identifying the cases in which the medicines, medical devices and other healthcare supplies samples could be misused and to apply the necessary measures.

16.8 The lists of addresses for the delivery of samples of medicines, medical devices and other healthcare supplies to the health professionals should be kept up-to-dated.

When healthcare professionals request their exclusion from these lists, their request must be fulfilled. The information collected must comply with the safeguards of the Federal Law on Protection of Personal Data Held by Private Parties.

16.9 Adherents will designate a professionally qualified person[9] to supervise, in coordination with the compliance officer, the observance of what is established in this section. CETIFARMA can rely on them to obtain the data to verify compliance with these provisions.

Article 17. Prevention of conflict of interest and respect for the autonomy of the healthcare professionals

17.1 In order to avoid influencing the cycle of prescription, acquisition, distribution, dispensing and/or administration of any pharmaceutical product, medical device or healthcare supply, no incentives or gifts of any kind shall be offered or given, directly or indirectly to government employees while exercising their duties in public health institutions, involved in the in the mentioned cycle.

17.2 Exceptions to the previous numeral:

17.2.1 Informative material useful for the medical practice, provided it adheres to this Code´s dispositions, as established in Article 13.

[9] "Professionally qualified person" will be understood as a person who has, at least, a bachelor's degree and has been trained in the regulatory and deontological processes that apply to the control of medical samples, medical devices and other healthcare supplies samples.

17.2.2 The delivery of educational materials in digital, electronic, or audiovisual media, as long they do not represent independent value or benefit for the healthcare professionals.

The distribution of this type of materials to healthcare professionals who are public servants will be subject to the provisions established by the respective authorities. In case they also exercise a private practice, conflicts of interest should be avoided.

17.3 Adherents should preferably provide medical-scientific publications in electronic forms, as well as to facilitate access to medical and/or scientific information platforms to institutions that train human resources for healthcare, and that provide medical care.

17.4 To support health institutions, as part of their social responsibility activities companies may provide medical and technological equipment only on loan or as a donation, considering the precepts established in numeral 8.8 of this Code. The equipment can be provided it does not substitute an obligation, it is not conditioned or associated in any way with promotional practices. HSC must adhere to the principles of integrity and transparency established in this Code, as well as to the applicable legal provisions.

Article 18. Continuing medical education

18.1 Adherents may organize educational or scientific events directly or indirectly via moral third parties. They can also sponsor events promoted by academic institutions and of healthcare professional associations. Companies will give priority to the use of technologies to organize or sponsor online educational or scientific events, particularly those that favor the participation of healthcare professionals from distant places. These supports will be considered as value transfers (VT), subject to the provisions of Article 27 of this Code.

Sponsorships will not be considered as When academic or scientific activities are organized by third parties not belonging to HSC and involve the purchase or rental of spaces or promotional stands, they cannot be subject to a sponsorship. These constitute commercial activities that must be subject to the applicable legal and tax duties.

18.2 Continuing medical education (CME) events such as congresses, conferences, refresher courses and workshops should promote scientific exchange, medical education and/or up to date information on the advances of in the fields of health or alternatives therapeutics., These events should be monitored and under no circumstances will the HSC use the support they provide as a mechanism to unduly influence the orientation or content of the CME activities.

18.3 When supports are provided for CME activities or for independent educational programs, they must comply with the guidelines of the applicable legislation, have a rigorous scientific content, be based on clinical evidence and recognized or certified by the corresponding academic authorities.

18.4 Under no circumstance will educational supports be granted for the purpose of influencing prescription decisions of medications, medical devices, and other healthcare supplies. Nor for the purchase, inclusion, exclusion, or modification of products of the National Compendium of Health Supplies for Public Health Institutions (Compendio Nacional de Insumos para la Salud de las Instituciones Públicas de Salud) or in the basic medicine lists of private institutions or

insurance companies.

18.5 Educational or scientific events will only be directed to healthcare professionals, medical researchers and/or experts directly related to the topic addressed.

Educational activities oriented to healthcare professionals working as government employees must be agreed with the authorities of each institution, who in turn, will be responsible of selecting the participants and complying with the applicable regulations.

18.6 Educational events shall be held in appropriate venues, consistent with the purpose of the meeting, and shall conform to ethical and professional standards.

18.7 Educational and/or scientific activities must use at least 80% of the scheduled time of each event, so that entertainment, sports, or recreational activities can not prevail over the former.

18.8 At the request of the HCS, healthcare professional associations shall implement mechanisms to ensure that participants in the events remain in the premises and during times scheduled for the academic activities.

18.9 Companies shall not organize simultaneous educational/scientific and promotional activities during the development of the academic program, to avoid impeding the educational objectives of the event.

18.10 In these events, Adherents may offer hospitality to the participating healthcare professionals, researchers, or experts. Their companions or any other person not related to the subject matter of the event, shall not receive support of any kind.

18.11 Adequate hospitality shall be understood as the payment or reasonable expense for: transportation from the place of origin to the place of destination and vice versa; food and lodging; and, if applicable, the registration fee for the event.

The hospitality provided should adhere to the standards and guidelines established in this chapter.

In accordance with the guidelines established in its procedures. CETIFARMA will determine if the hospitality provided is adequate. CETIFARMA will evaluate if it complies with this precept.

18.12 For healthcare professionals who work as government employees, hospitality must respect the provisions for travel expenses and tickets authorized for Federal, State or Municipal Public Administration. It will be the responsibility of civil servants, when acting in this capacity, to declare under oath of telling the truth, that he/she has the authorization of his/her superior to participate in the educational event and that the hospitalities he/she receives do not contravene the provisions indicated in the previous paragraph.

18.13 The hospitality offered will be the same for national and foreign residents, it will only cover the time established for the development of the event and may not be extended for other activities different from those of the event.

18.14 Adherents shall not sponsor or finance social, recreational, sporting or any other type of activities other than educational and/or scientific. All financial or in-kind support that the Adherents provide for CME programs shall be channeled to scientific or educational purposes.

Companies shall include in the contracts or accords they sign an accountability clause, by which the sponsored entity or organization agrees to comply with the defined uses of the sponsorship or support granted. They will also sign a consent clause by which they allow CETIFARMA's monitoring activities of the sponsoring company during the event.

Companies shall refrain from supporting or sponsoring educational events organized by third parties that include recreational or sporting activities that jeopardize the public image of the HSC, even when the sponsorships are not used to finance such activities.

18.15 Companies must have a record of the educational and scientific supports granted, in accordance with the transparency provisions established in Article 27 of this Code, and to include them in the report referred to in numeral 18.22.

18.16 Regarding the educational supports for provided to Patient Organizations (PO), these organizations will determine the persons who will attend the events.

18.17 Under no circumstances will support be provided for continuing medical education activities that are organized by companies or by third parties, as an incentive for healthcare professionals to use, prescribe, buy or recommend a particular product or to influence the outcome of a clinical study. The same principle is applicable to the funding of independent educational programs.

18.18 No payments or in-kind support should be provided directly or indirectly, to healthcare professionals, medical societies, healthcare institutions or patient organizations for activities that do not have an educational or scientific purpose.

18.19 Companies may pay professional fees to speakers and moderators who participate independently or on their behalf in meetings, congresses, symposiums, and similar events of an educational or scientific nature, provided that both parties expressly state that there is no conflict of interest, and the services are formalized with a contract or agreement.

To determine the amount of payment, the following will be taken onto account: indicators of the local market prices for these purposes, the healthcare professional's CV, the time invested and, if applicable, the reimbursement of travel expenses.

18.20 In the case of healthcare professionals who are government employees acting in that capacity, they must have the express authorization of the applicable authorities and they must declare under oath that the payment received does not contravene the precepts of the General Administrative Responsibilities Law and that they understand that the fee is to be considered as a value transfer of subject to the transparency provisions of Article 27 of this Code.

18.21 When meetings, congresses, symposiums, and similar events are sponsored by the Adherents, this fact will be recorded in all the documents related to them, including in any presentation, paper, or document that the companies or authors publish or disseminate by any means the of sponsorship.

18.22 Adherents will report the scientific and/or educational events organized or sponsored by themselves or by third parties, to CETIFARMA, in accordance with the following guidelines and periodicity:

18.22.1 Recurring events[10]: during the first quarter of each year, Adherents will present a report of the educational or scientific events that they plan to organize or sponsor in that year. This report must include the preliminary versions of the general and academic programs of each event, its final versions must be reported to CETIFARMA at least two months before the event takes place.

In this context, a general program is understood as the one that describes all the activities scheduled for the event; and an academic program details its schedules, topics, and speakers.

18.22.2 Episodic events[11]: the company will keep the record of these events, including their academic programs CETIFARMA may request a random sample to assess them.

The information indicated in this numeral will be presented in the formats established by CETIFARMA.

Companies are responsible of ensuring that the events they support comply with the provisions of CIETEMIS (Code of Integrity, Ethics and Transparency for Healthcare Supply Companies).

The reports submitted to CETIFARMA will be considered confidential. CETIFARMA can visit the venues to verify in that the events comply with the provisions of this Code.

18.23 Adherent´s shall not organize, or sponsor events abroad, when directed to healthcare professionals based in Mexico, unless:

18.23.1 More than 80% of the invited healthcare professionals come from different countries, and the location of the event is logistically convenient for most of them.

18.23.2 There are justifiable safety and/or costs reasons.

18.23.3 That the specialists, the information and/or the work materials required for the development of the event are located outside the country.

In the above cases companies must respect. the present Code, as well as the legal provisions that apply in the host country

Article 19. Clinical trials

19.1 A clinical trial is understood as any research conducted in human subjects with the objective of discovering or verifying the clinical, pharmacological and/or pharmacodynamic effects of an investigational medicinal product, identifying its adverse reactions and/or studying its absorption, distribution, metabolism, and excretion, with the objective of evaluating the

[10] A recurring event is one organized or sponsored by companies on a regular basis.

[11] An episodic event is the one that a company organizes or sponsors, in principle, for one time only. In the case that the event is repeated, it must be considered as a recurring event.

efficacy and safety of an investigational medicinal product. The terms clinical study and clinical trial are synonymous[12].

19.2 The participants in a clinical trial include researchers; healthcare professionals; sponsoring companies; contract research organizations (CRO); public and private health institutions; ethics committees in research; regulatory authorities[13]; voluntary patients and healthy volunteers.

19.3 Prior to their development, all clinical trials must be approved by the corresponding research and ethics committees. They must be carried out in accordance with research protocols, the applicable national legislation, and the provisions of internationally recognized human rights[14].

19.4 The studies of accelerated clinical experience and phase IV projects must be internally approved by the medical directors of the companies, to ensure that the benefits to the participants in the studies are greater than the risks.

19.5 Clinical trials should not conceal promotional activities of any kind.

19.6 In accordance with the national regulations all clinical trials must be formalized through contracts with the third parties involved. Consequently, the companies sponsoring a clinical trial are responsible for the entire research process, including those parts that are performed by an associated third party. Any payment in this matter will be considered a transfer of value, subject to transparency in accordance with Article 27 of this Code.

19.7 Contracts must specify the commitments, benefits, and payments to the parties, according to the fair market value, without including benefits not directly related to the study contracted. Likewise, they will include a specific declaration of non-conflict of interests of the parties.

19.8 Contracting clinical trials with public institutions will be subject to the provisions of the Science and Technology Law (Ley de Ciencia y Tecnología) and, when appropriate, to the guidelines established by the Coordinating Commission of the National Institutes of Health and High Specialty Hospitals of the Ministry of Health (Comisión Coordinadora de los Institutos Nacionales de Salud y Hospitales de Alta Especialidad de la Secretaría de Salud), and to the provisions of numeral 19.3 of this Code.

19.9 All clinical trials must be registered at the National Registry of Clinical Trials (Registro Nacional de Ensayos Clínicos, RNEC), responsibility of the Federal Commission for the Protection against Sanitary Risks, with which the companies will contribute to keep this information updated.

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[12] National Guide for the Integration and Operation of Research Ethics Committees, Ministry of Health, (Guía Nacional para la Integración y el Funcionamiento de los Comités de Ética en Investigación); Secretaría de Salud; Comisión Nacional de Bioética, México; 2016; p. 55. Retrieved on February 28th, 2018 from:

http://www.conbioetica- mexico.salud.gob.mx/descargas/pdf/registrocomites/Guia_CEI_paginada_con_forros.pdf

[13] Mexico's Ministry of Health, Mexico's National Bioethics Commission and The Federal Commission for Protection against Health Risks.

[14] International regulations on Human Rights are an essential part of CETIFARMA's documentary background, which is available for consultation in the Council's website, consistent with universally accepted transparency practices.

19.10 Informed consent is the voluntary, informed, and specific authorization of patients, authorized family members or legal guardians, depending on the case, and of healthy volunteers that will participate in a clinical research process.

It consists of providing clear, truthful, sufficient, timely and objective information about the research and explaining unequivocally and precisely the risks, benefits, and timing of the research to patients and healthy volunteers.

Pharmaceutical companies, CRO and/or authorized research units should obtain proof that patients and healthy volunteers understood the information provided and encourage them to pose any concerns or doubts they might have, offering clear answers to them.

19.11 Once the previous point has been covered, the signature of the informed consent of the patients or, when appropriate, of the authorized family members or legal guardians and of the healthy volunteers must be obtained, and these documents should be safe guarded by the entity responsible for the investigation.

19.12 Companies must ensure that in the formation of study groups for clinical trials, conducted, directly or through third parties, no one has taken advantage of vulnerable populations; pressured the participants; disqualified a competitor; or offered undue economic or material compensations to obtain the consent of the participants.

19.13 The confidentiality of the personal data of the subjects participating in the investigation must be ensured by the researchers or the respective CRO, depending on the case, and the sponsoring company, in accordance with the provisions of the Federal Law on the Protection of Personal Data Held by Individuals.

This provision is also applicable for biological samples and genetic material obtained during the clinical trial, in accordance with the provisions of the *Convention on Human Rights and Biomedicine*[15].

Article 20. Non-interventional studies

20.1 These are observational studies carried out during the marketing phase of a medicine, in accordance with the conditions established in the Prescribing Information where the drug is the investigated factor.

20.2 These studies should aim to answer a scientifically and ethically legitimate question.

20.3 They must adhere to good clinical practices and the provisions of this Code, as well as to the national and international regulations detailed in numeral 19.3 of this Code.

20.4 They should not interfere in any way with normal clinical practice. The decision to prescribe a medicine must be a product of the usual medical practice and clearly dissociated from the protocol of the trial and of the decision to include the patient in the study.

[15] The Convention for the Protection of Human Rights and the Dignity of the Human Being with Regard to the Applications of Biology and Medicine (Human Rights and Biomedicine, 1997), was signed by the members of the Council of Europe, as well as the Additional Protocol Concerning the Biomedical Research (2005).

20.5 No intervention, other than the usual diagnostic or follow-up clinical practice. will be performed on patients, and epidemiological methods will be used to analyze the collected data.

20.6 The provisions of numerals 19.6, 19.7 and 19.8 of this Code will regulate the employment of entities responsible of performing non-interventional studies.

20.7 These studies should not be used to promote the prescription of a specific product.

20.8 They must be carried out by the medical areas of the companies that sponsor the research and should not involve the commercial areas or the sales representatives.

20.9 Treatment must be subject to the professional and ethical criteria of MD, without any intervention of third parties.

20.10 In no case will medications be provided to the participants in the study, as this would constitute an intervention.

Article 21. Results of the studies

21.1 The reports of the studies will include the disclosure of positive and negative results, without excluding information of adverse effects and contraindications.

Privacy of the participant's data must be respected, in accordance with the provisions of the respective laws.

21.2 Publication, by any means, of the results of the studies must using specifically identify the authors and their sponsors. The latter shall guarantee that the authors make public their non-existence of a conflict of interest.

Article 22. Commitment to sanitary security and the environment

22.1 Companies shall comply with the legal norms and regulations on sanitary safety and environmental protection, particularly those referring to the handling and final disposal of packaging medicine's residues, expired or unused health supplies. at points of sale or in the homes of the consumers.

22.2 The industry may cooperate with the authority in the development of mechanisms to raise public awareness about the sanitary risks derived from self-medication and expired medicines; the importance of avoiding the accumulation and misuse of surplus medicines; the value of their proper disposal for the benefit of sanitary and human safety, as well as to mitigate environmental degradation.

22.3 Companies will adopt the necessary measures to promote and facilitate consumer's final safe disposal of medicines, containers, and other health supplies.

22.4 To comply with the above provision, companies may apply their own handling programs of domestic waste or adhere to the National System for Management of Medicine and Packaging Residues (Sistema Nacional de Gestión de Residuos de Envases y Medicamentos, SINGREM), created by the pharmaceutical industry for these purposes.

22.5 During the first quarter of each year, Adherents shall send evidence of compliance with the provisions set forth in this Article 22, the information must be sent to CETIFARMA, under oath of telling the truth. CETIFARMA may request at any time additional information from the Adherents in this respect.

If the company has subscribed to SINGREM, it must send to CETIFARMA copy of the valid certificate within the period indicated in this Code.

Article 23. Medical representatives

23.1 Medical representatives constitute the sales force of the HSC and represent companies in their interactions with health professionals and healthcare institutions.

23.2 The fundamental objective of the medical representatives is to provide information about the properties and characteristics of the HSC products to the healthcare professionals, with the purpose of promoting their appropriate use for the benefit of the patients.

The companies will be responsible of the information provided by their medical representatives to the healthcare professionals.

23.3 The interaction of the medical representative facilitates:

23.3.1 The provision of the information required by healthcare professionals to strengthen their knowledge about medicines, medical devices and healthcare supplies.

23.3.2 The collection of comments or observations made by the healthcare professionals about the use or side effects, among others, of the medications, medical devices or healthcare supplies, and directed to the corresponding area of the company any.

23.4 The activities of the medical representative are the responsibility of the companies, which:

23.4.1 Shall ensure that medical representatives have appropriate training, based on principles of integrity and ethical conduct.

23.4.2 Shall provide ongoing training to their medical representatives with the objective of promoting good practices on the ethical handling and provision of scientific information to health professionals.

23.4.3 Shall take measures to ensure that medical representatives comply with applicable laws, ethical principles, and the provisions of this Code in their interactions with healthcare professionals and point of sale personnel. Companies shall establish mechanisms to identify non-compliance and implement corrective measures as appropriate.

23.4.4 Shall establish a specific prohibition for medical representatives to offer incentives or accept conditions from healthcare institutions and professionals.to facilitate their work.

23.4.5 Will ensure that the interactions of the medical representatives with healthcare professionals are carried out as often as necessary to fulfill their information purpose.

23.4.6 Must not accept any type of conditioning, whether direct or indirect, for the access of their medical representatives to the facilities of the institutions providing healthcare services or doctor´s offices.

The support given to scientific medical education and refresher courses for healthcare professionals, cannot be considered as a condition to allow access of medical representatives to the mentioned facilities.

23.5 Adherents shall establish mechanisms to monitoring compliance with the above-mentioned provisions.

Article 24. Employment of healthcare professionals as consultants

24.1 Companies may employ healthcare professionals individually, as teams of specialists, and as consultants, to participate in training programs for the company's personnel, for continuing medical education activities and specialized advisory boards. In the case of research projects or clinical studies, they must adhere to universally accepted ethical principles and applicable regulations.

24.2 The requirements for contracting this type of services shall include the healthcare professional's written statement that he/she has no conflict of interest with the contracting company, his/her agreement to make this link public, and a confirmation that he/she is conscious of the provisions of this Code (Code of Integrity, Ethics and Transparency for Healthcare Supplies Companies, CIETEMIS).

24.3 The selection of healthcare professionals for the provision of these services shall be based exclusively on their expertise, skills, and experience to meet the requirements of the company and achieve the objectives established by the consultancy.

The number of health professionals to be employed, must be fully justified by the company in terms of the scope of the project; the program of activities, the sessions will establish the time strictly necessary for the development of the work, the role to be played by each contracted consultant and the expected results.

24.4 The payment for these services should be determined in accordance with fair market value and by no means in relation to the volume or value of past, present or future of a business with the healthcare professional. It shall be proportionate with the time spent, the work performed, and the responsibilities assumed, and it shall be satisfactorily documented.

24.5 The employment of healthcare professionals will not be used as an incentive to induce, recommend, prescribe, acquire, supply, or administer the products of the employing company, to unduly influence their decision making or the result of a clinical study.

24.6 The place and circumstances of any meeting with consultants must be consistent with the contracted services.

24.7 Adherents shall only cover travel expenses incurred individually by the consultant when the contracted services require his/her travel to places other than his/her place of residence, or when he attends a scientific conference or meeting on behalf of the company that employed him, provided this is established in the signed contract

24.8 In the case of contracting consulting services with public servants or regulatory agencies, they must comply with the principles and provisions of this Code, and particularly, when applicable, with the terms of numeral 18.20 For no reason will HSC attempt to unduly influence the decisions of these bodies.

24.9 Contracts for consulting services shall specify the scope, commitments of the contractor and the party employed, deadlines, expected results or deliverables, benefits and considerations.

24.10 This type of contracts will be considered as value transfers subject to transparency, in the terms of Article 27 of this Code.

The documentation related to these contracts will be protected by each company and must be available for CETIFARMA when required.

24.11 Adherents shall create the conditions so that the contracted healthcare professionals have absolute independence in the formulation of their opinions and analysis.

Article 25. Services provided by organizations of healthcare professionals

25.1 The employment healthcare professional scientific societies, organizations, or associations to provide services for a company, will only be permitted when:

25.1.1 The purpose is to collaborate in research, teaching, the organization of educational or scientific events, and to support with consulting services. Any activity outside of these purposes is not allowed.

25.1.2 Their employment does not constitute an incentive for the recommendation, prescription, purchase, supply, sale or administration of certain pharmaceutical products, medical devices, or healthcare supplies, or to influence the outcome of a clinical study.

25.1.3 It is supported by a contract signed by the parties, specifying the nature of the collaboration, the expected results, and the agreed benefits and financial compensations. These contracts shall be considered value transfers subject to the provisions of Article 27 of this Code and shall be available to CETIFARMA upon request.

25.1.4 The requirements for contracting this type of services shall include a proof of the legal constitution of the healthcare professional organization. As well as a written statement of no conflict of interest of the healthcare professional organization with the contracting company.

Article 26. Recognition of good practices

To encourage good practices, as well as integrity and transparency, CETIFARMA may issue accreditations to the companies.

26.1 Adherents that participate in programs of evaluation and certification of the standards adopted to comply with the provisions of this Code may obtain an Accreditation Certificate as a Company with Transparent Practices (Empresa con Prácticas Transparentes, EPT).

The accreditation must be based on a compliance evaluation, done by an independent, specialized third party recognized in this field of analysis. The accreditation is valid for three years and may be renewed at the end of the term by the same method.

26.2 CETIFARMA will be able to determine other type of awards or accreditations to the companies that make contributions to the sector in the area of good practices, training, case studies, public information in web pages related to the commitment to ethics and transparency, among others.

26.3 In all cases CETIFARMA will publish the corresponding announcements and methodologies in a timely manner.

26.4 Any contravention to the provisions established in this Code and in other ethical and deontological instruments issued by CETIFARMA will cause the revocation of the awards and/or accreditations granted to the company.

26.5 These accreditations will be made public on CETIFARMA's website.

Article 27. Transparency of value transfers

Strengthening ethical principles and values of integrity and transparency gives sustainability to the entrepreneurial practice of HSC and legitimizes their businesses, incongruence with the higher good of promoting and improving the health of patients and society.

The companies that integrate the HSC establish a series of interactions with healthcare professionals and their associations, with the institutions of the National Health System, patient organizations and educational institutions, to:

- ✧ Foster the updating and development of healthcare professionals by supporting continuing medical education (CME) programs and actions to reinforce or expand their knowledge of diseases, to advance the quality of the services they provide to patients, their families, and caregivers.
- ✧ Encourage research, innovation and the development of new treatments, medicines, medical devices, and healthcare supplies to improve prevention programs and the care of diseases and disabilities.
- ✧ Promote their products with integrity and transparency, adhering to ethical principles.

Documenting the indispensable interactions between HSC and third parties in the fields of healthcare gives visibility, helps prevent conflicts of interest, and provides evidence of the integrity standards of the companies. Transparency is a means to disclose relevant information about the company's interactions, to strengthen internal cohesion and the reputation of companies that practice accountability within an ethically sustainable culture.

For the purposes of this Article, value transfer (VT) shall be understood as any legitimate contribution, sponsorship, support or fee, based on legal and ethical principles, that the company makes directly or indirectly, in cash or in kind, to healthcare professionals, organizations, institutions or patient's organizations. As well as to formally constituted educational institutions for educational, informative and/or research purposes, as well as for altruistic or assistance objectives.

Medical samples, commercial transactions between companies and their distributors or services contracted with persons other than health professionals will not be considered as VT.

HSCs' will apply the following transparency guidelines:

27.1 Consolidate the transparency culture within their companies, among all levels of their personnel at and associated third parties with which they interact.

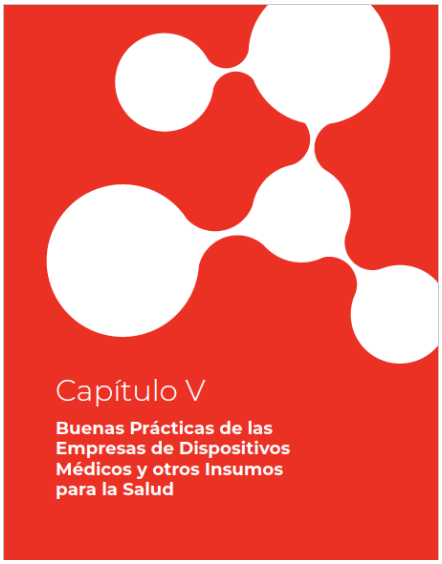
27.2 Establish policies that support the company's transparency of, considering the limitations imposed by laws on the protection of personal data and safeguarding information classified as confidential or reserved.

27.3 Document and report the value transfers (VT) made directly or indirectly, to the healthcare professionals and their associations, the institutions of the National Health System, the patient organizations, and educational institutions. Hereinafter, all of them will be referred to as recipients.

For the purposes of this Article, the information on VT will be presented by the companies in an aggregate manner to CETIFARMA, and the latter shall provide a standardized format for the report.

Chapter V.

Good practices of Medical Device Companies and other Healthcare Supply Companies (HSC)



The denomination of medical devices includes: the substance, mixture of substances, material, apparatus, or instruments (with the necessary software for their appropriate use or application), used alone or in combination in the diagnosis, monitoring or prevention of diseases in human beings or as auxiliary in the treatment of the same and of disabilities, as well as those used in the replacement, correction, restoration, or modification of the anatomy or of human physiological processes. Medical devices include products in the following categories: medical equipment, prostheses, orthoses, functional aids, diagnostic agents, dental supplies, surgical and healing materials, and hygienic products[16].

These products help healthcare professionals in making decisions on the diagnosis, monitoring, prevention and treatment of diseases and disabilities, as well as in the replacement, correction, restoration or modification of the human anatomy or physiological processes[17].In other cases, they generate or create synergies with other technologies or products, for safer and more effective uses of these products.

In addition to complying with the principles, values, good practices and general provisions of the Code of Integrity, Ethics and Transparency of Healthcare Supply Companies (CIETEMIS), medical devices and other health care supply companies shall adjust the management of their business to the following good practices.

[16] *Mexican Official Standard* (Norma Oficial Mexicana NOM-240-SSA1-2012), *Installation and operation of techno vigilance* (Instalación y operación de la tecnovigilancia); Ministry of Health ~~(Secretaría de Salud)~~; Official Gazette; October 30, 2012; first section; numeral 4.1.12, Mexico.

[17] *Guide for the Clinical Evaluation of Medical Devices* (Guía para la Evaluación Clínica de Dispositivos Médicos); National Center for Technological Excellence in Health; (Centro Nacional de Excelencia Tecnológica en Salud); Ministry of Health; Mexico; 2017; p.14.

Article 28. Objectives of interactions with institutions and healthcare professionals

The interactions of companies that produce, distribute or market medical devices and healthcare supplies[18] with the institutions of the National Health System, the healthcare professionals and their associations, the patient´s organizations and educational institutions will have to include the following among their main objectives:

- ✧ Strengthen the safe and effective use of medical devices and healthcare supplies for the benefit of better patient care.
- ✧ Promote research and development about devices and healthcare supplies.
- ✧ Support the continuing medical education of health professionals to stimulate their updating and the development of skills to handle medical devices and healthcare supplies to increase the patient's safety.

Article 29. Information on medical devices and healthcare supplies

All the provisions of Article 13 of the Code of Integrity, Ethics and Transparency of Healthcare Supply Companies will apply, except for numerals 13.10 and 13.12.

The information provided shall:

29.1 Indicate the clinical value of the company's medical technologies, their services, and procedures.

29.2 Be accurate and objective about the processes in which the products are used, the exact timing of their use and the expected health outcomes.

29.3 Indicate the technical support offered for the installation of the selected technology and/or to promote its appropriate and efficient use.

29.4 Medical representatives shall not interfere or modify the decision of a healthcare professional regarding the technology that he/she considers suitable for a specific clinical case.

Article 30. Continuing medical education (CME)

The supports granted by Adherents for the organization, organization and participation in congresses, seminars, symposiums, courses, or workshops of educational nature (events), organized by themselves or through third parties, shall comply with the general provisions of Article 18 of this Code (CIETEMIS).

Training and continuing education activities will be designed to provide, complement, and update healthcare professionals understanding, selection and operation of medical devices and healthcare

[18] According to the *Health Supplies Regulation*, Chapter IX, Art. 82. Other Healthcare Supplies include: "Medical equipment, prostheses, orthoses, functional aids, diagnostic agents, supplies for dental use, surgical material, healing, hygiene products and other devices for medical use, (which) require sanitary registration for their production, sale and distribution.

supplies, to strengthen their training and their capabilities in the diagnosis, treatment and care of patients.

Article 31. Training for the use of medical devices and supplies for health

31.1 Updating healthcare professionals or persons responsible of operating medical technologies shall be provided by the suppliers and shall focus on their safe and effective use.

31.2 Training shall be carried out in appropriate scenarios to facilitate the understanding of the information, familiarization with the use of the equipment, auxiliary products, reagents, or diagnostic systems, depending on the case, and preferably in the places where people will operate them.

Article 32. Promotional activities

32.1 Promotional activities of the Adherents shall comply with the general provisions of Article 14 of this Code (CIETEMIS).

32.2 Adherents assume the commitment to promote the proper use of medical devices and diagnostic systems with the unbiased promotion of their products and avoiding misleading or exaggerated information.

32.3 Promotional activities to publicize the characteristics, specificities and/or comparative advantages of medical devices and health supplies shall comply with the framework of the applicable legal requirements and the provisions of this Code Promotional activities shall be based on truthful information and respect for free competition.

32.4 In the event that a promotional activity involves a visit to the production plant, participation in an international parent company event or the demonstration of equipment that is difficult to transport (non-portable), companies may pay hospitality in the terms of this Code (CIETEMIS).

32.5 In the case of public servants, promotional activities and, if applicable, the invitation to visit demonstration sites, shall comply with the provisions of the of the General Administrative Responsibilities Law and the regulations defined by each public agency.

Any visit to equipment demonstration sites must derive from an invitation addressed to the head of the institution in question, who will select the participating public servant. It will be the responsibility of the latter to declare under oath that he/she has the authorization of his/her superior and that the hospitality received for the purposes of the visit does not contravene the applicable federal, state, or municipal public administration provisions regarding travel fares and expenses.

Article 33. Consulting Services

33.1 Adherents contracting consultancy services from healthcare professionals, their organizations, institutions that provide healthcare services and educational centers, will comply with the general provisions of Articles 24 and 25 of this Code.

33.2 The consulting contracts mentioned in the previous paragraph must be geared towards research and development activities, to advance knowledge in the field of health and medical devices, healthcare supplies and health diagnostic systems. As well as the development of new technologies; the improvement of existing services and products, as well as the quality and efficiency of patient care.

33.3 The participation of healthcare professionals in the provision of contracted services, will considerate following aspects:

33.3.1 Payment to a health professional in exchange for his/her input, understood as an intellectual property should be based on factors that preserve impartiality in the decision making and avoid inappropriate influence.

Contracting companies may sign license agreements with professionals who participate in the development of a product or technology regarding the intellectual property of their knowledge and experience, while respecting the legal provisions on copyright and industrial property.

33.3.2 In the event that a health professional provides a contribution that is novel, innovative, or considered by the company to be significant, it shall be properly documented to give the individual appropriate credit.

Article 34. Donations

34.1 Donations by Adherents to this group of companies, will be adjusted to the general dispositions indicated in numeral 8.8 of this Code.

34.2 Donations should facilitate access of the least favored population to medical technologies and may only be made to legally constituted non-profit organizations.

Article 35 Samples

35.1 Samples of healthcare supplies products provided by the Adherents shall comply with the general provisions indicated in Article 16 of this Code.

35.2 In accordance with the applicable laws and regulations, healthcare professionals can receive free samples of a product for evaluation, demonstration, familiarization and/or education to improve the care of their patients.

35.3 They may be provided in the quantities and frequencies indispensable for the effective use of the product, based on the medical criteria applicable to the health supply in question.

Article 36. Demonstration products or equipment

36.1 The equipment or products provided for demonstration may be granted on loan for a specific period. Occasionally, depending on a company´s criteria and policies, the loan can be made to carry out an appropriate evaluation of the equipment or products by the healthcare professionals.

36.2 These loans shall be documented prior to delivery of the equipment or products, specifying conditions of use, deadlines, and monitoring mechanisms by the company to ensure their proper use and avoid undue benefits for an institution or health professional.

36.3 Companies should ensure that demonstration products or equipment are returned or properly disposed of, according to their nature, at the end of the agreed evaluation period.

Article 37. Research

Adherents may provide support for research and development in the field of medical devices, healthcare supplies and diagnostic systems, in accordance with the provisions established in Articles 19, 20 and 21 of this Code (CIETEMIS), in accordance to the General Health Law and the Healthcare Supplies Regulation.

Article 38. Techno vigilance

It refers to the system of surveillance regarding the safety of medical devices. It includes a series of activities aimed at identifying and evaluating adverse incidents produced by medical devices in use, as well as detecting risk factors associated with them. It operates on the basis of systematic notifications, documentation and evaluation of adverse incident reports to determine their frequency, severity and occurrence of the incidents to prevent their incidence and minimize their risks. The information of the techno vigilance system is shared between competent authorities and manufacturers/distributors, in order to facilitate the activities in this field, as well as to ensure preventive and corrective actions, depending on the case, in the national territory and at the international level[19].

The purpose of techno vigilance is to ensure that medical devices available on the market perform as intended, in accordance with the manufacturer's intention of use (as recorded in the corresponding sanitary authorization issued by the Ministry of Health, and if not, to take the corresponding actions to correct and/or reduce the probability of recurrence of adverse incidents, thus seeking to improve the protection of the health and safety of medical device users[20].

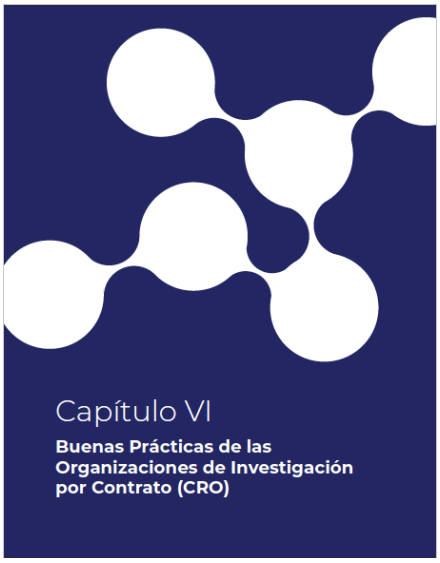
Adherents, as rights-holders of the sanitary registration of the medical devices are responsible of the implementation of techno vigilance activities of their products in Mexico, in accordance with the provisions of the Official Mexican Standard (Norma Oficial Mexicana) NOM-240-SSA1-2012 on installation and operation of the techno vigilance; to comply with this, they must have a techno vigilance unit[21].

Adverse incidents detected by Adherents or reported to them, must be notified in writing to the National Pharmacovigilance Center (Centro Nacional de Farmacovigilancia), in accordance with the established requirements and guidelines.

[19] *Mexican Official Standard,* op. cit; numeral 4.1.25.

[20] Ibidem; Introduction (Introducción).

[21] Ibidem; General Provisions (Disposiciones Generales), 5.1; and Responsibilities (Responsabilidades), 6.7.1.



Chapter VI.

Good practices of Contract Research Organizations (CRO)

The increase in life expectancy for a large part of the world population is a consequence of important advances in the prevention and the promotion of healthy lifestyles: including nutrition, sanitation, and education, together with research and the development of vaccines and new medicines. The biopharmaceutical industry has played an important role in combating diseases, both infectious and chronic degenerative, and improving and health recovery.

A crucial issue of this advancement has been the long and complex research and development processes that led to the discovery of new biopharmaceuticals. A process that has also required increasing amounts of financial resources.

In the context described above, national, and international regulations have established standards for the research and development of new medicines and other healthcare supplies, among others, medical devices. All of which need to be evaluated with a risk-benefit approach, to have evidence of their therapeutic efficacy and sanitary safety; and they are patentable.

Clinical trials are the mandatory bridge between the preclinical discovery of new medicinal products and their general use. Clinical trials are conducted before investigational new treatments are made available to healthcare professionals, for them to decide on prescription to their patients.

The biomedical research carried out in these clinical trials, is a multidimensional task that requires collaboration of many actors, among others, researchers, sponsors, public and private healthcare institutions, ethics committees and regulatory authorities. Their responsibilities during the process differ, however all of them are ethically responsible for the protection of the participants. This protection begins with an ethical and professional research design, and includes recruitment, monitoring, reporting adverse reactions and events throughout the investigation, and reporting the results, regardless of whether they are positive or negative.

Integrity in the research with human subjects has been under scrutiny for several decades. Consequently, multiple regulations, guidelines and directives have been issued. That is why it is relevant to conduct clinical research with the highest ethical and scientific standards, and to establish self-monitoring measures to achieve greater transparency and effective accountability in clinical research activities in general, and particularly in research for the development of new biopharmaceuticals, processes in which pharmaceutical companies are involved in different activities.

The universalization of clinical trials and the complexity of their regulation has made it necessary to outsource different research activities, mainly with Contract Research Organizations (CRO). In this context, CETIFARMA and the Alliance of Contract Research Organizations of Mexico (ACROM) agreed on the adherence of ACROM and its affiliates, to the self-regulatory framework of the pharmaceutical industry and the Codes issued by CETIFARMA. ACROM congregates the main organizations involved in the support and performance of clinical research in Mexico,

In addition to complying with the principles, values, good practices and general provisions of the Code of Integrity, Ethics and Transparency of Health Care Supply Companies ((CIETEMIS), especially those included in Article 19, Contract Research Organizations affiliated to ACROM shall adjust their conduct and activities to the following objectives and good practices.

Article 39. General objective

The companies affiliated to ACROM will have to align their practices to universal ethical principles, the Mexican regulations applicable to clinical research, and to the best international practices in integrity, ethics and transparency. The purpose is to promote an ethical culture and a Commitment to Transparency, whose guiding principle is the protection of the rights and integrity of research participants in the development of the clinical trials administered and performed by CRO. ACROM Affiliates voluntarily assume the obligation to adjust all their activities to the spirit of this document.

Article 40. Specific objectives

40.1 Be transparent and promote an ethical culture with the establishment and dissemination of principles, criteria for action and values among the Affiliates of ACROM and vis-á-vis society.

40.2 Strengthen integrity, ethics, and transparency practices, providing guidelines and advice to the Affiliates of the Industry and to those who interact with it in a relevant way.

40.3 Legitimize and facilitate free competition, to promote a socially responsible development of the Contract Research Organizations (CRO), with clear and fair rules, avoiding abuse, unfair competition, public image war and libel.

40.4 Strengthen good practices in the performance of clinical trials and consolidate society's trust in the integrity of research results.

40.5 Establish a permanent consultation mechanism between ACROM and its members, with the Authorities, specifically the National Bioethics Commission and the Federal Commission for the Prevention against Sanitary Risks.

40.6 Strengthen the image of a responsible pharmaceutical industry committed to ethical principles applicable in clinical research activities in which people participate, both as patients and as healthy volunteers.

Article 41. Scope

A framework for action in clinical research, involving human beings, is developed in this chapter. It is aligned to ethical and deontological instruments, which, in turn, adhere to universal ethical principles.

This framework contributes to the promotion of a culture of ethics and integrity in research, and of social responsibility of the CRO and the pharmaceutical sector.

The principles and guidelines established in this section complement, but do not to replace, the regulatory requirements, codes of conduct and ethical standards to which CRO must adhere in clinical trials with human beings.

In summary, the goals are oriented to:

- ✧ Promote a responsible and transparent performance, always attentive to scientific integrity, ethical and social significance of clinical trials and respect for the rights and safety of research participants.
- ✧ Work based on ethical and free market criteria that promote and attain order, harmony and fair benefits for all the actors involved in research, from shareholders and executives of the companies, to customers, suppliers and society at large, without affecting the safety of the research participants.

Article 42. Principles

The members of the Contract Research Organizations (CRO) affiliated to ACROM, understand that their basic responsibility is towards society and commit to adopt the following principles:

42.1 Integrity and excellence in research.

In accordance with the activities for which a CRO was contracted, it must ensure that the design, execution and the reports of the research are carried out with high ethical and scientific standards. All ACROM associates must recognize and accept the responsibility of promoting integrity in the research in which they participate, and in the truthfulness in the results obtained.

42.2 Ethical and professional standards

CRO must encourage respect, safety, and integrity of research participants. Be familiar with compliance with ethical and regulatory standards. Ensure that the information obtained, is recorded in an appropriate manner, that confidentiality and data privacy is maintained, and to ensure that any adverse reactions or events the participants may have, impacts in the environment are recorded. Perform their duties in accordance with the corporate responsibility of the CRO and pharmaceutical companies. Identify and report potential risks for the development of the research and/or its use for therapeutic purposes.

42.3 Respect for confidentiality

They must respect participants' rights to confidentiality and ensure that participants' confidential and private information is securely filed in compliance with the personal data protection laws.

42.4 Transparency and honesty

Honesty is a guiding principle with respect to individual and the organizational performance. A culture of transparency and honesty should be promoted in accordance with good clinical practice (GCP). It is important to clearly establish supervision or monitoring procedures to report in a prompt, constructive, and fair manner, noncompliance or transgressions of a protocol as well as breaches of integrity. It is also important to establish preventive and corrective measures.

42.5 Avoid conflicts of interest

Explicitly acknowledge and disclose any ethical, , deontological, financial, or commercial interests or conflicts related to the research and its funding. This applies in all ~~all~~ stages of the clinical trial, from its design, development, data collection, storage, to the analysis and reporting of data for funding, publication, participants recognition, and the peer review process.

42.6 Accountability

The results of outsourcing must be conveniently available for the sponsoring company, the regulatory authority and the corresponding ethics committee. The information must be properly substantiated.

Article 43. Ethical guidelines

In their interaction with the regulatory authority, the trial sponsor (sponsor), the clinical investigator (investigator), the research ethics committee (REC), and the participating public and private health care institutions, CRO should adhere to the following obligations and responsibilities:

43.1 With the researchers:

43.1.1 Guarantee that the safety, dignity, and integrity of the participants is respected and considered above any other objective.

43.1.2 They must ensure that any foreseeable risks are minimal, and that the potential benefits outweigh the risks. In protecting participants, they shall ensure that risks and potential benefits are clearly understood.

43.1.3 They must ensure that patient recruitment adheres to protocol and does not discriminate or favor the recruitment of vulnerable populations.

43.1.4 In case of an adverse event, contribute to give opportune care to the affected subjects.

43.1.5 Recruitment shall ensure that vulnerable population do not outnumber other types of participants.

43.1.6 Care should be taken to avoid incurring in participations that imply a conflict of interest.

43.2 With the research team:

43.2.1 Companies have the responsibility to promote good clinical practices (GCP) with all those involved in the research, as well as to avoid opaque practices and misconducts during the research.

43.2.2 Companies have the responsibility to clearly establish the authorized and non-authorized activities of the members of a research team.

43.2.3 Establish in writing the managerial and supervisory activities they will carry out and the mechanisms with which they will inform and sanction those who fail to comply with the established procedures.

43.2.4 Ensure that research sites have the necessary resources and comply with current regulations.

43.2.5 Researchers, sub-researchers, monitors, and other team members must have the credentials and the necessary capabilities to fulfill their responsibilities.

43.2.6 Establish a training and continuous development program for the personnel involved in the research team.

43.2.7 Ensure that the recruitment mechanisms comply with the provisions of the protocol and adhere to ethical and regulatory principles.

43.3 With the sponsor:

43.3.1 Submit a plan for the clinical trial to the authorities and research and ethics committees and obtain their corresponding approval.

43.3.2 Provide researchers with complete information about the product under study, its safety, and instructions for its correct use, and ensure that appropriate facilities are available.

43.3.3 Ensure that the trial protocol is adequately reviewed by a research and ethics committee.

43.3.4 Monitor the trial to ensure that the protocol is being followed, that data collection is adequate, that adverse events are reviewed and reported, and that all standards are being met.

43.3.5 No clinical trial should conceal a promotional activity and should not be used to promote the prescription of a specific product.

43.4 With the regulatory authority:

43.4.1 Ensure, when submitting the protocol for authorization, that it complies with the provisions of the Mexican legislation, codes of ethics and good practices and other requirements demanded by the authorities.

43.4.2 Ensure that the protocol has been authorized by the regulatory authority and that it is registered in their platforms and other countries, as applicable, particularly in the case of multicenter studies.

43.4.3 Report the adverse events found during the trial.

43.5 With the research and ethics committees:

43.5.1 Ensure that the clinical trial is evaluated by a Research and Ethics Committee (REC) and registered at the National Bioethics Commission.

43.5.2 Ensure that the informed consent has been reviewed and authorized by the REC and that the research subjects agree to participate in the study without undue influence.

43.5.3 Safeguard the rights, safety, and well-being of all trial participants; special attention should be paid to trials that may include vulnerable participants and those under pressure due to an emergency.

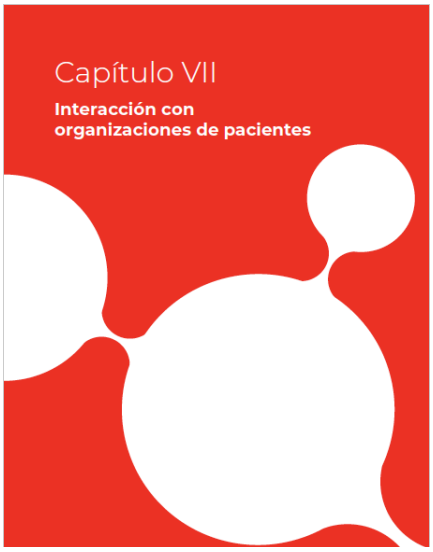
43.5.4 Inform in a timely manner the REC and the Federal Commission for the Prevention Against Sanitary Risks (about any amendments done and any relevant information for the protection of the participants.

43.5.5 Inform the REC and COFEPRIS of the progress of the study, at appropriate intervals according to the risk level of the study, but at least once a year.

43.5.6 In the collection of the information generated during the research; biases that could affect its analysis should be avoided.

43.5.7 Comply with the provisions of national legislation related to clinical trials and the international guidelines indicated in Article 19.3 of this Code.

Chapter VII.
Interaction with patient organizations



Article 44. Patient Organizations

Patient Organizations (PO) are non-profit, legally constituted civil groups that represent and support the needs and expectations of patients, with various activities such as caring for the ill; the search for therapeutic options; the promotion of self-care practices; obtaining easy-to-understand scientific information about available treatments; the prevention of diseases; and participation in the formulation of public policies or health education programs.

HSC will govern their interactions with patient organizations according to the following:

44.1 Respect the rights of patients established in the different international and national provisions, referred to in the introduction of this Code.

44.2 Recognize legally constituted PO as bodies representing patients.

44.3 Respect the autonomy of the PO and their independence to establish their policies and work programs.

44.4 Respect the diversity of the PO and avoid exclusion practices.

44.5 Interactions with PO may be carried out directly by companies or through their subsidiaries, foundations, associations, institutes, agencies or third parties linked to them. In any case, companies will be responsible for all such interactions and will ensure that the decisions of healthcare professionals and appropriate prescribing are respected.

44.6 Collaborations with the PO will be formalized with agreements, which establish objectives, scope, activities involved, calendars in which they will be carried out; amounts, sources, and destination of financing; obligations of the parties; direct or indirect support in kind and any other type of non-financial collaboration. The agreements must include an accountability clause describing the supports received by the PO.

44.7 Adherents are compelled to establish policies, guidelines, and procedures to formalize and register their collaborations with PO; to comply with them and ensure their follow up. In case of detecting deviations, they will require PO to apply the corresponding corrective measures. If deviations relate to the use of funds for purposes other than those agreed, Adherents must inform CETIFARMA.

CETIFARMA may request, at any time, information on the support given to the PO and its registration.

44.8 They will not condition the support they give to the PO, nor will they be able to limit other sources of sponsorship.

44.9 Companies can support educational programs of the PO, by sponsoring the production or acquisition of teaching or pedagogical materials for educational events.

In any of the cases, the sponsoring company can include in the materials a text regarding its sponsorship, but under no circumstances can the materials be used for the promotion of specific products.

44.10 Any support granted to a PO shall be considered a value transfer subject to the provisions of article 27 of this Code.

44.11 Adherents that sponsor the preparation and/or publication of PO materials shall not intervene in their content to favor their commercial interests. In collaboration with the organizations, they may correct inaccuracies or errors.

44.12 In the publications sponsored partially or totally by one or more Adherents, the sponsors shall be unequivocally identified.

44.13 Adherents require the specific authorization of the PO for the use of a logo, distinctive or material registered as their property. In this case Adherents must specify the purpose, the way in which the materials will be used, as well as time for which they will use them

44.14 For the sponsorship or organization, whether direct or indirect, of educational events of PO, Adherents shall comply with the provisions of Article 18 of this Code, as applicable.

Adherents will only be able to finance hospitality expenses for educational events via the PO and never individually to the patients, with whom they will not be able to establish a direct relationship at any time.

44.15 In accordance with the General Health Law and its regulations, the promotion of prescription HSC products is not allowed with patient organizations.

44.16 Adherents shall abstain from participating in, promoting, or sponsoring PO to induce the prescription, incorporation or exclusion of medicines and healthcare supplies in the National Compendium of Health Supplies for Public Institutions or in the basic medicine lists of private hospitals, for the benefit of their own business.

Chapter VIII.
Application and compliance with the Code

Article 45. In their activities and behavior Adherents are compelled to respect and comply with the principles, values and dispositions of the present Code of Ethics and Transparency, and in the deontological instruments issued by the CETIFARMA; especially those related to promotional and educational activities; donations; employment of healthcare professionals and their associations; development of clinical trials; measures targeted to guaranteeing patients safety. As well as the policies and actions to fight corruption in any of its forms.

Companies will integrate to their internal policies the provisions established in this Code and other deontological instruments issued by the CETIFARMA.

Adherents will be responsible of not complying with this Code and other deontological instruments issued by CETIFARMA, due to activities or behaviors of his/her own or by third parties acting on their behalf.

45.1 Adherence to the Code constitutes a commitment to put in practice an ethically sustainable culture in the exercise of a legitimate business, to promote it among all its personnel and with third party associates.

45.2 Adherents may consult or request advice from CETIFARMA on the application or interpretation of the provisions of the Code and other deontological instruments issued by the organization.

45.3 CETIFARMA together with the compliance officers of each company will disseminate and promote the provisions of this Code and will monitor their compliance.

45.4 In the case of possible complaints about activities of other adherent HSC that could represent a contravention to this Code or other deontological instruments issued by CETIFARMA, Adherents agree to first contact CETIFARMA and to present a duly documented file.

The information submitted by the parties in the process of the resolution of a complaint will be confidential and may not be used as evidence in other instances.

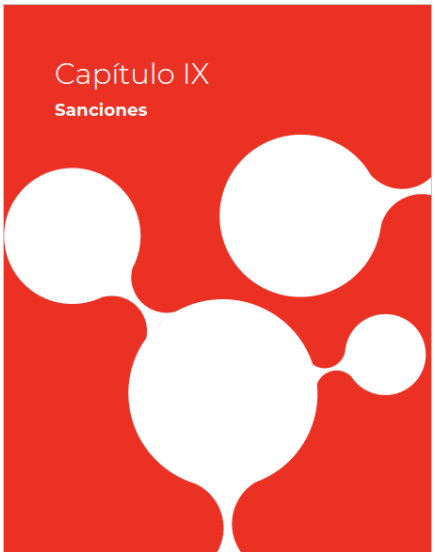
45.5 At a request of CETIFARMA Adherents could participate as an intervener the proceedings initiated against any other Adherent.

45.6 The members of CETIFARMA, as well as the denouncing company and the denounced company, shall preserve the confidentiality of the information of the complaint, and any other evidence presented during the process of analysis and until the resolution has been made public.

45.7 If there were conflict between the precepts of the different codes applicable to a certain activity, the strictest one will prevail and, if a controversy arises, CETIFARMA will be informed.

45.8 Nonobservance of any of the provisions of this Code and other deontological instruments issued by CETIFARMA, will be considered a contravention that and, in accordance with the provisions of the Code and CETIFARMA Regulations, it will give rise to a corresponding sanction.

45.9 Monitoring and verification of compliance with the provisions of this Code is a responsibility of general managers and compliance officers of the adhering companies, as well as of CETIFARMA. in accordance with the terms of its Regulations CETIFARMA will periodically report the results to its Board, as well as to the board of director of the adhering organizations.



Chapter IX.
Sanctions

Article 46. Breach of the Code

Any Adherent that fails to comply with the provisions of the Code of Integrity, Ethics and Transparency of Healthcare Supply Companies and those established in deontological instruments approved by CETIFARMA will be subject to the sanctions imposed by the latter.

Article 47. Determination of sanctions

In cases contraventions of the instruments mentioned in the previous paragraph, based on its regulations CETIFARMA will determine the sanctions and the procedures for their application. In the evaluation of the infringements CETIFARMA will consider the seriousness of the violation committed, as well as the impact it could have on the health of patients, on the responsibility of each company and on the credibility of HSC as a sector.

Article 48. Resolutions

48.1 CETIFARMA shall resolve the complaints presented to it or the ex officio investigations it carries out in a congruent and exhaustive manner.; It will analyze and evaluate with absolute impartiality and objectivity all the arguments and evidence presented by the parties. it will guarantee the right to a hearing to the denounced or investigated company and will substantiate and give reasons for its resolutions.

48.2 The resolutions issued by CETIFARMA will be final and unappealable and will be made public under the terms established by the organization´s regulations. Adherents are compelled to abide the preventive and corrective measures imposed, as well as the sanctions determined by CETIFARMA in accordance with this Code and the organization´s regulations.

48.3 In cases of non-compliance with the resolutions and contumacious recidivism, CETIFARMA shall determine additional sanctions.

Chapter X.
About CETIFARMA

Article 49. The activity of CETIFARMA

CETIFARMA will act within a framework of plurality, tolerance, respect for diversity and congruence, and will be the body in charge of:

49.1 Promoting and monitoring the application of the provisions of this Code and other self-regulation and self-control instruments, by randomly verifying Adherent's behavior in the activities considered in all instruments.

49.2 Reviewing the congruence between the procedures adopted internally by the companies and the provisions of the Code of Integrity, Ethics and Transparency of Healthcare Supply Companies (CIETEMIS), and any other deontological instrument issued by CETIFARMA. To comply with this provision, CETIFARMA may rely on the Adherents compliance officers.

49.3 Interpreting this Code and other deontological instruments and to provide advice to the Adherents.

49.4 Establishing alliances with analogous organizations and other national and international entities that can contribute to the enrichment of the contents of this Code and to strengthen the ethical, integrity and transparency culture of the Adherents.

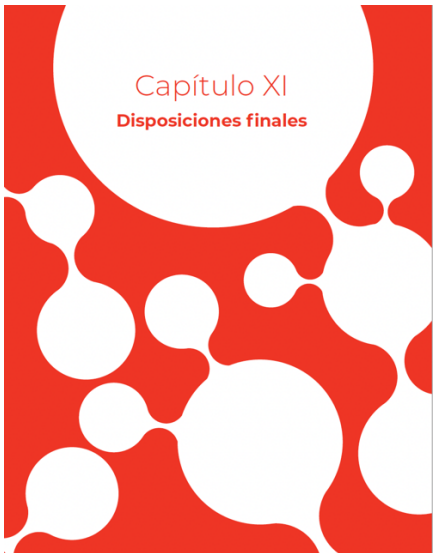
49.5 Receiving complaints and accusations of contraventions to the Code and other self-regulation instruments approved by CETIFARMA.

49.6 Participating as mediator in the resolution of disputes that arise among Adherents.

49.7 Imposing preventive and or corrective measures, as well as sanctions, based on this Code, on other deontological instruments issued in the future and CETIFARMA Internal Regulations.

49.8 Advise the Adherents in case of an unjustified complaint.

Article 50. CETIFARMA Internal Regulations' will determine the necessary provisions for its organization and the pertinent authority and capabilities for the execution of its functions. Adherents are obliged to comply with its provisions.



Chapter XI.
Final Provisions

Article 51. The Code of Integrity, Ethics and Transparency of Healthcare Supply Companies (CIETEMIS), was approved by the Council of Ethics and Transparency of the Pharmaceutical Industry established in Mexico (CETIFARMA) in its LXXXI ordinary session, held on October 6, 2020, and ratified by the General Assembly of the National Chamber of the Pharmaceutical Industry (CANIFARMA) in its ordinary session of June 23, 2021, and will come into effect on June 30, 2021.

Once this Code is in force, the codes in force up to that date will be rescinded.

Article 52. Adherents shall adapt the internal policies and procedures that are required to be in congruence with the provisions of the Code of Ethics and Transparency of Healthcare Supplies Companies (CIETEMIS).

Transitory Articles

SOLE. For the effects of numeral 27.3 of the Code of Integrity, Ethics and Transparency of Healthcare Supply Companies (CIETEMIS), CETIFARMA shall establish the terms under which the aggregated information on value transfers made by the HSC will be presented to the organization.

Glossary

1. ACCOUNTABILITY

Individuals, agencies, and organizations (public, private and social) are responsible of complying with their duties, as well as of reporting their performance and results.

It is an exercise by means of which institutions and organizations, public, private, or social, and the individuals that comprise them fully assume before society and the competent authorities the responsibilities derived from the exercise of their duties, so they report, explain, and justify their decisions and actions, and are subject to a system of evaluation and sanctions.

Source: *Propuesta de Glosario Hacia la Integridad*, PNUD, USAID, SFP y UNODC; Transparency International Glossary (Accountability); retrieved from: https://www.transparency.org/glossary

2. ADHERENTS

Legal persons that voluntarily adheres to the *Code of Integrity, Ethics and Transparency of Healthcare Supply Companies* and other deontological instruments issued by CETIFARMA, and agrees to comply with the provisions established and to include them as part of the corporate identity characteristics, which are expressed in conduct, behavior, and attitudes.

Source: *Código de Ética y Transparencia de la Industria Farmacéutica establecida en México*, 2013 (with adaptations).

3. ADVERSE DRUG REACTION

Harmful and unexpected response to a drug that occurs at doses normally recommended for the prophylaxis, diagnosis, or treatment of a disease, or for the reestablishment, correction, or modification of a physiological function.

Source: *Glosario de términos aplicados a Seguridad del Paciente*, Secretaría de Salud, retrieved from: http://www.calidad.salud.gob.mx/site/calidad/docs/dsp-sp_00F.pdf

4. ADVERSE EVENT REPORT (AER)

Also known as adverse reaction report). A report of serious adverse events, injuries, and deaths that the sponsor presents to the regulatory authority.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

5. ADVERSE REACTION

Unforeseen harm resulting from a justified act, carried out during the application of the correct procedure in the context in which the event occurred.

Source: *Glosario de términos aplicados a Seguridad del Paciente*, Secretaría de Salud, retrieved from: http://www.calidad.salud.gob.mx/site/calidad/docs/dsp-sp_00F.pdf

6. AFFILIATES

Legal persons that as such are associated to the National Chamber of the Pharmaceutical Industry; the Mexican Association of Pharmaceutical Research Industries; National Association of Drug Manufacturers; Commission of Manufacturers and Marketers of Infant Formulas, of the National Chamber of the Milk Industry; or the Alliance of Contract Research Organizations of Mexico.

Source: *Código de Ética y Transparencia de la Industria Farmacéutica establecida en México*, 2013 (with adaptations).

7. ALLIANCE OF CONTRACT RESEARCH ORGANIZATIONS OF MEXICO

Legally constituted in April 2009with the purpose of associating companies that perform clinical contract research. It also aims to collaborate with official bodies in solving clinical research problems in Mexico, to promote the importance of clinical research in the country and to represent its members with organizations and authorities. It has 16 affiliates.

Source: CETIFARMA (based on information from ACROM's website); http://www.acrom.org.mx

8. ARM

Any of the treatment groups in a randomized trial.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

9. AUTHORIZED GRANTEE

Civil organization or trust, with non-profit purposes, of a welfare, educational or social development nature, that has obtained approval from Mexico's Tax Administration System, to be able to issue tax-deductible receipts for the donations received.

Source: Sistema de Administración Tributaria (SAT) website.
http://www.sat.gob.mx/terceros_autorizados/donatarias_donaciones/paginas/default.aspx.

10. AVOID A RISK

Informed decision not to engage in a risky situation.

Source: *Guía Anticorrupción para las Empresas*, basada en el Estatuto Anticorrupción de la UNODC, Cámara de Comercio de Bogotá, Ministerio de Justicia de Colombia, Embajada Británica en Bogotá, Negocios Responsables y Seguros, 2014.

11. BELMONT REPORT

It was formulated in 1979 by the U.S. Department of Health, Education and Welfare; its title is *Ethical Principles and Guidelines for the Protection of Human Subjects in Research.* Named after the Belmont Conference Center, where a meeting of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was held, to discuss a clinical study on syphilis of 399 African Americans in Alabama (United States), which was conducted without their consent.

The document explains the principles that should be taken into account when using human subjects in research: 1) Respect for individuals (protect their ability to decide whether or not they wish to participate in the study, once all risks, benefits and potential complications have been explained); 2) Generosity (always increase the potential benefits to the subjects and reduce the risks); and 3) Fairness (the risks and benefits of a research study should be shared equally among the study subjects).

Source: *Código de Ética y Transparencia de la Industria Farmacéutica establecida en México*, 2013; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

12. BLINDING / MASKING

Procedure by which one or more of the investigators/subjects are unaware of the if they are receiving a treatment or not (placebo). The term blind means that the subjects are unaware of the treatment assignment and double-blind refers to the subjects, the investigator, the monitor and, in some cases, those analyzing the data being unaware of the treatment assignment.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

13. BRIBERY

In general, offering, promising, giving, accepting, or soliciting an advantage as an inducement for an action that is illegal, unethical, or a breach of trust. Inducements may take the form of gifts, loans, fees, fees, rewards, or other advantages (taxes, services, donations, favors, etc.).

Article 66 of the General Law of Administrative Responsibilities establishes that "Bribery will be committed by any private individual who promises, offers or delivers any undue benefit referred to in Article 52 of this Law to one or more Public Servants, directly or through third parties, in exchange for such Public Servants to perform or refrain from performing an act related to its functions or those of another Public Servant, or abuse their real or supposed influence, with the purpose of obtaining or maintaining, for himself or for a third party, a benefit or advantage, regardless of the acceptance or receipt of the benefit or the result obtained."

Source: *Propuesta de Glosario Hacia la Integridad*, PNUD, USAID, SFP y UNODC; Glosario de Transparencia Internacional; *Ley General de Responsabilidades Administrativas*, (DOF, 16-07-2016).

14. BUY OFF (SEE BRIBERY)

Any public servant who demands, accepts, obtains or intends to obtain, by himself or through third parties, due to his responsibilities, any benefit not included in his remuneration as a public servant, which could consist of money; securities; movable or immovable property, including through alienation at a price notoriously lower than the market price, will be guilty of bribery; donations; services; employment and other undue benefits for himself or for his spouse, blood relatives, civil relatives or for third parties with whom he has professional, labor or business relations, or for partners or companies of which the public servant or the aforementioned persons form part.

Source: *Ley General de Responsabilidades Administrativas* (DOF 18-07-2018), Article 52.

15. CASE REPORT FORM (CRF)

Printed, optical or electronic document designed to record and transmit to the sponsor all the information required in the research protocol for each trial subject.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

16. CERTIFICATION AS A COMPANY WITH TRANSPARENT PRACTICES

Recognition instituted by CETIFARMA in 2009 as an evaluation and certification program; CIETEMIS adherent companies can obtain it having accredited compliance with the standards established in the Code, in their daily business practices. The evaluation and corresponding proposal are made by an independent body from the industry and CETIFARMA. CETIFARMA independent board members are the ones who decide whether to grant the recognition.

Source: CETIFARMA website, https://cetifarma.org.mx/empresas-con-practicas-transparentes/

17. CLINICAL INVESTIGATOR

Physician responsible for carrying out the research protocol.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

18. CLINICAL MONITOR (CRA)

Person employed by the sponsor or by the CRO to review documents and ensure that the study is being conducted in accordance with the protocol.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

19. CLINICAL RESEARCH

Process of search, experimental evaluation of a product, substance, drug, medical device, diagnostic or therapeutic technique in human beings, where the objective of evaluation is safety and efficacy, always taking care of the bioethical and confidentiality aspects of the study subjects.

Source: ACROM website, http://www.acrom. org.mx/?page_id=38

20. CLINICAL TRIAL / CLINICAL STUDY OR CLINICAL RESEARCH

Study carried out on human beings. In the case of pharmacology, it includes the study of drugs in humans, their bioavailability, pharmacokinetics, pharmacodynamics, as well as any other property of the medicines. They must be preceded by preclinical studies, i.e. in laboratory animals, and must be conducted in accordance with the ethical principles exemplified by the Helsinki Declaration.

A clinical study is also defined as any systematic study that employs a carefully designed design to be carried out on human subjects, whether they are sick or healthy volunteers, and that respects the ethical principles established in the Helsinki Declaration.

The ultimate objective of clinical studies is to confirm the efficacy and safety of a drug or medical device. For this purpose, they seek to discover or verify the effects of the drug, including adverse reactions. They also investigate its absorption, bioavailability, distribution, biotransformation, elimination or other pharmacokinetic characteristics. The terms clinical trial and clinical study are synonymous.

Source: *Glosario de Términos Farmacológicos*, portal INFOMED del Centro Nacional de Información de Ciencias Médicas; *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

21. CLINICAL TRIALS REGISTRY

It is an information repository of new or ongoing clinical trials. The innovative industry that sponsors clinical trials registers the information on new and ongoing studies in a timely manner, complying with national and international regulations applicable to the type of study being reported.

Source: *Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases*, EFPIA, IFPMA, PhRma, JPMA (November 2008, with adaptations); retrieved from: http://www.jpma.or.jp/event_media/release/pdf/090416_shishin_e.pdf.

22. CODE

Statement of principles, values and performance criteria that establish standards of integrity, ethics, and transparency of the behavior that companies should follow. Adherence to the Code is voluntary and, based on this, companies assume the commitment to comply with it, which they make enforceable to all their personnel.

The provisions of the Code are promoted within the companies in accordance with a process that includes three stages: knowledge, through its dissemination; understanding, through training, analysis and reflection; and the generation of commitment, through the promotion of habits and a culture of compliance.

In addition, it includes a monitoring scheme and a system of complaints and denunciations, with the corresponding sanctions, in the event of non-compliance.

Source: *Propuesta de Glosario Hacia la Integridad*, Secretaría de la Función Pública, PNUD, USAID, UNODC (with adaptations).

23. COLLUSION

Collusion is committed by any private individual who carries out with one or more private parties, in matters of public contracting, actions that imply or have the purpose or effect of obtaining an undue benefit or advantage in federal, local, or municipal public contracting.

When private parties agree or enter contracts, agreements, arrangements or its combination among competitors, the purpose or effect of which is to obtain an undue benefit or cause damage to the Public Treasury or to the assets of the public entities, this will be considered as collusion. Transparency International (TI) defines it as a secret agreement between parties, in the public and/or private sector, to carry out actions intended to intentionally deceive with the aim of obtaining an unfair or illegal advantage.

Source: *Ley General de Responsabilidades Administrativas* (DOF 18-07-2018), Article 70; Transparency International Glossary; retrieved from:
https://www.transparency.org/glossary

24. COMMON RULE

Agreement to conduct U.S. government federally sponsored research with a homogeneous set of standards.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.
U.S. Government Department of Health and Human Services; retrieved from:
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

25. COMMON RULE, TITLE 45 PARAGRAPH 46

The regulation of title 45 paragraph 46 is based in large part on the Belmont Report and was written by the Department of Health and Human Services to provide basic protections for human subjects involved in biomedical and behavioral research that is supported by that Department. Title 45, paragraph 46, subparagraphs A through D, is also referred to as "the Common Rule."

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.
U.S. Government Department of Health and Human Services; retrieved from:
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

26. COMPARATOR (MEDICINE)

Marketed or non-marketed medicine (i.e., active control), or placebo, used as a reference in a clinical trial.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

27. COMPLIANCE

Responsibility for the promotion of a culture of observance with the provisions on integrity, ethics and transparency determined in deontological instruments freely subscribed by companies and established within a system of self-regulation, co-regulation, or regulation by mandate (law).

Its central topic is the management of non-compliance risks: identification, analysis, establishment of preventive measures, determination of actions to reduce them, promotion of habits in accordance with the provisions established in the codes to avoid them, evaluation of ethical performance, detection of deviations, promotion of corrective measures in those cases where non-compliance is proven and application of sanctions in those cases, where appropriate.

Source: CETIFARMA.

28. COMPLIANCE OFFICER

Person within each company accountable for the performance of the compliance responsibilities and, therefore, for the promotion of a culture of integrity, ethics, and transparency, and the provisions established in the codes and other deontological instruments to which the company has adhered, as well as for the management of non-compliance risks.

Among its main responsibilities are the alignment of the company's internal policies with the principles, values and provisions contained in the codes; the identification of ethical and integrity risks; the implementation of actions to prevent them and reduce their recurrence or even avoid them, As well as the implementation of activities to promote conducts, behaviors and attitudes in line with integrity, ethics and transparency in all areas and with all the personnel of the company, with the partners and third parties involved. Together with development of actions to monitor compliance with the self-regulatory or co-regulatory systems to which the company is incorporated, especially the deontological instruments issued by CETIFARMA.

Source: CETIFARMA.

29. CONFIDENTIALITY

Measures directed to prevent unauthorized individuals from having access to information owned by the sponsor or to the identity of a subject participating in an investigation.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

30. CONFLICT OF INTEREST

Circumstances that jeopardize the autonomy of decision or action of healthcare professionals, public servants and/or third parties, by giving priority to a personal, group or company benefit, over the benefit of patients or infants.

Transparency International (TI) defines it as the situation in which an individual or the entity for which he or she works (whether a government, a company, a media, or a social organization) is faced with choosing between the duties and demands of his or her position and his or her own private interests.

The General Administrative Responsibilities Law defines it as the possible impairment of the impartial and objective performance of the duties of a public servant due to personal, family or business interests (Article 3).

The OECD identifies three types of conflicts of interest:

Real: occurs when the situation confronts the obligations arising from the public service with private interests of officials that may unduly influence the execution of their powers and responsibilities.

Apparent: there is the appearance that the private interests of a public official may unduly influence the performance of his or her duties and responsibilities, although this may not actually be the case, it may generate suspicions that damage the public servant's image.

Potential: arises when a public official has private interests that may cause him/her to incur in an actual conflict of interest in the future.

Source: Fuentes: *Código de Ética y Transparencia de la Industria Farmacéutica*, 2013; *Ley General de Responsabilidades Administrativas* (Article 3). Transparency International Glossary; retrieved from:
https://www.transparency.org/glossary
Unidad Especializada en Ética y Prevención de Conflictos de Interés, Prevención e Identificación de Conflictos de Interés; retrieved from:
https://www.gob.mx/cms/uploads/attachment/file/128403/identificacio_n_conflicto_intere_s_8ago16.pdf

31. CONTRACT

A written, dated, and signed agreement between two or more parties that establishes its object, the provisions on the delegation and distribution of obligations and tasks, as well as economic issues and its term. A protocol can serve as the basis for a contract.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

32. CONTRACT RESEARCH ORGANIZATION (CRO)

A Contract Research Organization (CRO) is an organization, or a company (commercial, academic, or other) contracted by a sponsor to provide assistance to the pharmaceutical, biotechnology, and medical device industries, with the provision of outsourced professional services, according to the terms of a contract.

CRO support foundations, research institutions, universities, and governmental organizations (e.g., the US National Institutes of Health, as part of the NIH; and the European Medicines Agency, EMA, etc.) in the development of clinical research.

Specifically, CRO can provide services in biopharmaceutical development, biologic trial development, commercialization, preclinical research, protocol design, clinical search, clinical trial management, participant selection and research monitoring, pharmacovigilance, and evaluation of reports and preparation of materials for submission to the regulatory authority, among others.

The Code of Federal Regulations, the US Food and Drug Administration (FDA) defines a CRO as a "[...] legal entity that assumes, as an independent contractor to a sponsor, one or more of the sponsor's obligations, such as designing a protocol, selecting, or monitoring studies, evaluating reports, and preparing materials for submission to authorities".

CROs can range from large, full-service international organizations to small groups in specialized niches.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017; ACROM website, http://www.acrom.org.mx/

33. CONTROLLED CLINICAL STUDY

Study in which the therapeutic outcome of a treatment is compared with that of a reference treatment or placebo. The individuals who receive this reference treatment or placebo are part of the control group or witness group.

Source: *Glosario de Términos Farmacológicos*, portal INFOMED del Centro Nacional de Información de Ciencias Médicas.

34. CORRUPTION

Abuse of power for personal gain. It can be classified into grand, petty, and political corruption, depending on the amount of funds are lost and the sector in which it occurs.

This conduct deviates from the regulated public duties, due to a private nature consideration to obtain undue pecuniary or rank benefits, or the violation of rules due to considerations of a private nature.

It refers to the execution of actions that contradict the legal order of the State and that deviate from the established normative criteria.

In organizations, especially in public organizations, it consists in the practice of using their duties and means for the economic or other benefit of their managers.

Source: *Propuesta de Glosario Hacia la Integridad*, PNUD, USAID, SFP y UNODC; *Diccionario de la Lengua Española*, Real Academia de la Lengua Española; Transparency International Glossary, retrieved from:
https://www.transparency.org/glossary

35. CORRUPTION RISK

The possibility that, by action or omission, through the improper use of power, resources or information, the interests of an entity, and consequently of the State, may be harmed to obtain a private benefit.

The corruption risks materialize in reputational, legal, operational and contagion, among others.

Source: Proposed Glossary Towards Integrity, UNDP, USAID, SFP and UNODC; and, Anti-Corruption Guide for Companies, based on the UNODC Anti-Corruption Statute, Bogotá Chamber of Commerce, Colombian Ministry of Justice, British Embassy in Bogotá, Responsible and Safe Business, 2014.

36. COUNCIL OF ETHICS AND TRANSPARENCY OF THE PHARMACEUTICAL INDUSTRY

Body created in March 2005 by the National Chamber of the Pharmaceutical Industry (CANIFARMA) to establish integrity, ethics, and transparency as basic lines of action and development of the pharmaceutical companies that comprise it. To strengthen the development of a socially responsible and ethically sustainable pharmaceutical industry and thus, contribute to society´s welfare of and to the improvement in the care, health and safety of patients. CETIFARMA has technical and administrative autonomy and is governed by its Internal Regulations.

Source: *Código de Ética y Transparencia de la Industria Farmacéutica Establecida en México*, 2013; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

37. COURTESY

A show of cordiality and empathy towards a healthcare professional in the face of an occasional event that that impacts his or her personal life, such as the birth or death of a family member, marriage, professional promotion, Christmas, New Year's Eve or any other similar event. Courtesies are actions considered incompatible with the Code of Ethics, Transparency and Good Practices issued by CETIFARMA, as well as with other deontological instruments issued by it.

Source: *Código de Interacción con los Profesionales del Cuidado de la Salud de la Asociación Mexicana de Industrias Innovadoras de Dispositivos Médicos*, 2017 (with adaptations).

38. DECLARATION OF HELSINKI

Adopted in 1964 by the World Medical Association (WMA); it has been amended six times (most recently in October 2008). It self-regulates the medical community regarding research.

It recognizes that for the advancement of medical knowledge, science, diagnosis and treatment of disease, experimentation on human subjects is often required. However, it warns that this must be carried out with adherence to ethical principles that protect subjects participating in scientific studies, including *respect* (the right to make decisions about the risks and benefits of participating or not in a medical research study); *informed consent* (the acceptance to participate in research, without pressure and with the option to withdraw when one decides), and *welfare* (which must always be above the interests of science and society).

Source: *Código de Ética y Transparencia de la Industria Farmacéutica Establecida en México*, 2013; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

39. DEONTOLOGY

Set of moral standards, principles and rules that guide the conducts, behaviors, or attitudes of a person or a collective of professionals, to ensure an ethical and honest practice, as well as honorable and upright conducts of all those who subscribe to them.

Source: *Código de Ética y Transparencia de la Industria Farmacéutica Establecida en México*, 2013; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

40. DISTRIBUTOR

Individual or legal entity that packages or stores and distributes, and if applicable imports, goods for commercialization. It has an operating license or sanitary license depending on the type of products it sells.

Source: *Glosario de Insumos para la Salud*, COFEPRIS; retrieved from. http://www.cofepris.gob.mx/AS/Documents/Comercio%20Internacional/GLOSARIO%20INSUMOS.pdf

41. DONATION

Grants of money, products, goods or services by healthcare supply companies to medical associations or societies, patient associations, research centers, clinics and/or hospitals, charitable and private assistance institutions or civil society organizations, which are properly accredited by the Ministry of Finance and Public Credit (Secretaría de Hacienda y Crédito Público, SHCP) as non-profit companies and registered as authorized donors, for the purpose of supporting social and altruistic projects and/or participating in natural disasters or sanitary emergency situations decreed by the authority.

It is forbidden to make any donation with the purpose of influencing the decisions of physicians, healthcare professionals and/or public servants to favor the business of the donor company.

Source: *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

42. DRUG

Any substance or mixture of substances of natural or synthetic origin that has therapeutic, preventive, or rehabilitative effect, which is presented in pharmaceutical form and is identified as such by its pharmacological activity, physical, chemical, and biological characteristics.

When a product contains nutrients, it will be considered as a medicine, if the preparation contains individually or associated: vitamins, minerals, electrolytes, amino acids, or fatty acids, in concentrations higher than those of natural foods and is also presented in some defined pharmaceutical form and the indication for use contemplates therapeutic, preventive, or rehabilitative effects.

Source: *Ley General de Salud*, Article 221 (DOF 22-06-2017); Glosario *de Insumos para la Salud*, COFEPRIS; retrieved from: http://www.cofepris.gob.mx/AS/Documents/Comercio%20Internacional/GLOSARIO%20INSUMOS.pdf

43. EDUCATIONAL SUPPORT / SPONSORSHIP

Economic or in-kind contribution that healthcare companies grant to healthcare professionals for the exclusive purpose of updating, increasing, or improving their medical, pharmacological, or scientific knowledge in medical/scientific research advances, to improve the quality of life of patients. These supports will in no way be used to influence the decisions of physicians or healthcare professionals, or to favor decision making at the moment of medical prescription of a patient.

Source: adaptation of the definition of 'scholarship' contained in the Glossary of the *Código de Buenas Prácticas de Promoción, Códigos de la Industria Farmacéutica Establecida en México*, 2013.

44. ETHICAL BUSINESS LEADERSHIP

Stimulate the development of healthcare companies, whose business practices are based on ethical sustainability, that lead by example and congruence, in the pursuit of excellence and continuous improvement. Companies that include integrity in the operation of their legitimate business to provide high quality products and services, for the care and safety of patients and the benefit health in general.

Its objective is to generate trust among the members of the healthcare companies, the third parties involved, but above all among patients. As well as to act as a sector that promotes change with integrity in the social culture of responsibility and human improvement.

Source: *Código de Ética y Transparencia de la Industria Farmacéutica establecida en México*, 2013 (with adaptations).

45. ETHICAL CULTURE

Set of values, principles, beliefs, and norms that are fostered within a company to promote ethical conduct, behaviors and attitudes that provide identity and a sense of belonging to its members.

Source: CETIFARMA.

46. ETHICAL SUSTAINABILITY

Assumes integrity and ethics as guiding standards of a legitimate business and of each of its activities and interactions, based on a cultural platform of principles and values that foster habits of increasing compliance.

Source: CETIFARMA.

47. ETHICALLY SUSTAINABLE COMPANY

A company that assumes ethical principles and values as a form of its daily organizational behavior, that promotes a culture in line with it and practices congruence between what is thought, what is said and what is done. Based on the example of the top management, and its projection to the rest of the organization's structure and towards its partners and the third parties involved.

Source: CETIFARMA.

48. ETHICALLY SUSTAINABLE DEVELOPMENT

Process of growth and consolidation of a company, based on integrity and ethics as guiding principles of the legitimate business, its activities, and interactions, on the basis of a cultural platform of principles and values that foster compliance habits for the benefit of improved patient and infant care, safety, and health.

Source: CETIFARMA.

49. ETHICS

Set of integrity standards on conduct and behavior, applicable to the realm of government, businesses, and society; based on core values and fundamental norms that guide decisions, choices and actions.

Source: *Propuesta de Glosario Hacia la Integridad*, PNUD, USAID, SFP y UNODC; Transparency International Glossary.

50. EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS (EFPIA)

The European Federation of Pharmaceutical Industries and Associations (EFPIA) is a body representing the pharmaceutical industry operating in Europe. It has members of 33 national associations and 40 leading pharmaceutical companies. EFPIA is the voice on the European Union stage of 1,900 companies committed to research, development and providing new medicines to patients to improve their health and quality of life.

The 33 national associations correspond to the following countries: Austria, Belgium, Bulgaria, Cyprus, Croatia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Norway, the Netherlands, Poland, Portugal, United Kingdom, Czech Republic, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, and Ukraine.

Source: *Código de Ética y Transparencia de la Industria Farmacéutica Establecida en Méxic*o, 2013; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013; EFPIA website, https://efpia.eu/#/

51. EVENTS

Promotional, scientific-professional meetings, congresses, conferences, symposiums, workshops, seminars, training courses, refresher programs, or any other similar activity (including, but not limited to, meetings of and with experts, visits to manufacturing plants and research facilities, as well as meetings of researchers related to the performance of clinical trials and post-authorization studies), organized by Adherents directly or via third parties, and those for which they provide support for their realization.

Regardless of their modality they shall have as their purpose scientific exchange, medical education and/or detailed information on drugs, medical devices, or other healthcare supplies.

Source: *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013 (with adaptations); *Código de Buenas Prácticas de la Industria Farmacéutica* de Farmaindustria, España, 2016; *Disclosure Code of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations*, EFPIA, 2014.

52. FAVORABLE OPINION (IN RELATION TO ETHICS COMMITTEES)

A favorable report issued by the Research Ethics Committee regarding a clinical trial that has been reviewed and can be conducted at an institution in accordance with the standards established by the CEI, by the institution itself, by good clinical practice (GCP), and by the relevant legal requirements.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

53. FEDERAL COMMISSION FOR PROTECTION AGAINST HEALTH RISKS

Deconcentrated body of the Ministry of Health and a sanitary authority with administrative, technical and operational autonomy, whose mission is to regulate, control and prevent sanitary risks. to protect the population. The hazards include health risks caused by the use and consumption of goods and services, healthcare supplies, as well as by their exposure to environmental and occupational factors, the occurrence of sanitary emergencies and the provision of healthcare services, through the

Through COFEPRIS, the Ministry of Health exercises the powers of regulation, control and sanitary promotion established in Mexico's General Health Law (Ley General de Salud).

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017; COFEPRIS website (with adaptations).

54. FEDERAL COPYRIGHT LAW

A Law that regulates Article 28 of the Mexican Constitution; its objective is to safeguard and promote the Nation's cultural heritage; the protection of the rights of authors, performing artists, as well as publishers, producers and broadcasting organizations, in relation to their literary or

artistic works in all their manifestations, their interpretations or executions, their editions, their phonograms or videography, their broadcasts, as well as other intellectual property rights.

Source: *Código de Ética y Transparencia de la Industria Farmacéutica establecida en México*, 2013; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

55. FEDERAL LAW FOR THE PROTECTION OF PERSONAL DATA IN POSSESSION OF INDIVIDUALS

Its purpose is to protect personal data in the possession of individuals, with the objective of regulating their legitimate, controlled and informed treatment, to guarantee their privacy and the right to informational self-determination of individuals. The subjects regulated by this Law are individuals, whether private individuals or legal entities that handle the personal data, with the exception of: I) Loan information companies regulated by the Law to Regulate Credit Information Companies and other applicable provisions and, II) Persons who carry out the collection and storage of personal data, which is for exclusively personal use, and without purposes of disclosure or commercial use.

Source: *Código de Ética y Transparencia de la Industria Farmacéutica establecida en México*, 2013; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

56. FEDERAL LAW OF ECONOMIC COMPETITION

A Law that regulates Article 28 of the Mexican Constitution in matters of economic competition, monopolies, and free competition. Its purpose is to protect the process of competition and free participation with the prevention and elimination of monopolies, monopolistic practices, and other restrictions to the efficient operation of goods and services markets.

Source: *Código de Ética y Transparencia de la Industria Farmacéutica establecida en México*, 2013; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

57. FEDERALWIDE ASSURANCE FOR THE PROTECTION OF HUMAN SUBJECTS (FWA)

A permit granted by the U.S. federal government to approve a research site or institution for the performance of clinical trials.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

58. FOOD AND DRUG ADMINISTRATION (FDA)

Food and Drug Administration of the United States Government.

https://www.fda.gov

59. GENERAL HEALTH LAW

Law that regulates the right to health protection, that every person has in the terms of Article 4 of the Mexican Constitution. It establishes the bases and modalities of access to health services and the concurrence of the Federation and the local entities in matters of general health.

It states that the right to health protection has the following purposes: I) The physical and mental well-being of the person, to contribute to the full exercise of his capacities; II) The prolongation and improvement of the quality of human life; III) The protection and enhancement of values that contribute to the creation, conservation and enjoyment of health conditions that contribute to social development; IV) The extension of solidary and responsible attitudes of the population in the preservation, conservation, improvement and restoration of health; V) The enjoyment of health and social assistance services that effectively and timely satisfy the needs of the population; VI) The knowledge required for the adequate use of health services, and VII) The proportion of teaching, scientific and technological health research.

Source: *Código de Ética y Transparencia de la Industria Farmacéutica establecida en México*, 2013; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

60. GENERAL LAW OF ADMINISTRATIVE RESPONSIBILITIES

Law that derived from Mexico's National Anticorruption System created in 2016, in accordance with the provisions of Article 113 of the Mexican Constitution. Its purpose is to establish the basis of coordination between the Federal Government, the states, municipalities, and boroughs of Mexico City, for their proper operation, and the identification of administrative misconducts and acts of corruption by competent authorities to prevent, investigate and punish them.

It determines the administrative responsibilities of the subjects of this Law, (federal, state and municipal public servants, individuals and corporations linked to serious administrative misconduct of public servants) and the penalties that apply.

It establishes that companies are required to have an integrity policy and program, which must have at least seven elements: organization and procedures manual; code of conduct properly published and socialized; adequate and effective control, surveillance and auditing systems that evaluate compliance with integrity standards; adequate denunciation systems; adequate training and education systems and processes in integrity issues; human resources policies tending to avoid the incorporation of persons who may generate a risk to the integrity of the corporation; and, mechanisms that ensure transparency and publicity of its interests.

Source: *Ley General de Responsabilidades Administrativas*.

61. GENERIC

Pharmaceutical specialty with the same drug or active substance and pharmaceutical form, with the same concentration or potency, which uses the same method of administration. For which the required regulatory tests, have proven that its pharmacopoeia specifications, dissolution profiles or its availability or other parameters, as the case may be, are equivalent to those of the reference medicine and/or drug.

Source: *Glosario de Insumos para la Salud*, COFEPRIS; retrieved from: http://www.cofepris.gob.mx/AS/Documents/Comercio%20Internacional/GLOSARIO%20INSUMOS.pdf

62. GIFT SAMPLE

A free distribution sample of a medicine which complies with the requirements and specifications for the retail originals but contains a smaller number of units as specified in fractions V and VI of Article 226 of the General Health Law. Its purpose is to publicize its use among the public.

Source: Norma Oficial Mexicana NOM-072-SSA1-2012, *Etiquetado de medicamentos y de remedios herbolarios* (with adaptations); *Glosario de Insumos para la Salud*, COFEPRIS; retrieved from: http://www.cofepris.gob.mx/AS/Documents/Comercio%20Internacional/GLOSARIO%20INSUMOS.pdf

63. GOOD CLINICAL PRACTICE (GCP)

Standards for the design, conduction, monitoring, auditing, registration, analysis, and reporting of a clinical trial. These standards ensure that the data and results obtained are accurate and credible, and that the rights, integrity, and confidentiality of the trial subjects have been protected.

Source: International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), *Harmonized Tripartite Guideline for Good Clinical Practice E6 (R1)*, 1996. Retrieved from: https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

64. HEALTHCARE INSTITUTION

Also referred to as healthcare services provider institutions. They include all public and private institutions that, in accordance with applicable laws, provide healthcare services, in the terms defined by the General Health Law -Title Two, National Health System, Chapter I, Common Provisions, Article 5. Among other denominations, healthcare institutions may refer to as clinics, hospitals, teaching hospitals, institutes, specialty centers. Foundations, associations, schools, medical academies, or universities can also be considered as health institutions, as long as they provide healthcare services.

Source: CETIFARMA (2021).

65. HEALTHCARE ORGANIZATION (HCO)

Any form of organization adopted by healthcare professionals for the practice, promotion and/or representation of their profession. Healthcare professional organizations are usually known as a medical society, scientific society, association, college or council, among other names. They may or may not be part of a health care institution. Internationally, these organizations are known as Health Care Organizations (HCO).

Source: CETIFARMA (2021), based on *Código de Buenas Prácticas de la Federación Europea de Industrias y Asociaciones Farmacéuticas*, 2019; *Código de Buenas Prácticas de la Industria Farmacéutica, Farmaindustria*, España, 2020.

66. HEALTHCARE PROFESSIONAL (HCP)

All persons who carry out activities whose main purpose is to promote health. Specifically, this refers to any member of the medical, homeopathic, dental, pharmaceutical, nursing, and veterinary

professions, authorized to prescribe, recommend, or administer a pharmaceutical product. It also includes persons who because of their activities or responsibilities participate or have the capacity to influence the cycle of prescription, acquisition, distribution, dispensation and/or administration of any pharmaceutical product, medical device. or healthcare supplies Internationally they are referred to as a Health Care Professionals (HCP).

Source: CETIFARMA (2021), based on Mexico's General Health Law; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*; WHO (World Health Organization) website:
http://www.who.int/topics/health_workforce/es/OMS

67. HEALTHCARE PROFESSIONALS (HCP) WITH FACULTY TO PRESCRIBE

Healthcare Professionals must have a professional license issued by the competent educational authorities., They include physicians, homeopaths, dental surgeons, veterinarians, and licensed nurses. Nurses may prescribe when the services of a physician are not available and only medicines from the basic list determined by Ministry of Health (Secretaría de Salud).

The interns in social service, of any of the above-mentioned careers and nurses will be able to prescribe adapting to the specifications determined by the Ministry of Health (Secretaría de Salud).

Source: *Ley General de Salud*, Article 28bis (DOF 22-06-2017).

68. HEALTHCARE SUPPLIES

Healthcare supplies include medicines, psychotropic substances, narcotics, and the raw materials and additives involved in their manufacture. Medical equipment, prostheses, orthoses, functional aids, diagnostic agents, supplies for dental use, surgical and healing material and hygienic products, the latter under the terms of section VI of Article 262 of the General Health Law (Ley General de Salud).

Source: *Glosario de Insumos para la Salud*, COFEPRIS;
http://www.cofepris.gob.mx/AS/Documents/Comercio%20Internacional/GLOSARIO%20INSUMOS.pdf

69. HEALTHCARE SUPPLY COMPANIES (HSC)

Biopharmaceutical and related companies and their organizations.

Biopharmaceutical companies are those affiliated to the National Chamber of the Pharmaceutical Industry. The affiliation can be individual or via the organizations of local and multinational R&D companies. The organizations included are: The Mexican Association of Pharmaceutical Research Industries, the organization of local companies: the National Association of Drug Manufacturers, and the medical device manufacturers.

Related companies are those that have adhered to the biopharmaceutical industry's self-regulation system, its Codes of Ethics and CETIFARMA. They include, those affiliated to the Infant Formula Manufacturers Commission of the National Chamber of Milk Manufacturers; to the Mexican Alliance of Contract Research Organizations; and those other companies or organizations that in the future adhere to the Codes of Ethics and CETIFARMA, including those associated to continuing medical education.

Source: Internal Regulations of CETIFARMA.

70. HOSPITALITIES

Supports provided by healthcare companies to healthcare professionals that participate in educational or scientific events. These may include transportation from the place of origin to the destination and vice versa, lodging, food and, if applicable, registration fees. These supports are only granted to healthcare professionals, and in no case to their companions.

Hospitalities will not be provided for days prior or after the event, nor will they include the sponsorship or organization of entertainment activities (sports, recreational, etc.).

Source: *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

71. IND (INVESTIGATIONAL NEW DRUG)

Investigational New Drug Application.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

72. INDEPENDENT DATA MONITORING COMMITTEE

This Committee may be established by the sponsor to evaluate, at specified time intervals, the progress of a clinical trial, safety data and critical efficacy variables. As a result, the CIMD will recommend to continue, modify or discontinue the trial.

These committees are also known as: Data and Safety Monitoring Board, Monitoring Committee, or Data Monitoring Committee.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

73. INDUSTRIAL PROPERTY LAW

Its purpose is to I) establish a system to encourage the permanent improvement of the country´s industrial and commercial processes and products; II) promote and encourage innovations of industrial application, technical improvements and the dissemination of technological knowledge to the productive sectors III) in accordance with the interests of consumers, promote and encourage the improvement of the quality of the goods and services in industry and commerce;; IV) favor creativity in the design and presentation of new and useful products; V) protect industrial property with regulations and by awarding patents for inventions, utility model registrations, industrial designs, trademarks, and commercial adds; publication of commercial names; declaration to protect the Denominations of Origin or Appellations of Origin, and regulation of industrial secrets;

VI) prevent acts that jeopardize industrial property or that constitute unfair competition related to it, and establish the corresponding sanctions and penalties; and VII) establish legal security conditions for the parties involved in the operation of franchises, as well as guarantees of a non-discriminatory treatment for all franchisees of the same franchisor.

Source: *Código de Ética y Transparencia de la Industria Farmacéutica establecida en México*, 2013; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

74. INFORMATIONAL MATERIAL

Refers to any material prepared by Adherents, whether written, electronic, audio, or visual, that provides information to healthcare professionals on relevant topics related to the products or services they provide.

Source: *Código de Ética, Transparencia y Buenas Prácticas de Comercialización y Publicidad de los Sucedáneos de la Leche Materna o Humana para Lactantes*, 2016.

75. INFORMED ASSENT

Affirmative agreement regarding the decision to participate in clinical research by a minor or a non-competent person.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

76. INFORMED CONSENT (IC)

According to the Clinical Practice Guide (NOM-012-SSA3-2012) of the National Bioethics Commission (COMISIÓN NACIONAL DE BIOÉTICA, CONBIOÉTICA), the term "[…] informed consent letter in research is the written document, signed by the principal researcher, the patient or his/her relative, guardian or legal representative and two witnesses, with which the research subject accepts to voluntarily participate in a research and to undergo an experimental procedure, once he/she has received sufficient, timely, clear and truthful information on the expected risks and benefits. The names of the witnesses their addresses and the relationship they have with the research subject must be registered".

Source: *Guía de prácticas clínicas de la CONBIOÉTICA // NOM-012-SSA3-2012* "Que establece los criterios para la ejecución de proyectos de investigación para la salud en seres humanos", numeral 4.3.

77. INTEGRITY

Compliance with the highest standards of ethical conduct, so that these are reflected in transparency, honesty and congruence between the commitments assumed by the companies and their members, and what they affirm and, above all, what they demonstrate in their practices and behaviors.

Source: *Propuesta de Glosario Hacia la Integridad*, PNUD, USAID, SFP y UNODC; Glosario de Transparencia Internacional (with adaptations).

78. INTERNATIONAL COUNCIL ON HARMONIZATION OF TECHNICAL REQUIREMENTS FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE (ICH)

Founded in 1990, it is a joint project of the European, North American, and Japanese regulatory authorities and pharmaceutical industry (regions where most new drugs are developed), to harmonize the technical and scientific requirements for medicine registration. In doing so, it aims to rationalize the use of animals, humans, and materials in the development of new medicines, as well as to reduce the time required for the use of the new medicines.

Source: *Código de Ética y Transparencia de la Industria Farmacéutica establecida en México*, 2013; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

79. INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS ASSOCIATION (IFPMA)

The International Federation of Pharmaceutical Manufacturers Association represents research-based pharmaceutical companies, and regional and national associations worldwide. It brings together industry and the broader healthcare community to foster innovation, promote resilient regulatory systems and high-quality standards, maintain ethical practices, and advocate for sustainable healthcare policies to meet global needs. It has three types of membership: full, associate and affiliate. Its headquarters are in Geneva, Switzerland.

Source: IFPMA website; https://www.ifpma.org/.

80. INTERRELATIONSHIP

Activities carried out, organized, or sponsored by pharmaceutical, medical device or other healthcare supply companies, research contract organization or organizations under their control - subsidiaries, foundations, associations, institutes, agencies, third-party suppliers, etc.- from which collaborations, support and/or consideration of any kind can derive, directly or indirectly, in favor of a third party.

Source: *Código de Buenas Prácticas de la Industria Farmacéutica*, Farmaindustria, España, 2016.

81. INVESTIGATIONAL MEDICINAL PRODUCT

Pharmaceutical form of an active substance or placebo being investigated or used as a reference in a clinical trial, including medicinal products with marketing authorization when used or combined (in the formulation or packaging) in a manner different from the one authorized, or when used to treat an unauthorized indication or to obtain further information about an authorized use.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

82. INVESTIGATOR'S MANUAL (MI)

Collection of clinical and non-clinical data on the investigational drug; relevant to the study of said drug in humans.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

83. LAW ON PUBLIC SECTOR ACQUISITIONS, LEASING AND SERVICES OF THE PUBLIC SECTOR

Its purpose is to regulate the application of Article 134 of Mexico's Constitution in topics of acquisitions, leasing of movable goods and provision of services of any nature carried out by: I) The administrative units of the Presidency of the Republic II) The Ministries, and the Legal Counsel of the Federal Executive; III) The Office of the Attorney General of the Republic; IV) Decentralized agencies; V) Companies with majority state participation and trusts in which the trustor is the federal government or a parastatal entity, and VI) The federal entities, municipalities

and public entities of one or the other, with total or partial charge to federal resources, pursuant to the agreements with the Federal Executive.

Source: *Código de Ética y Transparencia de la Industria Farmacéutica establecida en México*, 2013; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

84. LOAN OF MEDICAL TECHNOLOGICAL EQUIPMENT

Contract by which a healthcare supply company allows the temporary use of medical-technological equipment free of charge for research purposes or for a priority health program. These loans can be made to research centers, clinics and/or hospitals, charities, or legally constituted private assistance institutions.

The contract must clearly describe the medical-technological equipment being loaned, the purposes, and period of the loan, the terms of use of the equipment and the conditions under which it must be returned.

Source: CETIFARMA; *Diccionario de la Lengua Española*, Real Academia de la Lengua Española (*comodato*); Código Civil Federal, Título Séptimo, Article 2497 (DOF 09-03-2018).

85. MEDICAL DEVICES AND AUXILIARY HEALTHCARE PRODUCTS

They refer to a substance, mixture of substances, material, apparatus, or instrument (including the software necessary for its appropriate use or application), which are used alone or in combination for diagnosis, monitoring or prevention of diseases in humans or as auxiliaries in the treatment of disease and disability. These devices and products are also used in the replacement, correction, restoration or modification of human anatomy or physiological processes. Medical devices include products in the following categories: medical equipment, prostheses, orthoses, functional aids, diagnostic agents, supplies for dental use, surgical and healing materials, and hygienic products.

Source: *Glosario de Insumos para la Salud*, COFEPRIS; retrieved from: http://www.cofepris.gob.mx/AS/Documents/Comercio%20Internacional/GLOSARIO%20INSUMOS.pdf

86. MEDICAL EQUIPMENT

Apparatus, accessories, and instruments for specific use, intended for medical, surgical care or procedures for exploration, diagnosis, treatment, and rehabilitation of patients, as well as those for carrying out biomedical research activities.

Source: *Ley General de Salud*, Article 262, fraction I (DOF 22-06-2017); *Glosario de Insumos para la Salud*, COFEPRIS.

87. MEDICAL SAMPLE

Presentation of a medicinal product with the requirements and specifications of the original for sale to the public, containing a smaller number of units, in accordance with the provisions of the General Health Law (Ley General de Salud) and the corresponding regulations. Samples are classified as section IV1/ of Article 226 of the above-mentioned Law and companies provide them free of charge to healthcare professionals.

The companies are responsible of the follow-up of the medical sample, from its production to its distribution to institutions or healthcare professionals. The distribution to hospital centers will be carried out in accordance with the procedures determined by each of them.

Source: *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.
Acuerdo que establece los lineamientos que deberán observarse en los establecimientos públicos que presten servicios de atención médica para regular su relación con los fabricantes y distribuidores de medicamentos y otros insumos para la salud (DOF 12-08-2008).
Norma Oficial Mexicana NOM-072-SSA1-2012, *Etiquetado de medicamentos y de remedios herbolarios* (Apartado 4.1 Definiciones, numeral 4.1.31); retrieved from:
http://www.cofepris.gob.mx/MJ/Documents/Normas/nom-072ssa1211112.pdf

88. MEDICINE

Any natural, synthetic, or biotechnological substance that has pharmacological activity and that is identified by its physical, chemical properties or biological actions, which is not presented in a pharmaceutical form and that meets the conditions to be used as a medicine or ingredient of a medicine.

Source: *Glosario de Insumos para la Salud*, COFEPRIS; retrieved from:
http://www.cofepris.gob.mx/AS/Documents/Comercio%20Internacional/GLOSARIO%20INSUMOS.pdf

89. MEDICINE FOR HUMAN USE

Any substance or combination of substances that are presented as having properties for the treatment or prevention of human diseases; that may be used in humans or administered to humans to restore, correct, or modify physiological functions by exerting a pharmacological, immunological, or metabolic action, or for establishing a medical diagnosis.

Source: *Código de Buenas Prácticas de la Industria Farmacéutica*, Farmaindustria, España, 2016.

90. MEDICATION SAFETY

The characteristic of a drug of being used with a very small probability of causing unjustifiable toxic effects. Medication safety is a relative trait and in clinical pharmacology its measurement is problematic, due to the lack of operational definitions, as well as for ethical and legal reasons. However, measurements such as the range of therapeutic concentrations allow, in some cases, a safety comparison in the use of certain drugs.

There are other safety indicators established in laboratory animals that offer some utility, especially the determined safety factor. It is worth noting that there is a distinction between drug safety and toxicity, considering that toxicity is an intrinsic trait of the drug, while safety is a function of the drug and the conditions of use. The term harmless should not be used as a synonym for safety, since all drugs have the capacity to cause some harm.

Source: *Glosario de Términos Farmacológicos*, portal INFOMED del Centro Nacional de Información de Ciencias Médicas.

91. MEXICAN ASSOCIATION OF PHARMACEUTICAL RESEARCH INDUSTRIES

Founded on March 23, 1950, as the Association of Manufacturers and Importers of Medicinal Products (Asociación de Productores e Importadores de Artículos Medicinales). In 1994 it changed its name to Mexican Association of Pharmaceutical Research Industries. It congregates 60 Mexican and multinational laboratories dedicated to the development of innovative medicines that improve people's quality of life.

Source: AMIIF website; retrieved from:
http://amiif.org/acerca-de-amiif/nosotros/

92. MISCONDUCT BY PRIVATE PARTIES

Behavior of individuals or legal entities (bribery; unlawful participation in administrative proceedings; influence peddling; use of false information; collusion; improper use of public resources; and, improper hiring of former public servants) that are linked to serious administrative misconducts referred to in Chapters III and IV of Title Three of the General Law of Administrative Responsibilities, in terms of the mentioned Law sanctions correspond to the Court.

Source: *Ley General de Responsabilidades Administrativas*, Articles 3, and 66 to 72.

93. MONITORING

A continuous and systematic procedure to verify the efficiency and effectiveness of a policy, process, or procedure; - also used to validate compliance with provisions, as those established in the Code (CIETEMIS Achievements and weaknesses are identified in order to recommend preventive and corrective measures, as the case may be, to optimize the expected achievements.

Monitoring provides elements from practice to rectify the operation and provides feedback to adjust or enrich the planning, programming, and execution phases.

Source: *Manual de Políticas de Autocontrol y Gestión del Riesgo de Lavado de Activos y Financiación del Terrorismo*, Deloitte (with adaptations); retrieved from:
https://www2.deloitte.com/co/es/pages/about-deloitte/articles/Manual_SAGRLAFT_Deloitte.html

94. MONITORIZATION

The act of overseeing the development of a clinical trial and ensuring that it is carried out, archived, and published in accordance with the protocol, the Standard Operating Procedures, Good Clinical Practice (GCP) guidelines, as well as current regulations.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

95. MULTICENTER TRIAL

Clinical research conducted in more than one research site and carried out by more than one researcher according to a single protocol.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

96. NATIONAL ASSOCIATION OF MEDICINES MANUFACTURERS

Founded in May 1945, it congregates 26 national pharmaceutical laboratories. Their objective is to offer, to physicians and patients, locally manufactured medicines, with state-of-the-art technology and in accordance with the strictest international quality parameters.

Source: ANAFAM website; retrieved from:
http://anafam.org.mx/nosotros/.

97. NATIONAL CENTER OF PHARMACOVIGILANCE

Agency that depends of the Federal Commission for Protection against Sanitary Risks, its mission is to monitor the safety and efficiency of medicines for human use that are marketed in the country. Its main purpose is to protect and inform healthcare professionals and the public of possible risks of medicines use. within the health sector.

It has the authority to determine whether there is a causal association relation between the administration of a medicine and the suspicion of an adverse reaction.

Source: *Código de Ética y Transparencia de la Industria Farmacéutica establecida en México*, 2013; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013; Centro Nacional de Farmacovigilancia (CNFV); retrieved from:
http://www.controlsanitario.gob.ec/cnfv/.

98. NATIONAL CHAMBER OF THE PHARMACEUTICAL INDUSTRY

Civil association established in 1946 under the Law of Chambers and Business Organizations. It groups national and global companies established in Mexico and exercises their institutional representation before the national authorities. It has 186 members in the specialties of Medicines for Human Use, for Veterinary Use, and Medical Devices.

Source: CANIFARMA website (with adaptations); retrieved from:
https://www.canifarma.org.mx

99. NATIONAL HEALTH SYSTEM

Federal and local agencies and entities of the public administration, individuals or legal persons from the social and private sectors that provide healthcare services, as well as the coordinating mechanisms for activities, whose objective to comply with the right to health protection.

Source: *Ley General de Salud*, Article 5, (DOF 24-01-2020).

100. NEW DRUG APPLICATION (NDA)

Collection of all clinical, pre-clinical, pharmacological, pharmacokinetic, and stability information necessary for an FDA approval, for the marketing of a new drug.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

101. NEW MOLECULE

A substance of natural or synthetic origin that is the active ingredient of a drug, not previously used in the country, and whose efficacy, safety, and therapeutic purposes have not been fully documented in the scientific literature.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

102. NEW MOLECULES COMMITTEE

Consultation body that is part of the COFEPRIS, whose aim is to support the analysis and evaluation of the information on safety, efficacy, and quality of new health supplies; of new indications for registration purposes, or of products that due to their traits require evaluation by groups of specialists.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

103. NON-PRESCRIPTION DRUG (Over the Counter Drugs)

Medicines that can be dispensed without a prescription and are available in some countries in self-service in pharmacies or other outlets. Some non-prescription medicines may be advertised to the public.

Source: *Glossary of Pharmaceutical Terms*, Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (World Health Organization).

104. NÜREMBERG CODE

Published on 20 August 1947 following the Nuremberg Trial, in which several doctors, as well as part of the Nazi hierarchy, were convicted of atrocious experiments and very serious violations of human rights. It is considered the most important document in the history of ethics in medical research because it establishes the duty of the "Informed Consent" from the patient. The Helsinki Declaration and various UN declarations are based on this Code.

Published on August 20, 1947, as a result of the Nuremberg Trial, in which several physicians were convicted, as well as the Nazi hierarchy, and condemned for atrocious experiments and gross violations of human rights. It is considered the most important document in the history of ethics in medical research since it establishes the obligation to request the patient's informed consent.

Source: *Código de Ética y Transparencia de la Industria Farmacéutica establecida en México*, 2013; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

105. OFFICE FOR HUMAN RESEARCH PROTECTION (OHRP)

U.S. federal agency that issues pronouncements and ensures compliance with regulatory guidelines by institutions conducting research.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

106. ORIGINAL PRODUCT

First version of a drug developed and patented by a pharmaceutical company, which has exclusive rights to market the product for 20 years. An original product has a unique trade name for marketing purposes, also called a "brand name".

Source: *Glossary of Pharmaceutical Terms*, Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (World Health Organization).

107. OTHER HEALTHCARE SUPPLIES

Medical equipment, prostheses, orthoses, functional aids, diagnostic agents, etc., in accordance with the provisions of the General Health Law (Ley General de Salud).

Source: *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

108. PATIENT

Person who requires and seeks medical care.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

109. PATIENT ORGANIZATION

Non-profit association, that represents and supports the needs of patients, with diverse activities such as the care of patients, the search of therapeutic options, and contribution in the formulation of healthcare policies, information and health promotion programs.

Source: *Código de Buenas Prácticas de Interacción de la Industria Farmacéutica con Organizaciones de Pacientes*, 2013.

110. PATIENT SAFETY

A set of interrelated actions whose aim is to prevent and reduce adverse events, which produce harm to the patient as a result of the medical care he/she receives.

Source: *Glosario de términos aplicados a Seguridad del Paciente*, Secretaría de Salud; retrieved from: http://www.calidad.salud.gob.mx/site/calidad/docs/dsp-sp_00F.pdf

111. PHARMACEUTICAL PRODUCT

Any product with a valid sanitary registration, prescribed by a healthcare professional and that is used in the prevention, diagnosis, and treatment of human diseases.

Source: *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

112. PHARMACOVIGILANCE

Discipline and process of monitoring drug safety and adopting measures to reduce the risks and increase the benefits of medicines. It is a key function of public health.

It encompasses the science and activities related to the detection, evaluation, understanding, and prevention of adverse events, suspected adverse reactions, adverse reactions, or any other safety issues related to the use of medicines and vaccines.

Source: *Glossary of Pharmaceutical Terms*, Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (World Health Organization); retrieved from: http://www.cofepris.gob.mx/AZ/Paginas/Farmacovigilancia/Farmacovigilancia.aspx

113. PHASE I STUDY

One of the four phases of the clinical trials. This phase seeks to establish the effects of a new drug in humans, it is carried out in a small number of patients or in healthy volunteers, to determine the toxicity, absorption, distribution, and metabolism of the drug.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

114. PHASE II STUDY

Its purpose is to evaluate the safety and efficacy of a drug in individuals with a given pathology, for which the drug under study was developed.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

115. PHASE IIa STUDY

It is a Pilot Study designed to evaluate the efficacy (and safety) in a specific group of individuals with the pathology for which the drug was developed. Objectives may focus on dose-response, type of subject, dosing frequency, or other safety and efficacy characteristics.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

116. PHASE IIb STUDY

It's a Controlled study designed to evaluate the efficacy (and safety) in a specific group of individuals with the pathology for which the drug was designed. These clinical trials represent the most rigorous demonstration of the drug's efficacy.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

117. PHASE III STUDY

Pre-approval study, that is performed with a large number of individuals. In this phase, the study drug can be compared with the standard of care.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

118. PHASE IIIa STUDY

Study that is performed after the efficacy of the drug has been demonstrated, but prior to its submission to the regulatory authority. These studies are done with the populations in which the drug is intended to be used. They provide additional safety and efficacy information in a larger

population of individuals. These studies may also be used to evaluate the effectiveness of the drug in certain conditions of a population (e.g., renal insufficiency).

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

119. PHASE IIIb STUDY

Study that is carried out after the dossier is submitted to the authority; it can be used to evaluate additional aspects to the initial ones, for example, quality of life It may also be carried out in the period between submission to the regulatory authority and the approval for marketing.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

120. PHASE IV STUDY

Study that is conducted after the drug has been approved by the regulatory authority; it may compare the drug with another drug with similar effects, explore other populations or adverse events.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

121. PILOT STUDY

Study designed to obtain information, develop the logistics and identify management requirements to carry out subsequent studies. Although pilot trials are often unblinded, they may also be single-blinded or double-blinded and may include tight control on all appropriate variables. The term "pilot" refers to their purpose as a trial.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

122. PIVOT STUDY

Usually, a Phase II study presents information that the regulatory authority uses to decide whether to approve a drug. These studies tend to be well-controlled, randomized and, when possible double-blinded.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

123. PLACEBO

Inactive substance that resembles the one being studied; used as a control to evaluate the psychological effects that could be present in the effect of the drug.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

124. PRESCRIPTION

A written order (prescription) usually issued by a physician to a pharmacist for the provision of a drug or treatment to his or her patients. A prescription may contain several elements. The maximum number of items in a prescription is regulated in many countries.

Source: *Glossary of Pharmaceutical Terms*, Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (World Health Organization).

125. PRESCRIPTION DRUG

Products that must be dispensed on presentation of a prescription written by a physician.

A drug is subject to prescription when: it may represent a danger, directly or indirectly, even when used correctly, if used without medical control; it is frequently used and in an incorrect manner, and as a result may pose a direct or indirect danger to the human health or contain substances or preparations of the same drug, whose activity and/or reactions require investigation.

It is normally prescribed by a physician to be administered parenterally; the drug is dispensed on an outpatient basis, but its use may produce very serious adverse reactions, requiring a prescription issued by a specialist and special vigilance during treatment.

Source: *Glossary of Pharmaceutical Terms*, Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (World Health Organization).

126. PRIVATE CORRUPTION

Whoever directly or through an intermediary, promises, offers, receives, or grants to directors, administrators, employees or advisors of a company, association or foundation a gift or any unjustified (undue) benefit in order to favor him or a third party, to the disadvantage of the company, association or foundation.

Source: *Propuesta de Glosario Hacia la Integridad*, PNUD, USAID, SFP y UNODC.

127. PROACTIVITY

Ability of the management of the healthcare companies to have clarity in their vision and to advance in its construction. To anticipate and prepare for future and probable events, to enhance their development and generate conditions for improvement in patient care and safety. To achieve higher levels of trust in their products and services, due to their quality and effectiveness, as well as for the integrity in their actions and the transparency of their interactions.

Source: CETIFARMA.

128. PROMOTION

Any activity performed, organized, or sponsored by a healthcare company or by third parties under its control -subsidiaries, foundations, associations, institutes, agencies, etc.-, intended, directly or indirectly to promote the prescription, supply, recommendation, sale, acquisition or consumption of medicines, medical devices and other healthcare supplies, in compliance with the laws, regulations and standards applicable.

The promotion directed to the healthcare professionals will have the purpose of informing about healthcare products with a current sanitary registration, so that based on their professional ethics they may decide freely about their use.

Source: *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.
Código de Buenas Prácticas de la Industria Farmacéutica, Farmaindustria, España, 2016 (with adaptations).

129. PROMOTIONAL MATERIAL

Any printed, audiovisual, or digital material, whose purpose is to encourage proper prescription and use of medicines, medical devices, and other healthcare supplies, among health professionals.

The information authorized to be disseminated among the public, shall be limited to products registered and authorized by the Mexican authorities, adhering to the precepts of the General Health Law (Ley General de Salud), its regulations and standards. As well as to the provisions of the Code of Ethics and Transparency of Health Companies and the deontological instruments issued by CETIFARMA.

Source: *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

130. PUBLIC or CIVIL SERVANT

Any person who holds an employment, position, or commission in a federal, state, municipal or autonomous governmental institution. Thus, all persons working in a public healthcare institution are civil servants, regardless of the level, position or function performed.

Source: CETIFARMA.

131. QUALITY ASSURANCE

Procedures designed to ensure that studies are conducted in compliance with good clinical practice (GCP) guidelines and that the generated data are accurate.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

132. QUALITY CONTROL (QC)

Operational techniques and activities that are undertaken within the Quality Assurance System, to verify that quality requirements have been met in the development of the trial activities.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

133. RANDOMIZATION

Procedure of random assignment of trial subjects to treatment or control groups, with the aim of reducing biases.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

134. RECRUITMENT

Procedure by which the subjects that meet the inclusion criteria, are enrolled in a research.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

135. REDUCTION OF RISKS OF ETHICAL BREACHES

Selective application of appropriate prevention and management techniques and principles, to reduce the incidence of breaches to the provisions of the Codes of Ethics, Transparency and Good Practices (CIETEMIS) or in other deontological instruments issued by CETIFARMA, and of facing its consequences, or both.

Source: *Guía Anticorrupción para las Empresas*, basada en el Estatuto Anticorrupción de la UNODC, Cámara de Comercio de Bogotá, Ministerio de Justicia de Colombia, Embajada Británica en Bogotá, Negocios Responsables y Seguros, 2014 (with adaptations).

136. REGULATORY AUTHORITIES

Agencies that have the authority to determine and monitor compliance with mandatory standards of the specific fields or specialties, in this case healthcare. In ICH's *Good Clinical Practice Guidelines*, the term Regulatory Authorities includes both the authorities that review the clinical data submitted and those that carry out inspections.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017 (with adaptations).

137. REPUTATIONAL RISK

Possibility of loss incurred by an entity due to disrepute, bad image, negative publicity, whether true or not, regarding the institution and its business practices, causing distrust, deterioration of image, loss of clients, decrease in revenues or legal proceedings.

Source: *Guía Anticorrupción para las Empresas*, basada en el Estatuto Anticorrupción de la UNODC, Cámara de Comercio de Bogotá, Ministerio de Justicia de Colombia, Embajada Británica en Bogotá, Negocios Responsables y Seguros, 2014 (with adaptations).

138. RESEARCH AND DEVELOPMENT

Activities associated with the design or execution of preclinical studies (defined by the OECD in its Principles of Good Laboratory Practice), clinical trials and post-authorization studies.

Source: *Código de Buenas Prácticas de la Industria Farmacéutica*, Farmaindustria, España, 2016.

139. RESEARCH COORDINATOR

Individual to whom the researcher assigns some administrative activities.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

140. RESEARCH ETHICS COMMITTEE

The Research Ethics Committee (CEI) is an autonomous, institutional, interdisciplinary, plural, and consultative collegiate body, created to evaluate and dictate research protocols involving human subjects.

In accordance with the provisions of Articles 41 Bis and 98 of the General Health Law, all healthcare establishments of the national health system (public, social and private sector's) where research with human subjects is done, are obliged to have a CEI.

Source: Comisión Nacional de Bioética, CONBIOÉTICA; retrieved from: http://www.conbioetica-mexico.salud.gob.mx/interior/registrocomites/cei.html

141. RESEARCH PROTOCOL

According to COFEPRIS it is the written work plan that establishes the objectives, procedures, methods, and acceptance criteria, to conduct a study.

A document that describes the objectives, design, methodology, statistical considerations, and organization of a clinical trial. The protocol usually provides the background and rationale for the trial, although both may be included in other documents referred to in the protocol. In the Good Clinical Practice Guidelines of ICH, the term protocol refers to both the original protocol and its successive amendments.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017; Glosario *de Insumos para la Salud*, COFEPRIS; retrieved from: http://www.cofepris.gob.mx/AS/Documents/Comercio%20Internacional/GLOSARIO%20INSUMOS.pdf

142. RESEARCH SITE

Place where the activities related to a trial are carried out.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

143. RISK

In general terms it refers to the impact and probability that a threat (or series of events/threats) may adversely affect the achievement of objectives. It is measured in terms of the consequences and probabilities or the likelihood of occurrence of an incident.

In clinical studies or research, it is the measure that evaluates the likelihood of health damage or its severity on health.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017; *Propuesta de Glosario Hacia la Integridad*, PNUD, USAID, SFP y UNODC; *Guía Anticorrupción para las Empresas,* basada en el Estatuto Anticorrupción de la UNODC, Cámara de Comercio de Bogotá, Ministerio de Justicia de Colombia, Embajada Británica en Bogotá, Negocios Responsables y Seguros, 2014.

Glosario de términos aplicados a Seguridad del Paciente, Secretaría de Salud, retrieved from: http://www.calidad.salud.gob.mx/site/calidad/docs/dsp-sp_00F.pdf

Evaluación de Riesgos, Deloitte, November 2015 (with adaptations), retrieved from: https://www2.deloitte.com/content/dam/Deloitte/mx/Documents/risk/Evaluacion-Riesgos-COSO.pdf

144. RISK ANALYSIS

Systematic use of available information and the results of studies done specifically to identify: the frequency, the areas and activities, that can lead to circumstances of non-compliance with the regulatory provisions applicable to healthcare supplies companies, and the magnitude of their

consequences. All this, to apply preventive measures to avoid possible non-compliance and, if applicable, to determine the corresponding sanctions.

The above mentioned applies to the companies established in the legal framework, as well as to those adhered to the self-regulatory framework contained in the *Code of Integrity, Ethics and Transparency of Healthcare Supplies Companies*, CIETEMIS.,

Source: *Propuesta de Glosario Hacia la Integridad*, PNUD, USAID, SFP y UNODC; *Guía Anticorrupción para las Empresas*, basada en el Estatuto Anticorrupción de la UNODC, Cámara de Comercio de Bogotá, Ministerio de Justicia de Colombia, Embajada Británica en Bogotá, y Negocios Responsables y Seguros, 2014.

145. RISK CONTROL

Stage of the risk management that involves the implementation of policies, standards, and procedures to eliminate or mitigate adverse risks.

Source: *Guía Anticorrupción para las Empresas*, UNODC, Cámara de Comercio de Bogotá, Ministerio de Justicia de Colombia, Embajada Británica y Negocios Responsables y Seguros, 2014.

146. RISK MANAGEMENT

Structured process implemented at all levels of an organization, to identify and address the risks and opportunities in its processes, focusing on individual solutions.

Systematic application of policies, procedures, and management practices to the tasks of setting the context, identifying, analyzing, assessing, treating, monitoring, and communicating risks.

Culture, processes, and structures aimed at obtaining potential opportunities while managing adverse effects.

Source: *Guía Anticorrupción para las Empresas* basada en el Estatuto Anticorrupción de la UNODC, Cámara de Comercio de Bogotá, Ministerio de Justicia de Colombia, Embajada Británica en Bogotá, Negocios Responsables y Seguros, 2014 (with adaptations); *Glosario de términos aplicados a Seguridad del Paciente*, Secretaría de Salud; retrieved from:
http://www.calidad.salud.gob.mx/site/calidad/docs/dsp-sp_00F.pdf

147. RISK PREVENTION

Identifying, assessing, and responding to risks that may impact the fulfillment of a company's objectives, strategic and operational initiatives, and ethical provisions.

Source: *Evaluación de Riesgos*, Deloitte, November 2015 (with adaptations); retrieved from:
https://www2.deloitte.com/content/dam/Deloitte/mx/Documents/risk/Evaluacion-Riesgos-COSO.pdf

148. SAFE PRACTICES

Series of good practice recommendations for healthcare professionals, which are applied in different care settings, to prevent and avoid adverse events.

Source: *Glosario de términos aplicados a Seguridad del Paciente*, Secretaría de Salud; retrieved from:
http://www.calidad.salud.gob.mx/site/calidad/docs/dsp-sp_00F.pdf

149. SAFETY CULTURE

It is the aggregate of individual and collective values, attitudes, perceptions, competencies, and behavioral patterns, which determine healthcare managements' commitment to minimize the possible harm that could be suffered by the patients due to the use of medicines, medical devices or other healthcare supplies or their participation in clinical trials.

Source: *Glosario de términos aplicados a Seguridad del Paciente*, Secretaría de Salud (with adaptations); retrieved from:
http://www.calidad.salud.gob.mx/site/calidad/docs/dsp-sp_00F.pdf

150. SANITARY AUTHORIZATION

Administrative act by which the competent sanitary authority allows a moral or private person to carry out activities related to human health, in the cases and with the requirements and modalities determined by the General Law of Health and other applicable general provisions.

In the case of imported healthcare supplies, an Import Sanitary Permit is required.

Source: Glosario de Insumos para la Salud, COFEPRIS; retrieved from:
http://www.cofepris.gob.mx/AS/Documents/Comercio%20Internacional/GLOSARIO%20INUMOS.pdf

151. SANITARY AUTHORIZATION COMMISSION

It is part of COFEPRIS. It is responsible of issuing, extending or revoking the authorization of projects for the use of medicines, materials, devices, apparatus, procedures or experimental activities on human beings for scientific research purposes, based on sufficient scientific evidence to prove their preventive, therapeutic or rehabilitative efficacy.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

152. SANITARY ORGANIZATION

Any legal person or entity organized as a medical or scientific association, healthcare institution (whatever its legal or organizational form) such as hospitals, clinics, foundations, universities and other academic entities, scientific societies (excluding Patient Organizations), or through which one or more healthcare professionals provide healthcare services.

Source: *Código de Buenas Prácticas de la Industria Farmacéutica*, Farmaindustria, España, 2016.

153. SANITARY REGISTRATION

The Ministry of Health will authorize drugs, only when it is demonstrated that their production processes, the substances they contain and the medicines themselves meet the required safety, efficacy, and quality features, and that they comply with the provisions of the General Health Law and other general provisions.

To obtain an authorization, companies must previously demonstrate compliance with good manufacturing practices and production processes of the medicine, as well as the certification of its active ingredients. The verifications are a responsibility of the Ministry of Health or its authorized third parties. If applicable, recognition will be given to certifications issued by

competent authorities of the country of origin Provided that there are recognition agreements regarding the certification of medicines, between the competent authorities of both countries.

Source: *Ley General de Salud*, Articles 22 and 22 bis (DOF 22-06-2017).

154. SANITARY SAFETY

In accordance with the precepts of the General Health Law, the Ministry of Health, federal entities and, where appropriate, municipal governments will issue provisions specifically related to safety measures, as well as other provisions, to protect the health of the population.

Source: *Ley General de Salud*, Articles 402, 403 and 404.

155. SCHOLARSHIP

See *educational support* (above).

The term scholarship is not used in the CIETEMIS to refer to educational support or aid, to avoid confusions with its academic or fiscal connotations.

Source: CETIFARMA.

156. SCIENTIFIC AND EDUCATIONAL MATERIAL

Include support instruments, tools, and teaching aids (printed or electronic books; audiovisuals; data storage systems, etc.) to provide medical and scientific information to healthcare professionals.

Source: University of Antioquia, Colombia; retrieved from:
http://aprendeenlinea.udea.edu.co/banco/html/materialeseducativos/

157. SELF-CONTROL

The capacity of each company and/or health supply industry to evaluate its performance considering provisions related to integrity, ethics, and transparency. To identify, control, monitor and implement any risk management measure required; to. To detect and assess deviations and non-compliance behaviors, and apply, if necessary, of the corrective measures; and as part of a scheme to promote a culture of compliance, enhance actions geared towards a continuous improvement of the company/industry.

Source: *Manual de Políticas de Autocontrol y Gestión del Riesgo de Lavado de Activos y Financiación del Terrorismo*, Deloitte (with adaptations). Retrieved from:
https://www2.deloitte.com/co/es/pages/about-deloitte/articles/Manual_SAGRLAFT_Deloitte.html

158. SELF-REGULATION

System created by one or several organizations to guide their corporate conduct and activities, and that of their personnel with eminently preventive regulations and supervision of their compliance, with an independent authority, not related to the government. The ethical basis of self-regulation in a business context rely on objectivity, autonomy, integrity, transparency, and efficiency.

The self-regulation system has the following components:

1. A voluntary decision, and without external pressure, of an industry or profession to design, establish and comply with a system of ethical and integrity standards and provisions, to regulate their activities, interactions. and behaviors.
2. The formulation of a Code based on the agreed system of standards and provisions, the applicable legal framework, and the principles and values shared by the industry, the companies that comprise it and the third parties that collaborate with them. In this specific case, the *Code of Integrity, Ethics and Transparency of Healthcare Supplies Companies*, CIETEMIS).
3. A follow-up system to monitor compliance with the standards and provisions defined in the Code (CIETEMIS).
4. A body responsible of the administration, promotion, examination, and evaluation of the effectiveness of the self-regulatory system and compliance with the Code's precepts (CIETEMIS). In charge of a periodic updating of instruments and processes to continuously strengthen the self-regulatory system
5. A system of ethics with consequences:
   a) That motivates and recognizes the companies that prevent improper practices by complying with the rules and provisions of the Code (CIETEMIS). A system that identifies and disseminates good practices that help form habits; and that promotes a culture of compliance by conviction.
   b) That makes the actions and interactions of the adhering companies transparent as evidence of the integrity and legitimacy of their performance.
   c) That operates a system of complaints that guides, conciliates and, ultimately, sanctions non-compliance with the Code (CIETEMIS).

Source: CETIFARMA.

159. SEVERE ADMINISTRATIVE MISCONDUCTS

Administrative offenses of public servants are classified as severe in terms of the General Law of Administrative Responsibilities. They include: bribery; embezzlement; diversion of public resources; improper use of information; abuse of functions; acting under conflict of interest; responsibility for improper hiring; hidden enrichment or concealment of conflict of interest; influence peddling; concealment; and contempt), and they are sanctioned by the Federal Court of Administrative Justice, and its counterparts in the federal entities.

Source: *Ley General de Responsabilidades Administrativas*, Articles 3, and 52 to 63.

160. SEVERE ADVERSE DRUG REACTION (EVENT)

Harmful health situation that occurs to a patient or a subject of a clinical investigation, to whom the drug has been administered at any dose, which:

- Causes death of the patient.
- Endangers the patient's life.
- Makes hospitalization of the subject necessary or requires to be extended.
- Causes permanent or important disability or incapacity.

- Gives rise to an anomaly or congenital malformation.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

161. SITE MANAGEMENT ORGANIZATION (SMO)

Organization that provides clinical trial-related services to a CRO, pharmaceutical companies, or a research site.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

162. SOURCE DATA

All information contained in the original files and certified copies, related to clinical findings, observations, or other clinical trial activities that are necessary for the reconstruction and evaluation of the trial. Source data are contained in the source documents.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

163. SOURCE DOCUMENTS

Original documents with data and registers, for example: medical records, clinical and administrative charts, laboratory reports, memoranda, subjects' diaries or evaluation questionnaires, medication dispensing records, data recorded by computerized instruments, copies or transcripts certified after verification as exact copies, microfiches, photographic negatives, microfilms or magnetic media, radiographs, subjects' files and records kept in the pharmacy, in the laboratories and in the medical-technical departments involved in the clinical trial.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

164. SPONSOR

Healthcare companies support the realization of continuing medical education and training activities for healthcare professionals, as well as their assistance to the events.

In the case of clinical studies and research, it is an individual, government agency, healthcare institution or pharmaceutical company who is responsible for initiating, administering, and financing the clinical investigation.

Source: Fuente: *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013; *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

165. STANDARD TREATMENT

Accepted intervention that is considered effective or the best option for treatment for a specific pathology.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

166. SUB-INVESTIGATOR

Helps design and lead a research, at a research site.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

167. SUBJECT OF INVESTIGATION

Individual who participates in a clinical trial, either receiving the investigational drug or acting as a control.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

168. SUSTAINABLE ETHICS

Assuming integrity and ethics as the guiding principles of legitimate business and of each of activity and interaction, based on a cultural platform of principles and values that encourage behaviors of increasing compliance.

Source: CETIFARMA.

169. TECHNO-VIGILANCE

Its purpose is to ensure that medical devices available in the market function as indicated, in accordance with the manufacturer's intention of use (indicated in the corresponding sanitary authorization issued by the Ministry of Health. When deviating from the above, to ensure that the corresponding actions are taken to correct and/or reduce the probability of recurrence of adverse incidents, thus seeking to improve the protection of the health and safety of medical device users.

It is a documented process to verify the quality, performance, efficacy, and safety of medical devices once they have been used under real conditions, to identify and qualify the side effects and adverse reactions produced, as well as to specify the risk factors associated to them.

By means of the notification, registration, and systematic evaluation of the secondary or adverse events identified, their frequency, severity and incidence are determined. Having these, makes it possible to mitigate the probability of recurrence or to address the consequences of such incidents, applying the corresponding preventive and corrective measures.

According to Article 38 of the Health Supplies Regulation, side effects and adverse reactions must be made known immediately to the Ministry of Health by the holder of the registration, distributors or marketers of the supplies.

Source: *Seguridad de Dispositivos Médicos: Tecnovigilancia*, Lisbeth R. Rincón Cabrera (Presidente de la Sección Reactivos y Sistemas de Diagnóstico de la CANIFARMA), presentación en el IV Congreso de Farmacovigilancia organizado por COFEPRIS, (México, noviembre 2010); retrieved from: https://www.gob.mx/cofepris/acciones-y-programas/antecedentes-tecnovigilancia

170. THIRD-PARTY ASSOCIATE

Any individual or legal entity that, for any reason, acts in the name and/or on behalf of one or more healthcare supply companies (HSC).

Source: CETIFARMA (2021).

171. TRACEABILITY

Ability to be able to identify each step in a process, that will set the trajectory of a result or product.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017; Glosario *de Insumos para la Salud*, COFEPRIS, retrieved from: http://www.cofepris.gob.mx/AS/Documents/Comercio%20Internacional/GLOSARIO%20INSUMOS.pdf

172. TRANSPARENCY

Promote access to information of the main interactions of healthcare companies, with the aim of generating trust, credibility, and legitimacy. Presentation of evidence of corporate practices, based on ethics, integrity, fair competition and legitimate businesses.

Source: CETIFARMA.

173. UNEXPECTED ADVERSE REACTION

A reaction of a nature or severity inconsistent with the information available on the drug (e.g., Investigator's manual for an investigational drug not authorized for marketing or the drug's label in the case of an authorized drug).

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017; *Glosario de términos aplicados a Seguridad del Paciente*, Secretaría de Salud; retrieved from: http://www.calidad.salud.gob.mx/site/calidad/docs/dsp-sp_00F.pdf

174. UNIT OF MEASUREMENT AND UPDATING

Economic reference in Mexican currency (pesos), to determine the amount of payment of obligations and assumptions provided for in federal laws, laws of the federal entities, as well as in the legal provisions emanating from all the above.

The UMA is published annually by the National Statistics and Geography Institute with daily, monthly, and annual values. The monthly value is calculated by multiplying the daily value by 30.4 times and its annual value is calculated by multiplying its monthly value by 12.

Source: Instituto Nacional de Estadística y Geografía (INEGI); retrieved from: https://www.inegi.org.mx/temas/uma/

175. UNITED NATIONS EDUCATIONAL, SCIENTIFIC, AND CULTURAL ORGANIZATION (UNESCO)

Created on November 16, 1945. It is entrusted with the task of creating conditions conducive to a dialogue among civilizations, cultures, and peoples, based on respect for common values. Its strategies and activities are based on concrete goals, which are embodied, for example, in the UN's Millennium Development Goals. Its mission is to contribute to the consolidation of peace, the eradication of poverty, sustainable development and intercultural dialogue through education, the sciences, culture, communication, and information.

Source: *Código de Ética y Transparencia de la Industria Farmacéutica establecida en México*, 2013; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

176. UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS

Adopted by the UNESCO General Conference (October 19, 2005), it deals with ethical issues related to medicine, life sciences and related technologies applied to human beings, considering their social, legal, and environmental dimensions. It is addressed primarily to States, but also towards individuals, groups, communities, institutions, public and private enterprises, where appropriate.

Source: Universal Declaration on Bioethics and Human Rights, Article 1, UNESCO, 2005; *Código de Ética y Transparencia de la Industria Farmacéutica Establecida en México*, 2013; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

177. VALUE TRANSFER

Any legitimate payment, contribution, support, or fee, based on legality and ethical principles, that a healthcare supply company makes, directly or indirectly, in cash or in kind to a healthcare professional; a medical or healthcare professionals association or organization; a healthcare service institution, whether public or private; or to a patient organization. As well as to any other person or entity that may influence decisions on the therapy of a patient, or that has educational, promotional, research and development, altruistic or assistance purposes.

Medical samples, commercial transactions between companies and distributors or services with other professionals will not be considered value transfers.

Source: CETIFARMA and Farmaindustria (Spain).

178. VULNERABLE SUBJECTS

Individuals whose willingness to volunteer for a clinical trial may be unduly influenced by the expectation, justified or not, of benefits associated to their participation or of retaliatory response by hierarchical superiors in the event of their refusal to participate. Examples include members of a group with a hierarchical structure, such as medical, pharmacy, dental or nursing students, subordinate laboratory or hospital personnel, pharmaceutical company employees, members of the armed forces and prisoners. Other vulnerable subjects include patients with incurable diseases, people in nursing homes, unemployed or beggars, patients in emergency situations, ethnic minority groups, vagabonds, nomads, refugees, minors, and those who are incapable of giving their consent.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

179. WELL-BEING (OF THE SUBJECTS IN A CLINICAL TRIAL)

Physical and mental integrity of subjects participating in a clinical trial.

Source: *Guía de prácticas éticas para las CRO*, CETIFARMA-ACROM, 2017.

180. WORLD HEALTH ORGANIZATION (WHO)

Coordinating authority for sanitary activities of the United Nations system. WHO plays a leadership role in global health affairs, shapes the health research agenda, sets standards, articulates evidence-based policy options, provides technical support to countries, and monitors global health trends.

Source: *Código de Ética y Transparencia de la Industria Farmacéutica establecida en México*, 2013; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

181. WORLD MEDICAL ASSOCIATION (WMA)

International organization representing physicians, founded in Paris on September 18, 1947with the participation of representatives of 27 national medical associations. The purpose of its creation after World War II, was to ensure the independence of physicians and to promote the highest standards of ethical conduct and medical care.

The WMA is constituted by an independent confederation of professional associations, it is financed with the annual dues of its members (currently near to100 countries).

Source: *Código de Ética y Transparencia de la Industria Farmacéutica establecida en México*, 2013; *Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México*, 2013.

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5. *Código de Ética, Transparencia y Buenas Prácticas de Comercialización y Publicidad de Sucedáneos de la Leche Materna o Humana para Lactantes*; Cámara Nacional de Industriales de la Leche; Comisión de Fabricantes de Fórmulas Infantiles; México; 2016.
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Mexican & most foreign Institutions, Laws & Acronyms

	English	Spanish	Acronym
1.	Alliance of Contract Research Organizations of Mexico	Alianza de Organizaciones de Investigación por Contrato de México	ACROM
2.	Certification as a Company with Transparent Practices	Certificación de Empresa con Prácticas Transparentes	EPT CETIFARMA
3.	Code of Ethics and Transparency of the Pharmaceutical Industry established in Mexico, 2013	Código de Ética y Transparencia de la Industria Farmacéutica establecida en México, 2013	CET
4.	Code of Ethics, Transparency and Best Practices for Marketing and Advertising of Breast Milk Substitutes for Infants	Código de Ética, Transparencia y Buenas Prácticas de Comercialización y Publicidad de Sucedáneos de la Leche Materna o Humana para Lactantes	
5.	Code of Good Practice of the Pharmaceutical Industry, Farmaindustria	Código de Buenas Prácticas de la Industria Farmacéutica, Farmaindustria, España.	
6.	Code of Good Practice on Pharmaceutical Industry Interaction with Patient Organizations.	Código de Buenas Prácticas de Interacción de la Industria Farmacéutica con Organizaciones de Pacientes.	CBIOP
7.	Code of Good Promotional Practices for the Pharmaceutical Industry established in Mexico, 2013.	Código de Buenas Prácticas de Promoción de la Industria Farmacéutica establecida en México, 2013.	CBPP
8.	Code of Integrity, Ethics and Transparency of Healthcare Supplies Companies.	Código de Integridad, Ética y Transparencia de Empresas de Insumos para la Salud.	CIETEMIS
9.	Code of Interaction with Healthcare Professionals 2017.	Código de Interacción con los Profesionales del Cuidado de la Salud 2017, AMIID, México	
10.	Committee of Ethics and Transparency in the Medical-Industry Relationship, of the National Academy of Medicine	Comité de Ética y Transparencia en la Relación Médico-Industria de la Academia Nacional de Medicina	CETREMI
11.	Compendium of Health Supplies for Public Institutions	Compendio Nacional de Insumos para la Salud de las Instituciones Públicas	

12.	Contract Research Organization	Organización de Investigación por Contrato	CRO
13.	Council of Ethics and Transparency of the Pharmaceutical Industry	Consejo de Ética y Transparencia de la Industria Farmacéutica	CETIFARMA
14.	European Federation of Pharmaceutical Industries and Associations	Federación Europea de Industrias y Asociaciones Farmacéuticas	EFPIA
15.	Federal Commission for Protection against Sanitary Risks	Comisión Federal para la Protección contra Riesgos Sanitarios	COFEPRIS
16.	Federal Copyright Law	Ley Federal de Derechos de Autor	
17.	Federal Court of Administrative Justice	Tribunal Federal de Justicia Administrativa	
18.	Federal Law for the Protection of Personal Data Held by Private Parties	Ley Federal de Protección de Datos Personales en Posesión de Particulares	
19.	Federal Law of Economic Competition	Ley Federal de Competencia Económica	
20.	General Health Law	Ley General de Salud	LGS
21.	General Law of Administrative Responsibilities	Ley General de Responsabilidades Administrativas	LGRA
22.	Glossary of Healthcare Supplies	Glosario de Insumos para la Salud	
23.	Glossary of Patient Safety Terms	Glosario de Términos Aplicados a Seguridad del Paciente	
24.	Guide of Ethical Practices for CROs.	Guía de Prácticas Éticas para las CRO	
25.	Healthcare services provider institutions	Institución de Salud	
26.	Healthcare Supply Companies	Empresas de Insumos para la salud	EMIS
27.	Health Supplies Regulation	Reglamento de Insumos para la Salud	
28.	Import Sanitary Permit	Permiso Sanitario de Importación	
29.	Independent Data Monitoring Committee	Comité Independiente de Monitorización de Datos	CIMD
30.	Industrial Property Law	Ley Federal de Protección a la Propiedad Industrial	

31.	Infant Formula Manufacturers Commission	Comisión de Fabricantes de Fórmulas Infantiles	CFFI-CANILEC
32.	Law of Acquisitions, Leasing and Services of the Public Sector	Ley de Adquisiciones, Arrendamientos y Servicios del Sector Público	LAASSP
33.	Law of Chambers and Business Organizations	Ley de Cámaras y Organismos Empresariales	
34.	Law to Regulate Credit Information Companies	Ley para Regular las Sociedades de Información Crediticia	
35.	Mexican Association of Pharmaceutical Research Industries	Asociación Mexicana de Industrias de Investigación Farmacéutica	AMIIF
36.	Mexican Constitution	Constitución Política de los Estados Unidos Mexicanos	CPEUM
37.	Mexico's Tax Administration System	Sistema de Administración Tributaria	SAT
38.	Ministry of Finance and Public Credit	Secretaría de Hacienda y Crédito Público	SHCP
39.	Ministry of Health	Secretaría de Salud	SS
40.	National Association of Medicines Manufacturers	Asociación Nacional de Fabricantes de Medicamentos	ANAFAM
41.	National Center of Pharmacovigilance	Centro Nacional de Farmacovigilancia	CNFV
42.	National Chamber of Milk Manufacturers	Cámara Nacional de Industriales de la Leche	CANILEC
43.	National Chamber of the Pharmaceutical Industry	Cámara Nacional de la Industria Farmacéutica	CANIFARMA
44.	National Health System	Sistema Nacional de Salud	
45.	National Registry of Clinical Trials	Registro Nacional de Ensayos Clínicos	RNEC
46.	National System for Management of Medicine and Packaging Residues	Sistema Nacional de Gestión de Residuos de Envases y Medicamentos	SINGREM
47.	National Statistics and Geography Institute	Instituto Nacional de Estadística y Geografía	INEGI
48.	Official Gazette of the Federation	Diario Oficial de la Federación	DOF

49.	Research Ethics Committee	Comité de Ética en Investigación	CEI
50.	Sanitary Authorization Commission	Comisión de Autorización Sanitaria	CAS
51.	Science and Technology Law	Ley de Ciencia y Tecnología	
52.	Standard Operating Procedures	Procedimientos Normalizados de Operación	PNO
53.	Unit of Measurement and Update	Unidad de Medida y Actualización	UMA-INEGI
54.	Value Transfer	Transferencia de valor	TDV

CETIFARMA

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