CODES OF THE PHARMACEUTICAL INDUSTRY ESTABLISHED IN MEXICO

NATIONAL CHAMBER OF THE PHARMACEUTICAL INDUSTRY COUNCIL OF ETHICS AND TRANSPARENCY OF THE PHARMACEUTICAL INDUSTRY

EDITION 2010

CODES OF THE PHARMACEUTICAL INDUSTRY ESTABLISHED IN MEXICO

CODES OF THE PHARMACEUTICAL INDUSTRY ESTABLISHED IN MEXICO

Segunda edición, 2009.

D.R. © 2009 Consejo de Ética y Transparencia de la Industria Farmacéutica Av. Cuauhtémoc 1481, 3er. piso, Col. Santa Cruz Atoyac, Delegación Benito Juárez, México 03310 D.F. Tel/fax (52-55) 5601-2865 / CETIFARMA@CANIFARMA.org.mx

CUIDADO EDITORIAL, DISEÑO Y PRODUCCIÓN María Martha Covarrubias Newton

APOYO EN LA REDACCIÓN DE CONTENIDOS Noemí Stolarski Rosenthal

CORRECCIÓN DE ESTILO Gabriel Soto Cortés

INVESTIGACIÓN ICONOGRÁFICA Unai Miquelajáuregui

AGRADECIMIENTOS

El CETIFARMA agradece la colaboración de los asociados de la CANIFARMA que hicieron aportaciones en la actualización de los presentes códigos.

ISBN en trámite / Códigos de la Industria Farmacéutica establecida en México

Se permite la reproducción parcial o total del contenido de la presente obra, sin fines lucro, siempre y cuando se cite la fuente.

Impreso y hecho en México



The international trend and the growing incorporation of self-monitoring measures designed to enhance transparency and effective accountability are embedded in a context where society is expressing the need for promotion of ethical and socially responsible behavior among companies. In this sense, the global impact actions promoted by the World Health Organization -which, in 1999, established a set of guidelines in order to increase transparency in its relation with the health care industry, including the pharmaceutical companies- are considered of utmost importance; as well as the measures undertaken by the World Medical Association (2004) to ensure transparency in the relationship of the medical profession with the Pharmaceutical industry.

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) joined these initiatives by updating its Code of Good Practices for the Promotion of Medicines, enforced in January 2007.

The National Chamber of the Pharmaceutical Industry (CANIFARMA), integrated by national and multinational companies established in Mexico, began this process in 2005, by taking the following steps. Its first initiative was the creation of the Council of Ethics and Transparency of the Pharmaceutical Industry established in Mexico (CETIFARMA) -autonomous management organism responsible of the elaboration, promotion, enforcement and observance of the codes of ethics and other self-regulatory and self-monitoring instruments.

The second initiative was the approval by CANIFARMA's affiliate members of the Code of Ethics and Transparency of the Pharmaceutical Industry established in Mexico. Subsequently, the Code of Good Practices of Promotion was elaborated and went into effect in 2006; and, in addition, the Code of Good Interaction Practices of the Pharmaceutical Industry with Patient Organizations was approved in 2009. The application and observance of these codes is obligatory and affiliate companies of the referred chamber are required to make a written endorsement of compliance.

Other companies and organizations, non-members of CANIFARMA, may also adhere if they decide to adopt and apply the codes issued by CETIFARMA.

With this updated version, CETIFARMA provides CANIFARMA's members, adherents and any person interested, the following documents that offer orientation and define a behavioral framework that abides by universal ethical principles, thus contributing to the promotion of both an ethical culture and of activities of social responsibility.

This publication includes:

- The Code of Ethics and Transparency of the Pharmaceutical Industry, where the conceptual guidelines and standards regulating the conduct of CANIFARMA's members and adherents to the code are established.
- The Code of Good Practices of Promotion, which defines the behavioral principles with an ethical foundation that rules the relationships between pharmaceutical companies and health care professionals.
- The Code of Good Practices of Interaction of the Pharmaceutical Industry with Patient Organizations, where the guidelines are established to regulate relationships between the Pharmaceutical Industry and the Patient Organizations grounded on universal ethical principles and respect for human dignity.

RESENTACIÓN

CODE OF ETHICS A	ND TRANSPARENCY9
CHAPTER I	Conceptual basis9
	1. General purpose9
	2. Specific objectives9
	3. Strategic purpose10
	4. Ethical principles10
	5. Fundamental operating principles11
	6. Moral values14
CHAPTER II	General provisions15
CHAPTER III	Members rights15
CHAPTER IV	Members's obligations15
CHAPTER V	Of the members's conduct18
CHAPTER VI	Of the cooperation between members23
CHAPTER VII	Sanctions24
CHAPTER VIII	Procedure for the enforcement of sanctions24
CHAPTER IX	In relation to CETIFARMA27
CODE OF GOOD PR	COMOTIONAL PRACTICES

O N T E N T

002 01	0000	no no no no n	2 1 10 10 11	 	
Introdu	uction			 	29

1. Purpose of the Code of Good Promotional Practices (CBPP)		
2. Scope	.30	
3. General guidelines	.32	
4. Ethical behavior criteria	.33	
5. Award for the development of transparency and social		
responsibility in the promotion of medicines of		
The Pharmaceutical Industry in Mexico	.46	
6. Enforcement rules		
7. Breaches and sanctions		
8. Admission procedures of complaints		
and ruling of infringements	.49	

CODE OF GOOD INTERACTION PRACTICES OF THE PHARMACEUTICAL

INDUSTRY WITH PATIENT ORGANIZATIONS	
Introduction	53
Principles	53
Purpose of the Code	54
Scope	54
Guidelines	54

C



CODE OF ETHICS AND TRANSPARENCY OF THE PHARMACEUTICAL INDUSTRY IN MEXICO



1. GENERAL PURPOSE

The purpose of the Code of Ethics is to set an operating framework for the companies and individuals in the field of the Pharmaceutical Industry established in Mexico, by promoting an ethical culture and a commitment to transparency, in order to enhance the development of the industry, preserving the integrity of its users and protecting the general interest of society.

Therefore, the affiliate and adherent members to this Code voluntarily assume the obligation to adjust all their activities to the spirit of the present document.

2. SPECIFIC OBJECTIVES

- Promote transparency and disseminate an ethical culture, by setting principles, operational criteria, and values among the industry's members and society in general.
- Mediate and advise on ethical and transparency issues, by providing guidelines and consultancy to the members of the industry and to those interacting with it in a relevant manner.
- Legitimize and facilitate free competition, in order to promote a socially responsible development of the Pharmaceutical Industry, under clear and fair rules, avoiding opportunism, abuse, unfair competition, public image battles and libel.

- Strengthen the relationship to the environment, in order to consolidate the sector's acceptance and recognition by the community, the government, the political leaders and international authorities.
- Be inclusive and improve communication among members of the industry, enforcing the legitimacy, plurality and legality of the different bodies that constitute and represent it.
- Foster a positive impression of the industry in the public opinion, enhancing its image as a responsible and secure industry.

3. STRATEGIC PURPOSE

To promote a responsible, reliable and transparent Pharmaceutical Industry, always mindful of potential abuse or unfair practices that might jeopardize compliance with the ethical principles conceived to guarantee society's well being and the development of a responsible industry towards the environment.

To work in accordance with ethical and free trade parameters, promoting order, harmony and fair benefits for all parties involved in the Pharmaceutical Industry, including company shareholders and executives as well as customers, suppliers and society in general.

4. ETHICAL PRINCIPLES

The members of the Pharmaceutical Industry define the following principles as their basic responsibilities towards society:

a) Responsibility towards human life and health

To assure that medicines and health-related products are truly useful to preserve and improve the quality of human life. Special attention should be drawn to their safety, quality and therapeutic effectiveness, and to an efficient distribution that ensures their availability and existence in pharmacies.

b) Supportive commitment to society and the development of the country To perform pharmaceutical activities which provide healthcare services to society, due to the impact of its products in people's health and development. To generate high quality sources of employment and specialization, thus contributing to intellectual capital formation and high value added processes. Excel as a clean Industry, and collaborate with the community in emergency and disaster situations.

c) Commitment to transparency in free trade and with society

To act in good faith, without confusing, by any means, in terms of the products, the company or the commercial activity of competing companies,



and to avoid practices that are likely to mislead the consumer. Monopoly practices that tend to decrease, harm or avoid competition and free concurrence in the production, processing, distribution or commercialization of pharmaceutical products, will be sanctioned.

d) Responsibility for the viability and strength of the Pharmaceutical Industry

To create conditions that encourage the adequate performance of all participating parties (government, distributors and suppliers, professionals, healthcare institutions, patient organizations and media), thus increasing the credibility of the Pharmaceutical Industry within the Mexican society.

5. FUNDAMENTAL OPERATING PRINCIPLES

a) To act in accordance with sound trading practices and in strict compliance with the prevailing legislation.

Members of the sector must abide by the current laws, regulations and general applicable dispositions issued by competent authorities, and comply with the industry's regulations. Therefore, broad knowledge of legislations on sanitary, trade and ecological matters and guidelines, as well as national and international agreements on bioethics and biosecurity issues is strongly recommended.

In order to achieve compliance with this principle, the administrative bodies of the chambers, associations and companies participating in the pharmaceutical sector, shall establish the proper measures and monitoring procedures to verify that their associated members abide by the regulations applied to the different activities they perform. **b**) To proceed in accordance with a professional, honest and upright conduct allowing a transparent and orderly development of the market.

It is the responsibility of the sector members to act with integrity, since their conduct not only affects their own reputation and that of the companies or entities to which they are associated, but also of the Pharmaceutical Industry as a whole, and can have an impact on the well-being of the people that consume their products.

Members will encourage participating chambers, associations and companies to engage in supervising that the transactions in which they are involved will take place according to the standards of sound trading practices and to these conceptual guidelines.

c) To encourage the fulfillment of healthcare needs,

and promote the user's confidence in pharmaceutical products.

The sector members must generate confidence among users by operating in good faith and in a transparent and fair manner, without putting other interests at stake.

As a requirement of this principle, participating chambers, associations and companies must make use of the proper mechanisms and procedures to ensure the transparency of their members' activities, and to facilitate access and availability of their products.

d) To avoid conflicts of interest between clients, regulatory institutions, authorities and third parties.

Personal or family relations, or any other relationship that implies a professional link with clients or companies that could generate conflicts of interest, must be transparent.

By conflict of interest we understand a circumstance that jeopardizes the free will or free action of the health care professionals, whenever personal or business profit receives priority over the patient's best interest.

Participating chambers, associations and companies shall establish institutional and regulatory mechanisms in order to avoid potential conflicts of interest in the different fields of their activity.

e) To provide accurate, clear, complete, reliable and permanent information to the market and society in general.

Market efficiency depends, to a great extent, on the truthfulness, opportunity and clarity of public information. All information regarding the industry and its products must be sufficient and fair.

Participating chambers, associations and companies must have efficient

information systems in order to ensure strict compliance with this principle.

f) To protect information confidentiality

The main purpose of this principle is to safeguard confidential information related to research, trade and worldwide operations of the members of the sector. Information shall be disclosed only to competent authorities and entities.

Confidentiality will not prevail, once the information holder has disclosed it in any way and by his own accord.

Participating chambers, associations and companies must refrain from using confidential information of other industry members and to develop proper monitoring systems in order to avoid undue disclosure or inappropriate use of information.

g) To promote responsible prescription and discourage self-medication.

Due to their social responsibility and their commitment to the viability and improvement of the Pharmaceutical Industry, sector members must prevent practices regarding the improper use of medical prescriptions, that prevail among consumers, distribution and dispensation channels.

Chambers, associations and companies shall employ all available means to stimulate and promote the proper use of medical prescriptions, and prevent pharmacy employees from prescribing. According to the provisions of the General Health Law (Ley General de Salud), only over-the-counter products are authorized for sale without a medical prescription.



h) To compete fairly.

Market competition must be fair and respect intellectual rights, or any other member's rights, must be strictly enforced.

Industry members must ensure that the pharmaceutical market competition is carried out in good faith and in an honest way, avoiding unfair practices

6. MORAL VALUES

In accordance with the ethical and operating principles described in this Code, the following moral values have been identified as substantive elements:

A. TRANSPARENCY

To clarify the actions and interactions of all members and parties involved in the Pharmaceutical Industry. Evidence-based practice must be supported, leaving no doubt or ambiguity of intention.

B. PROACTIVE RESPONSIBILITY

Considering the well being of society as a major goal, to anticipate the effects of our actions and assume their consequences.

C. SOCIAL WELL-BEING

Within a social perspective our actions must excel, seeking to promote social well-being.

D. JUSTICE

To encourage recognition of virtue or fault in such a way that only those who truly deserve it will be rewarded or sanctioned.

E. LEGALITY

To comply with the prevailing laws and rely on common sense, as means to achieve harmony and social well- being.

F. LEADERSHIP

To generate confidence among the industry members and act as an agent of change in a framework of social responsibility and human development.

G. SUBSIDIARITY

To assist the members of the industry in the development of ethical practices and support them in the diffusion of an ethical culture among the sector, thus generating a broader social impact.

H. HONESTY

To ensure compliance with the values adopted in the Code of Ethics, with the provisions of the norms and regulations governing the sector; and to promote honesty and congruence in their field of influence.

I. RESPONSIBLE EXCERCISE OF FREEDOM

To facilitate adequate decision-making, grounded in the transparency of information and knowledge.



- Art. 1. Definitions. For the purpose of this Code the following terms mean:
- a. CANIFARMA: National Chamber of the Pharmaceutical Industry.
- **b.** Industry: The Pharmaceutical Industry established in Mexico.
- **c.** Affiliate members: The individuals or companies participating as such in the National Chamber of the Pharmaceutical Industry.
- **d.** Adhering members: The persons and companies that hereby abide by the Code of Ethics and Transparency of the Pharmaceutical Industry and the deontological instruments set forth by the Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA).
- e. Members: Both the affiliate and the adhering members.
- **f. Code**: The present Code of Ethics and Transparency of the Pharmaceutical Industry.
- **g. CETIFARMA**: The Council of Ethics and Transparency of the Pharmaceutical Industry, governing body responsible of promoting an ethical culture and monitoring compliance with the provisions of this code and of all self-regulatory and self-monitoring instruments approved by the Council of CANIFARMA. It is also responsible of receiving complaints, resolving controversies, and publishing results and, if required, of the application of sanctions and corrective measures. This Council is composed of eleven individuals: President, Vice-president, Secretary, Treasurer, and seven Vocals.

Art. 2. This code establishes the standards that should regulate the practices and behavior that are expected of all Members.

A follow-up enforcement of the provisions stipulated by this Code will be carried out through documentary inspection of specific matters and, when required, random visits to the companies will be undertaken in order to verify the information on the field.

Art. 3. All Members, by the mere fact of being a part of CANIFARMA, are obliged to adjust their behavior and practices to the provisions of this Code; and therefore must be fully committed to comply with the Code's terms.

When proceeding to their registration, CANIFARMA's members will make a written statement to abide by the Code and all other deontological instruments set forth by CANIFARMA and CETIFARMA, thus ensuring to adjust their behavior and practices to their provisions.

CETIFARMA will determine on an annual basis the fees due by adhering members. Every year they will make a written ratification to abide by the Code and all other deontological instruments set forth by CETIFARMA.

The persons and companies interested in adhering to the codes and selfregulatory instruments approved by CETIFARMA, must present to its director and executive secretary an application for membership and comply with the procedure stipulated in chapter VI, art.15 of CETIFARMA's Regulations.

Art. 4. In those cases in which it is necessary to determine the scope of the provisions of this Code, CETIFARMA will be the appointed instance to resolve whatever issues may arise.





Art. 5. All members will have the right to:

- a) File complaints against any member who does not comply with the provisions of this Code and with the self-regulatory and self-monitoring instruments approved by CANIFARMA and CETIFARMA.
- **b**) Request the testimony of another Member in order to confirm, explain or clarify the evidence that has been submitted to CETIFARMA.
- c) Suggest changes or modifications to this Code and other deontological instruments issued by CETIFARMA in order to promote a continuous actualization and better implementation.



- Art. 6. All members have the following obligations:
- a) To strictly comply with the conduct guidelines and provisions set in this Code and with the self-regulatory and self-monitoring instruments approved by CANIFARMA and CETIFARMA.
- b) To adopt measures ensuring that their companies comply with the provisions of this Code and other deontological instruments approved by CANIFARMA and CETIFARMA. To collaborate with all the verification measures instrumented by CETIFARMA when required.
- c) To assist and support CANIFARMA.
- **d**) To comply with the preventive and corrective measures as well as the sanctions determined by the Council whenever a breach or violation of the code is ruled.
- e) To communicate and transmit information to CETIFARMA each time a member's conduct is such as to endanger the user's health or discredit the image and credibility of the Industry.
- **f**) To provide honest, fair and objective justification of the complaints submitted to CETIFARMA and supply all the information relevant to the case.



Art. 7. All members must act in strict accordance with the following principles:

1. AS A COMPANY

To acknowledge the difference of criteria and interests among the industry both individually and as a group, with mutual respect of each other's point of view, and always promoting proper analysis and dialogue in order to reach an agreement.

To excel in the business sector by an exemplary behavior; adding up the values stipulated in this Code to the prevailing values of each company, fully committing thereby to exercise with the highest level of professionalism, honesty and transparency in all their commercial operations.

To maintain free and impartial criteria when expressing an opinion, regarding any query about their company, if the information requested is not confidential.

To fully respect the dignity and human rights of their own staff and the other Member's staff, without any kind of discrimination, promoting self-challenge and continuous improvement.

To refrain from offering contributions, bonds, gifts, commissions or any other benefit in kind, that contravenes laws, international agreements and dispositions of codes approved by CANIFARMA and CETIFARMA, to any person or entity whether public or private, national or foreign, in order to favor their own business.

To maintain good relations with fellow Members, always searching and promoting mutual support in order to dignify the Industry. Good relations should also be maintained with any other third parties and with society in general.

To refrain from making unfair comments that could threaten the reputation, name, commercial credit, moral integrity and personal image of other Members or of the reputation of the industry as a whole.

2. AS A PHARMACEUTICAL COMPANY

To promote the growth and qualitative development of the Pharmaceutical Industry in Mexico with transparency and equity.



To reinforce CANIFARMA, as the representative body of the industry by fully complying with the obligations as a member.

To always act with social responsibility in the best interest of the Industry, the pharmaceutical sector and the health of society.

To act in a spirit of solidarity in case of natural disasters or sanitary emergency, by responding to the authorities' requirements on behalf of society.

To produce or commercialize medical products for both the domestic and foreign markets with the highest quality, security and efficiency standards.

To strictly follow sanitary standards and good manufacturing practices; to verify the quality of the supplies and to respect the conditions and terms of the sanitary registration of the products.

To provide accurate and objective information to sanitary authorities, healthcare professionals and general audience about the characteristics of the products, including their commercial, scientific and technical features, in strict accordance with the prevailing law and the codes approved by CANIFARMA and CETIFARMA. To strictly comply with the provisions of the General Health Law (Ley General de la Salud) and its advertising policies, as well as with the other standards in this field and the Code of Good Promotion Practices (Código de Buenas Practicas de Promoción) and the Code of Interaction with Patient Organizations (Código de Interacción con Organizaciones de Pacientes). Promotional socially responsible activities include:

- a) The conduct of medical representatives.
- **b**) Printed promotional material.
- c) Distribution of medical samples.
- d) Advertising.
- e) Donations.
- f) Sponsorships.
- g) Medical meetings and symposiums.

T R A N S P A R E N C Y

A N D

ETHICS

ЧО

CODE

To always act in a responsible manner towards human life and health.

To ensure the transparency of all donations, particularly in case of natural disasters and sanitary emergencies, by applying the mechanisms set by each company or those stipulated by CETFARMA and CANIFARMA, when required.

To make sure that medicines and health-related products properly contribute to preserve and improve the quality of people's life, with special attention on the product's guarantee of safe usage, its quality, therapeutic efficiency, as well as a proper market distribution that ensures a permanent supply and availability in pharmacies.

To perform the activities of a pharmaceutical company always with the aim of providing an extensive service to society with efficient products that may improve health and human development. To promote the training of technicians and professionals, and take care of the environment, contributing to the development of a clean industry and a sustainable environment.

To promote conditions that will encourage the other parties involved in the sector (such as the Government, distributors and suppliers, health care professionals, health institutions and, if applicable, patient organizations) to have a proper performance and increase therefore the credibility of the Pharmaceutical Industry within the Mexican society.

3. COMPLIANCE WITH THE LAW

To strictly comply with the prevailing laws, regulations and general provisions, as well as with the official standards and regulations in effect. In order achieve this, personnel in charge must have a broad knowledge of all legal provisions in the sanitary, commercial, administrative, economic, environmental and other fields related to the activity.

4. INDUSTRIAL AND INTELLECTUAL PROPERTY RIGHTS

To respect rigorously the industrial and intellectual property rights of the lawful proprietors, always making sure, in the most appropriate way, that those who work on behalf of the Members also abide by such provisions, avoiding any kind of abuse, and committing to comply with each and every stipulation to this effect both in the Federal Copyright Law (Ley Federal del Derecho de Autor) and the Industrial Property Law (Ley de la Propiedad Industrial) and other applicable provisions, as well as in the contracted agreements particularly those related to patents and brands.

5. SECRECY AND CONFIDENTIALITY

- a) To follow the confidentiality regulations concerning any product, equipment, device, service, technology, technical assistance, procedures, market information, sales strategies or price lists and advertising campaigns, which access, use or disclosure is restricted or designated as confidential information, or protected by any patent, brand, industrial secrecy, copyright or any right or privilege in accordance with the prevailing law or contracted agreements.
- **b**) To maintain the confidentiality of the information and issues under analysis by CETIFARMA.

6. SALES TO THE PUBLIC SECTOR

To fully and loyally comply with the precepts of the Public Sector Procurement Laws (Ley de Adquisiciones, Arrendamientos y Servicios del Sector Público) and the corresponding provisions and regulations.

During the acquisition process, through a public bidding or any other procedure of government acquisitions, there should be no attempt either to exert undue influence upon the decision-making process, or to gather confidential information from government officials acting on behalf of a government office or entity.

7. INFORMATION AND ADVERTISING

- a) To refrain from taking undue advantage of the clients, of any product, individual, company, commercial brand or symbol, through mass media advertising. Such conduct must be specially reinforced in case of natural disasters or sanitary emergency.
- b) To give accurate and objective explanations on the characteristics, functions, advantages or disadvantages of the products or services.
- c) To refrain from discrediting competitors or spreading any false or inaccurate information about their activities or products.
- d) To strictly comply with the corresponding legal provisions.

8. FREE COMPETITION

a) To refrain from taking part in any monopolistic practice that tends to decrease, to harm or to prevent free competition in the production, processing, distribution and commercialization of the pharmaceutical products in the market.

b) Agreements should not be convened with the competitors to manipulate or increase price levels, potential markets, territory or client distribution; about restricting or conditioning production; about impeding distribution or commercialization channels or encouraging the exclusion of any product form the sale points.

9. MEDICAL PRESCRIPTION

- a) To fight against inadequate procedures prevailing between the users and the medicines distribution and dispensing system.
- **b**) To promote the proper use of medicines as well as the respect of medical prescriptions and to abstain from encouraging substitution of medicines, by the pharmacy employee's.

10. DONATIONS

Donations will be part of the activities of social responsibility and will be granted to non-profit organizations and institutions in order to support altruistic and social projects, refraining to use donations as means to promote products from the donor companies.

11. ECOLOGY

To abide by universally accepted ethical principles of sustainability and to comply with the legal dispositions regarding the preservation and improvement of the environment, particularly in aspects such as packaging, waste and residues final disposal; and to support CANIFARMA's efforts to promote and develop a clean and social responsible industry.

12. OTHER CHAMBERS AND ASSOCIATIONS

To support the administrative authorities of other pharmaceutical chambers or associations participating in the pharmaceutical industry in the establishment of the proper procedures and control measures, in order to verify that the members linked to them comply with the laws applicable to their activities and with the codes of ethics formerly approved by them.



Art. 8. All Members shall accept to share information related to the Pharmaceutical Industry, within the defined limits of the law and provided that it is not considered confidential or restricted and can be shared extensively by all the Members.

The information disclosed is for the sole benefit of the Members and will not be revealed or exposed to third parties that are not members of CANIFARMA, unless authorized by the Council of the referred Chamber.

Members shall try to promote training activities in order to maintain the professionals and technicians of the Pharmaceutical Industry and health-related companies updated in the areas of their practice, and able to transmit to their students the latest knowledge and skills on the field, both in theory and in practice.

Members involved in a training activity shall always emphasize the following subjects for the benefit of the new professionals and the Pharmaceutical Industry:

- a) Commercial practices based on loyalty and free competition.
- b) Fight against corruption.
- c) Respect of intellectual property.
- d) Ethical and transparent management.



Art. 9. Members who are able to participate in training activities or curriculum planning are compelled to supervise that the new generations receive full training in the different fields of the Pharmaceutical Industry and respond to the work requirements of the market.



Art.10. Any Member who has not complied with the provisions stated in this Code of Ethics and those established in the deontological instruments approved by CETIFARMA, will be subject to a sanction imposed by CETIFARMA.

Art. 11. The seriousness of the alleged violation will be evaluated prior to the imposition of the sanctions, depending on the impact of the breach over the users' health and over the reputation and stability of the activity of the Pharmaceutical Industry and its members, and on the responsibility of each company involved.

All sanctions must be justified and sustained.

Art. 12. Sanctions may consist of:

- 1. A reprimand.
- **2**. A financial penalty.
- 3. Temporary suspension of Member's Rights.
- 4. Permanent suspension or expulsion.



Art. 13. In order to initiate an investigation procedure against a Member, the complainant will submit a complaint to CETIFARMA. Nevertheless, this Council may proceed to investigate ex-officio any possible breach, when deemed appropriate.

Art. 14. The complaint of a possible breach or infringement of the provisions of this Code and other deontological instruments approved by CETIFARMA may be submitted by any Member, via the Chief Executive or managing director of the company, the Health Authority through its representatives or officials, health care professionals and consumers. The complaint must abide by the proceedings developed by CETIFARMA for this purpose and meet the requirements established in CETIFARMA's internal regulations.

Art. 15. Complaints must be submitted to the Council of Ethics and Transparency (CETIFARMA).

The complainant will sign under oath a written complaint that includes at least the following information:

- For members, or representatives of the health authorities and institutions: company name and address, telephone numbers and email address.
- For health care professionals: name, copy of the professional license, address, telephone numbers and email address.
- For consumers: name, address, telephone numbers and email address
- Name and address of the reported company.
- Provisions of the Code of Ethics and/or of other deontological instruments allegedly infringed and, if appropriate, the rules, regulations and standards applicable in the case.
- A summary of the documents and infringement evidence and all other relevant information supporting the case.

Art. 16. Once this complaint has been submitted, CETIFARMA's members, in plenary session, will proceed to review the report and one member will be appointed to study the case and to gather sufficient evidence, in order to present, in the shortest term, a detailed report to CETIFARMA. The report will include the reasons why the complaint was accepted and the evidence that was submitted, as well as the necessary arguments and legal grounds to dictate the respective ruling.

CODE OF ETHICS AND TRANSPARENCY

CETIFARMA's constituents are bound to protect absolute confidentiality on the matters revealed to them in the exercise of their duties; they must avoid disclosing any information related either to the complaint or to the parties involved. The complainant and the respondent are also compelled to confidentiality during the examination procedures and until CETIFARMA's ruling of the complaint.

Art. 17. The respondent Member has the right to a hearing by the Executive Director and/or to attend to one plenary session of CETIFARMA, prior notification of the motives of the accusation, to be able, within the term of ten working days, to prepare his appeal and file the supporting evidence to prove his innocence; on the assumption that, if he does not submit his response and evidence in the term stated above, he will be deemed to have lost his right, and therefore, to have accepted the facts and/or conducts as charged.

Art. 18. The information provided by the parties during the complaint's examination procedures cannot be used as proof in other instances.

Art. 19. Once these stages have been completed, including the defendant's right to a hearing and his right to appeal, CETIFARMA will dictate in plenary session the pertinent ruling which is final and conclusive.

CETIFARMA will determine the terms and conditions of ruling disclosures.



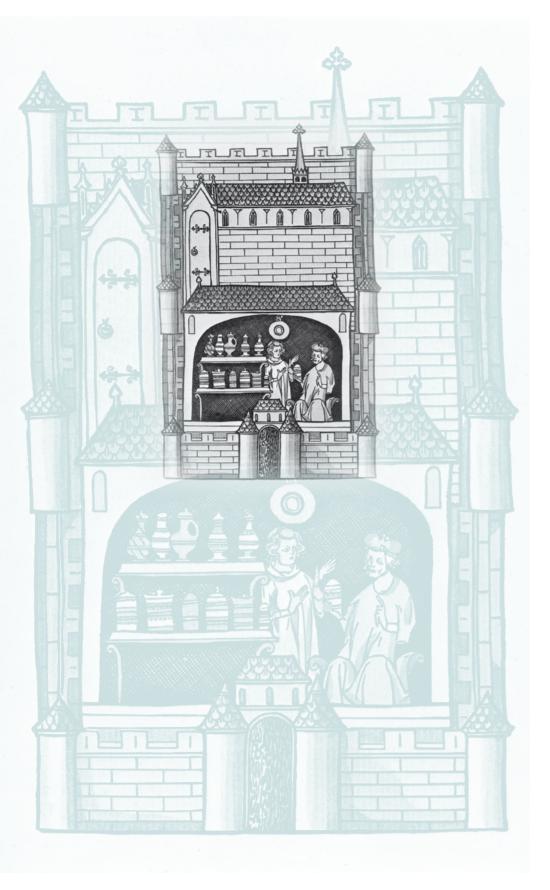
Art. 20. CETIFARMA will always act within the boundaries of plurality, tolerance and respect for diversity. It is the body in charge of:

- a) Promoting and sustaining the enforcement of the provisions of this Code and other self-regulatory and self-monitoring instruments in regard to the conduct of its Members, with random verifications of its proper implementation.
- **b**) Supervising congruence between the company's internal procedures and the provisions of the Code of Ethics and any other deontological instrument issued by CETIFARMA.
- c) Receiving complaints about alleged breaches of the codes and other selfregulatory instruments approved by CANIFARMA and CETIFARMA.
- **d)** Imposing corrective or preventive measures as well as sanctions designed to the specifics of the present Code and other deontological instruments.
- e) Making a proper interpretation of this Code.
- f) Advising members facing unjustified complaints.
- g) Acting as a mediator in the resolution of disputes that may arise in the practice between or against the Members.

This Code of Ethics was updated and approved on September 23, 2009, by the Council of Ethics and Transparency of the Pharmaceutical Industry established in Mexico (CETIFARMA).

CODE OF ETHICS AND TRANSPARENC





CODE OF GOOD PROMOTIONAL PRACTICES



Responding to the changes that have taken place in the world and the community, the Pharmaceutical Industry established in Mexico engaged, since the mid-nineties, in activities to promote the capacity of the pharmaceutical companies to meet, not only the market's needs, but the particular requirements of the Mexican society, in order to advance in the development of ethical and responsible practices. These practices aim to fulfill the need to strengthen compliance with law and transparency in their activities, thus contributing to the construction of justice and equity for the well-being of the Mexican people.

These practices were also designed to instrument the agreements and covenants that CANIFARMA has subscribed over time with the Mexican health authorities, in the promotion of auto-regulatory measures concerning institutional advertising (08-31-04) and medicine promotion (12-19-03), among others.

The Mexican Code of Good Promotional Practices (CBPP) was developed in accordance with the above mentioned considerations and acknowledging other national and international initiatives, particularly the ones undertaken by FARMAINDUSTRIA of Spain, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), who's Codes comply with the standards in this field. The Code is based, among other standard-setting instruments, on the provisions established by the Code of Ethics and Transparency of the Pharmaceutical Industry (Chapter III Art. 6, Chapter IV Art.7 numbers 1, 2, 3 and 7, Chapter V Art. 8 paragraphs a, b, c, and d, Chapter VI, Chapter VII and Chapter Viii), approved March 31, 2005 in General Assembly, and contains the principles of behavior that define the proper conduct and values in terms of honesty, transparency, veracity, fairness and responsibility. Additionally, other concepts and practices are defined in order to foster ethical and socially responsible behavior in all their activities, including research, development, manufacture, distribution promotion and distribution of medicines, health auxiliary materials and diagnostic systems.



1. PURPOSE OF THE CODE OF GOOD PROMOTIONAL PRACTICES (CBPP)

1.1 PURPOSE

To define the principles of behavior that provide a framework, within an ethical context, to the relationship between the pharmaceutical companies associated to CANIFARMA and those adherent to this Code, with the health care professionals, in order to ensure that: their promotion practices and their support to training programs, courses and scientific events do not exert undue influence on the medical judgment in medicine prescription.

1.2 OBJECTIVE

To establish standards for the ethical promotion of pharmaceutical products, health auxiliary materials, diagnostic systems and reagents aiming to promote the transparent interaction of the companies with the health care professionals, without obstructing the exchange of medical and scientific information or the organization of academic and promotional events, which have to be undertaken in compliance with the provisions prescribed by this Code.



This Code defines a behavioral framework for the promotional activities undertaken in Mexico by pharmaceutical companies or by Mexican companies established in foreign countries, where their representatives interact with the authorities or other health care professionals, by promoting medicines, dispensing medical samples or sponsoring professional or scientific events. It also considers the promotion of a rational use of medicines, incentive and hospitality management and support of clinical studies based on universally accepted ethical principles. The purpose of promotion directed towards the health care professionals is to provide information about medicines with a valid sanitary registration certificate, enabling them to decide freely about their use, based on their ethical responsibility.

2.1 FOR THE PURPOSE OF THIS CODE, THE FOLLOWNG TERMS MEAN:

- Promotion: an activity undertaken, organized or sponsored by a pharmaceutical company or under its authority (subsidiaries, foundations, associations, institutes, agencies, etc.) which supports prescription, dispensing, sale and acquisition or administration of its medicines, complying with applicable rules, regulations and standards.
- Health care Professionals: professionals in the fields of medicine, dentistry, pharmacy or nursing, authorized to prescribe, recommend or administer a pharmaceutical product.
- Pharmaceutical Product: a product with a valid sanitary registration certificate which is to be used by prescription order from a health care professional and applied for prevention, diagnosis and treatment of human illness.
- Medical sample: a presentation of a pharmaceutical product in accordance with the prevailing laws and regulations, which is to be offered to the health care professionals directly and freely and in reasonable amounts, with the sole purpose of letting them know and be familiar with such products and/ or to initiate treatment. Medical samples must not be commercialized in any form.
- Hospitality: supports that do not exceed the cost that health care professionals would be willing to absorb by themselves in similar circumstances, including: payment of round-trip travel expenses, lodging, meals, and eventual registration fees. These aids will be provided to health care professionals but will not be extended, under any circumstance, to accompanying persons.

The companies affiliated to CANIFARMA and its adherents must comply with the letter and spirit of this code, sustaining the same standards of behavior in their relationship with health care professionals, regardless of the place or conditions.



3.1 PRINCIPLES

This code seeks to assure that CANIFARMA, as a self-regulating entity, establishes the behavioral standards that will govern its members relationships with the health institutions and health care professionals, including the interactions with physicians, nurses, pharmacists and professionals in charge of the administration, prescription, purchase or recommendation of prescription medicines, to ensure transparency in the promotion of medicines and compliance with the ethical principles and the prevailing laws and regulations, particularly within the relation of the industry with the patients and their organizations.

3.2 PRECEDENCE OF THE RELASHIONSHIP BETWEEN PATIENTS AND HEALTH CARE PROFESSIONALS

Relationships between the pharmaceutical industry personnel and the health care professionals should encourage the development of a medical practice committed with the patients' well-being, based on truthful and accurate information, tested and up-to-date scientific evidence, in order to contribute to the appropriate use of the medicines that have been certified by the Health Authorities.

3.3 SOCIAL RESPONSIBILITY AND COMPLEMENTARITY

Health protection and access to quality health-care systems are fundamental responsibilities of governments, however, collaboration of all the parties involved (industry, health care professionals, pharmacies and patients) is a requirement to succeed. Acknowledging the current effort of society to encourage the development of companies with ethical values and good practices, the Pharmaceutical Industry has committed itself: to promote new medicines for the prevention, treatment or cure of illness; to work with the authorities in order to guarantee that the medicines and the information provided to patients and health care professionals, contributes to develop the autonomy and the capacity for decision-making of the physicians and population in general, in order to enforce credibility and competitiveness.

3.4 TRANSPARENCY

- a) Promotional activities must not disguise their purpose or true nature.
- b) All promotional material of medicines, health-related material and their use, sponsored by a pharmaceutical company, must clearly indicate the sponsorship's provider.
- c) Clinical evaluations, trials, after-sales experience programs and studies subsequent to authorization, must not be confused with promotion. Such evaluations, programs and studies should be undertaken with a scientific or educational aim and abide by universal ethical principles.
- d) Interactions of the Pharmaceutical Industry with the health care professionals can create conflicts of interest in the provision of samples, training opportunities, invitation to meetings or other promotional activities; in situations of doubt or uncertainty, CETIFARMA will be the regulatory body responsible for the guidance on professional behavior standards, within the scope of its jurisdiction and in compliance with the Code of Ethics and current regulations.
- e) The relationship with the regulatory bodies' staff must strictly abide by the current laws and standards and with the principles established in the Code of Ethics and Transparency of the Pharmaceutical Industry, and should not influence unduly the decision-making process.
- f) Laws, regulations and deontological codes applicable to the pharmaceutical field should be observed in all circumstances. Before preparing materials or undertaking promotional activities, the companies are responsible for the verification of local requirements and of making sure that they also comply with the codes of ethics of the pharmaceutical companies themselves.



4.1 MEDICAL INFORMATION

The medical and scientific departments of the laboratories affiliated to CANIFARMA and those adhering to the codes must assure that the information provided to the health care professionals is accurate, balanced, fair and objective and sufficiently complete to enable the recipients to form their own opinion of the therapeutic value of the medicine.

Laboratories must take scientific and moral responsibility for the content of the information provided. If outsourcing companies participate in the information process, laboratories will be the ones responsible to ensure these companies comply with this code. This is a non- renunciable responsibility.

Therefore, the following guidelines must be met:

4.1.1 Information and/or graphic materials must be accurate, factual, up-to-date, and strictly scientific, and conform to current legal and regulatory standards. Ambiguities or exaggerations should be avoided by all means.

4.1.2 Information must be grounded on scientific evaluation and related empirical evidence that must be kept at the disposal of the health care professionals, if required. It must not induce confusion by means of distortion, unjustified pressure, omission or any other mean.

4.1.3 When scientific information is provided and is not part of the prescribing information duly approved or authorized by the sanitary registry of the Ministry of Health, it should be strictly limited to a scientific audience, avoiding the promotion, directly or indirectly or through a third party, of any unauthorized directions of use.

4.1.4 All promotional material, including advertising in printed, audiovisual or electronic media, must be legible and in strict accordance with the terms established in the sanitary regulation issued by the corresponding authorities and with the ethical principles included in the Code of Ethics and Transparency of the Pharmaceutical Industry Established in Mexico.

4.1.5 Graphic material must be adequately presented so that the topics treated can be readily understood. Particular care should be taken with the promotional graphic material to ensure it is not misleading as to the nature of a medicine. Claims or comparisons shall not be included unless scientifically tested.

4.1.6 Internet promotion of prescription medicines addressed to health care professionals must be duly approved by the corresponding authorities. It must clearly identify the sponsoring pharmaceutical company and be disclosed in scientific websites. Companies must adopt the proper measures to ensure promotion of prescription medicines in their websites will only be accessible to health care professionals.



4.1.7 Information or claims about side effects must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no adverse or side effects.

4.1.8 When promotional material refers to published studies, these must be faithfully reproduced or clear references must be given enabling an easy accessibility. A faithful reproduction is one that reflects the full meaning and content of the original source in an objective manner, without adding or excluding any information that could mislead or confuse the recipient.

4.1.9 As an example of this, when the effectiveness and safety of different active principles are compared for advertising purposes, information such as the statistical appraisal of the results must not be omitted. Statistics, conclusions, or any other data derived from different studies using different methodologies, must not be mixed or compared, unless resulting from systematic reviews or meta-analysis where the homogeneity criteria is specified. Adaptations that may introduce bias or induce confusion are unacceptable.

4.1.10 Exaggerated claims that a product or a substance has special properties are only acceptable if they can be sustained and are included in the authorized registry.

4.1.11 The expression "new molecule" must not be used to describe a medicine that has been available or generally promoted for more than two years in Mexico.

4.1.12 All information, claim or comparison included in the promotional material must be substantiated and fair. Particularly, any comparison between different medicines must be scientifically sustained and must comply with the regulations of fair competition standards. It must not be denigrating and comparisons must be grounded on equivalent elements and relevant evidence.

4.1.13 Product trademarks of other companies can only be mentioned when the trademark's ownership is unequivocally indicated.

4.2 PROMOTIONAL ACTIVITIES

Promotion of medicines among health care professionals and authorized information to be disseminated among the general public is limited to those medicines certified and authorized by the Mexican authorities, complying with the corresponding rules and standards. As for prescription medicines, it must contain information about their use, safety, efficacy and other aspects of the clinical profile of the products. Particularly, the information must disclose the benefits and contra-indications, side effects and main warnings related to its use, avoiding any misleading claim or exaggeration.

Promotional activities directed to health care professionals should help them sustain their therapeutic decisions. Therefore:

4.2.1 Promotion can be complementary and must be compatible with the national health policies and has to comply with the regulations and standards in effect.

4.2.2 Promotional activities in which information of specific medicines is provided to health care professionals must comply, with the provisions of the Ministry of Health (Secretaría de Salud); companies should avoid presenting these activities as academic events, according to the terms of paragraph 4.6 of this chapter.

4.2.3 All activity or promotional material must recognize the specific nature of medicines and the characteristics of the target audience, and must not cause offense or reduce confidence in the pharmaceutical industry.

4.2.4 Promotional material must not imitate the products, messages, presentation or general layout adopted by other companies in a way that is likely to mislead, lure or confuse, or encourage unfair competition.



4.2.5 All material related to medicines and their use, which is sponsored by a pharmaceutical company, must clearly reveal the sponsors data.

4.2.6 When a company, directly or indirectly, finances, sponsors or organizes the publication of promotional materials in journals or magazines, it must be expressly stated that this material is not presented as an independent editorial matter and the sponsorship of the company must be clearly displayed.

4.2.7 Material related to medicines and their uses, whether promotional or not, which is sponsored by a pharmaceutical company, must clearly indicate that it has been sponsored by that company.

4.2.8 Quotations from medical and scientific literature or from personal communications must faithfully reproduce the view of the author.

4.2.9 All data obtained from papers presented in meetings, or from research reports that are transmitted on radio, television or any other media on behalf of a pharmaceutical company, must not be used without the formal permission of the authors and/or sponsors, and must clearly display their name.

4.2.10 Under no circumstances, can promotional material be distributed in a final version, to which no further amendments will be made, if it has not been certified and authorized by the medical authorities of the laboratory and the person in charge of confirming its compliance with the Codes. These authori-

ties must certify that the material's final form has been examined: that it abides by the provisions of this Code and by the applicable standards on advertising practices; that it complies with commercial authorizations and, in particular, with the information of the sanitary registry in effect. Presentations must be true and faithful to the medicine's stated characteristics.

4.3 PROMOTION OF THE APPROPIATE USE OF MEDICINES

Promotional activities directed towards consumers must be undertaken with the aim of generating a new culture in regard to rational and appropriate consumption of medicines, encouraging the guidance of health care professionals authorized to prescribe. Therefore, promotional campaigns should tend to:

4.3.1 Discourage self-prescription and product recommendations among consumers.

4.3.2 Promote respect for the physician's prescription in terms of proper dosages and methods of use.

4.3.3 Respect the procurement and supply procedures of prescription medicines, if required by law.

4.3.4 Respect the physician's prescription of a specific product, in such a way that the pharmacy employee is not induced to modify it for the benefit of a particular company.

4.3.5 Inform the patient or consumer about the properties of the medicines he/she is using, of the importance of concluding the treatment prescribed by the physician, and about the risks of substituting the prescribed medicine for another one, without knowledge and proper medical supervision.

4.3.6 Laboratories must appoint a person responsible for pharmacovigilance matters in order to compile, collect and analyze all the information provided by the medical representatives or any other source, concerning doubts and side effects of the medicines they commercialize. They will encourage collaboration with the National Pharmacovigilance System (Sistema Nacional de Farmacovigilancia) among prescribers. When requested, they will make the pertinent information available to the health authorities and the health care professionals.

Companies must present annually, on the month of December, a listing of the adverse events reported to the sanitary authorities; this report will be presented in the format designed by CETIFARMA. The written evidence of the reports will remain in possession of the companies.

4.4 MEDICAL SAMPLES

In compliance with current laws and regulations, medical samples are presentations of pharmaceutical products, provided directly, in fair amounts and without cost to health care professionals, so that they may get to know and be familiar with the products and/or in order to initiate a treatment. Commercialization of medical samples is prohibited. Therefore, companies must comply with the provisions of the General Health Law (Ley General de Salud) and its regulations as well as with the following guidelines:

4.4.1 Samples of a product may not be offered or supplied with the aim of seeking or rewarding prescription practices.

4.4.2 Samples may not be sold, purchased or commercialized in any form and, therefore, must have a "not for sale" label clearly displayed. Non-compliance with the aforementioned conditions will be reported to CETIFARMA who will proceed in accordance with the provisions of the Code of Ethics. Samples must not be used as gifts or provided to health care professionals for other purposes than a free provision to their patients.

4.4.3 In accordance with the provisions defined in international agreements and determined by the national health authorities, provision of medical samples containing psychotropic or narcotic substances is forbidden.

4.4.4 Companies must have thorough and up-to-date control of their samples, including their manufacture, storage, delivery to regional coordinators or others, and provision to medical representatives and physicians. Adopted measures on this matter will be reported to CETIFARMA who will proceed, in due time, to the corresponding evaluation and verification.

Any deviation identified by the company must be reported to CETIFARMA in order to be informed, in due time, of possible misuses.

4.4.5 Mailing lists for the delivery of promotional material must be regularly updated. Requests by health care professionals to be removed from such lists must be complied with.

4.4.6 Provision of medical samples to hospitals and physician offices must respect the General Health Law (Ley General de la Salud), its regulations, and the agreements and laws established for this purpose.

4.4.7 Pharmaceutical companies must appoint a professionally qualified person to supervise compliance with the provisions of this chapter.

4.5 PHARMACEUTICAL STAFF

The primary role of medical representatives is to provide information about the properties and characteristics of the pharmaceutical products in order to inform and promote their proper use for the patients benefit. Medical visits enable to:

4.5.1 Provide detailed information to the health care professionals for which the pharmaceutical company takes full responsibility.

4.5.2 Respond to the health care professionals' questions and offer the specific information they request to extend their knowledge of the medicines.

4.5.3 Obtain all comments or observations of the physicians on the use of the medicine, concerning side effects or any other topic.

The activities of medical representatives imply the responsibility of the laboratories and therefore:

4.5.4 Medical representatives must be given adequate training and maintain ethical standards in the exercise of their duties in order to assist health care professionals.

4.5.5 Laboratories must provide permanent training to the medical representatives both in terms of the products and the ethical handling of scientific information.

4.5.6 Medical representatives must respect the prevailing laws, the ethical principles and the provisions of this Code.

4.5.7 Laboratories must ensure that medical representatives do not offer incentives or accept any undue conditioning factor in order to facilitate their activity.



4.5.8 Laboratories must ensure that the frequency and timing of the medical representatives' visits to health professionals is sufficient and adequate for information purposes.

4.5.9 No conditions should be imposed or donations requested, either directly or indirectly, for the medical representative's access to the health care professionals. Even if the support of scientific actualization is one of the activities of the pharmaceutical industry, such support must not be provided as a condition of access to health care professionals.

4.5.10 Representatives of the Pharmaceutical Industry working with pharmacies are bound to abide by the provisions of this Code.

4.5.11 When a medical representative adopts unethical conducts, the company must apply immediate corrective measures.

4.6 ACADEMIC EVENTS

Congresses, lectures, symposia, meetings and similar scientific or educational events, sponsored by pharmaceutical companies or by any other third party financed or supported by them, must have, as a main purpose: scientific exchange, medical education an/or information about medicines.

Whenever support for continuing education or independent educational programs is being provided, education of health care professionals should be encouraged, primarily, to improve their knowledge on patients care. In each

COOD

ЧO

PROMOTIONAL PRACTICES

case, programs must comply with the guidelines of the applicable laws; they must have a strict scientific content sustained, if required, on clinical evidence; and, most important, they must be accredited and certified by the corresponding academic authorities.

Support in general will not be offered, under any circumstance, in order to have any kind of influence on the decision-making to prescribe medicines or to buy, include, exclude or modify the official product catalogs.

Therefore:

4.6.1 These events must be directed only to health care professionals, medical researchers and/or experts, directly related to the topic of the event; they must be held in proper venues, consistent with the main purpose of the meeting; and no entertainment, sport or leisure activity should prevail over scientific activities, which should occupy, at least, 80% of the scheduled time. Pharmaceutical companies must request from the professional health associations or organisms the application of mechanisms ensuring that event participants will remain in the location and respect the schedule of the academic activities.

4.6.2 A proper venue is one that facilitates academic or informative purposes, avoiding ostentatious settings or places considered mainly as entertainment sites.

4.6.3 Pharmaceutical companies may provide proper hospitality to health care professionals, medical researchers or experts participating in the event, but not extend it to persons who are not involved with the meeting's topic. No financial aid or any other kind of support will be provided to these persons.

4.6.4 The concept of proper hospitality includes the reasonable cost or payment of round-trip travel expenses, lodging and meals and eventual registration fees.

4.6.5 The hospitality provided will be the same for national residents and foreigners; it will be limited to the time period established for the development of the event, and must not be extended to other activities that do not relate to the meeting's topic.

4.6.6 Pharmaceutical companies shall not offer support or sponsor activities unrelated to the academic field.

4.6.7 Funding and support in kind, granted by the Pharmaceutical Industry for continuous education medical programs, must be exclusively designated for scientific and academic purposes.

4.6.8 Pharmaceutical companies may grant financial aid or scholarships to a health care professional in order to attend scientific or educational events, in accordance with the health institutions where these professionals develop their activities.

4.6.9 Under no circumstances funding will be offered to induce health care professionals to use, prescribe, buy or recommend a specific product, or to influence the results of a clinical study. The same criteria may be applied to independent educational programs funding.

4.6.10 Direct or indirect payments shall not be made to physicians or health care professional associations for the promotion of events with no academic or educational purpose (e.g. board meetings).

4.6.11 The payment of reasonable fees –according to the market indicators for this purpose- and reimbursement of out of pocket expenses for speakers at meetings, congresses, symposia and similar professional or scientific events, are permissible.

4.6.12 When pharmaceutical companies are sponsoring meetings, congresses, symposia and similar events, it should be mentioned in all the documents relating to the meeting, and in any published paper, abstract or document related to such meetings.

4.6.13 When pharmaceutical laboratories or third parties organize or sponsor scientific and/or educational events, CETIFARMA must be notified by them, in due form, at least two months prior to the event.

CETIFARMA may verify, if required, that the development of an event complies with the provisions of this Code. Non-fulfillment of this stipulation will be considered as a breach to the present Code.

4.6.14 No pharmaceutical company may organize or sponsor events outside the country directed to health care professionals residing in Mexico, unless:a) More than 80% of the invited health care professionals come from abroad

and the prospective venue is more convenient for the majority of the participants.

b) Justified motives exist in terms of security or costs.

In these cases, this Code must be respected, as well as the specific legal provisions applied by the host country.

4.7 CONTRACTING HEALTH CARE PROFESSIONALS AS CONSULTANTS

4.7.1 Accredited health care professionals may be contracted on a consultancy basis to provide their support and scientific knowledge, such as: helping in the development of medical products; participating in clinical studies or other research; giving lectures in presentations for the sales departments, in meetings, or to train laboratory staff.

4.7.2 Remunerations to health care professionals must not exceed the market value of the services provided. The location and circumstances of a consultants meeting must be consistent with the consultancy services provided.

4.7.3 Laboratories will only pay for reasonable out of pocket expenses, incurred individually by the consultant attending a scientific conference or a third party's meeting, in their capacity as health care professionals or in representation of a laboratory. Under no circumstances, health care professionals, whatever their accreditation is, will be contracted in order to induce the use, prescription, purchase or recommendation of a specific product or to influence the results of a clinical study.

4.7.4 Government employees or staff from regulatory bodies must not be assigned for consultancy services when a conflict of interest is involved.

4.7.5 Pharmaceutical companies must compel health care professionals contracted as consultants to disclose this activity, to avoid conflicts of interest.

PROMOTIONAL PRACTICES

ЧО

CODE

4.8 SERVICES PROVIDED BY HEALTH CARE PROFESSIONAL ORGANIZATIONS

Contracting scientific societies, organizations or associations integrated by health care professionals in order to provide services to a pharmaceutical company will only be permitted when:

a) the aim is to collaborate in research or academic activities or the organization of professional or scientific events; any other activity that does not respond to this purpose is not permitted;

b) it does not induce to the recommendation, prescription, purchase, supply, sale or use of specific medicines or influence the result of a clinical study.

4.9 INCENTIVES AND GIFTS RELATED TO PRACTICE

4.9.1 No gifts of significant commercial value may be offered to health care professionals, or incentives of any kind as an inducement to use, prescribe, purchase or recommend a specific product or influence the results of a clinical study.

4.9.2 No gifts, bonuses, pecuniary advantages, benefits in kind, or any sort of incentive may be offered or promised to health care professionals administrative staff or government employees involved in the cycle of prescription, purchase, distribution, dispensing and administration of medicines, except in the case of inexpensive promotional aids related to the practice of medicine or pharmaceutical activities. An inexpensive promotional aid means one which does not exceed the equivalent of ten times the current minimum daily wage applied in Mexico City.

Nothing may be offered or provided under conditions that may influence health care professionals' prescription practices.

4.9.3 The provision of objects such as books or material on optical, magnetic, electronic support and scientific material is accepted provided their commercial value does not exceed overall the equivalent of fifty times the minimum daily wage.

4.9.4 Medical equipment donations are part of the social responsibility activities of the company; they must not be associated to promotional practices and have to be properly channeled by the institution.

4.9.5 According to their guidelines, companies will make available to the public, information concerning the donations granted in order to promote transparency.

4.10 STUDIES

They include clinical research, understood as an intervention activity in which health care professionals, as well as patients and healthy volunteers, are involved. They should be conducted in accordance with the research protocols abiding by the international and national standards, and with support of the corresponding ethical committees.

In order to promote the participation of health care professionals and

health institutions in clinical studies and research, employees of the pharmaceutical industry must adhere to the following requirements:

4.10.1 To obtain formal and free consent from the persons subject of research.

4.10.2 To present evidence that the protocols and research have been authorized by the authority and the independent ethical and research committees, and that they comply, at the least, with provisions of the Nuremberg Code, the Declaration of Helsinki, the Belmont Report, the Universal Declaration on Human Rights and Bioethics and the corresponding regulations in Mexico.

Accelerated clinical experience research and phase IV projects must be approved internally by the medical director in order to assure that the benefits for the participants will be superior to the risks.

4.10.3 To provide accurate and unequivocal information about the risks and benefits involved when participating in such studies.

4.10.4 To assure that the study groups are constituted without taking advantage of the population in vulnerable conditions. Moral pressure must not be exerted, and undue material compensations to obtain consent from participants must be avoided.

4.10.5 To provide information on the positive and negative results of the research, particularly concerning adverse side effects.

4.10.6 When results are being published in specialized or widespread distribution magazines, pharmaceutical companies will request from the authors to disclose the presence or absence of conflict of interest.



5. AWARD FOR THE DEVELOPMENT OF TRANSPARENCY AND SOCIAL RESPONSIBILITY IN THE PROMOTION OF MEDICINES OF THE PHARMACEUTICAL INDUSTRY IN MEXICO

Members participating in subsequent programs of evaluation and accreditation of standards adopted in order to comply with the provisions of this Code, may initially obtain an award for their compliance with specific processes and, in a second stage, obtain their certification as a Company with Transparent Practices.

Awards will have a two-year period of validity, after which they must be ratified; certifications will be valid for three years and will also be subject to ratification.



6.1 Pharmaceutical companies affiliated to CANIFARMA and those that abide by the Code of Ethics and Transparency issued by the referred Chamber agree to comply in their promotional activities with its principles and criteria.

Companies affiliated to CANIFARMA or abiding by its codes will respond for possible infringements to this Code, committed by third parties acting on their behalf or representation.

6.2 Furthermore, in their capacity as companies established in Mexico, they will continue to comply with the provisions of: the General Health Law (Ley General de la Salud), the Health Products Regulation (Reglamento de Insumos para la Salud) and its applicable standards, the Regulation on Advertising (Reglamento en Materia de Publicidad) and the Pharmaceutical Industry Code of Ethics and Transparency (Código de Etica y Transparencia de la Industria Farmaceútica).



6.3 If a conflict should take place between the rules of the different codes, applicable in a given promotional activity, the strictest standard will prevail, and if any controversy should arise, CETIFARMA must be notified.

6.4 The Executive Director of CETIFARMA is responsible of monitoring compliance with the provisions of this Code, and will provide periodical information to its Council and CANIFARMA's Executive Council.

6.5 Companies that are subject to the provisions of this Code agree to submit initially to CETIFARMA any eventual complaints regarding promotional practices of other companies associated to CANIFARMA.

6.6 Both the complainant and the respondent companies agree to preserve the confidentiality of the complaint, and any other relevant information, until the resolution of the conflict has been ruled by CETIFARMA.



7. BREACHES AND SANCTIONS

7.1 Breaches will be classified as minor, serious and very serious based on the following criteria:

- If the nature of the breach harms the relationship between associates and/ or adherents.
- **II**. If the nature of the breach implies a potential risk for the patients health.
- **III**. If the breach has an impact on the medical profession and the scientific credibility of the resulting practice.
- IV. If the reputation of the Pharmaceutical Industry is affected.
- V. If it leads to unfair competition.

7.2 Once the breach has been ruled, the following aggravating and attenuating circumstances must be taken into account:

Aggravating:

- a) Degree of intentionality.
- b) Disregard to previous warnings.
- c) Recidivism.
- d) Concurrence of several breaches in the same act of infringement.

- e) Financial benefits for the laboratory derived from the breach.
- f) Damage to another laboratory.
- g) Analogous practices to the ones denounced, failing to follow the principles of honesty and truth.

Attenuating:

- a) Adoption of corrective measures prior to the complaint or during the examination procedures.
- b) Opportunity in the collection of evidence.
- c) Prompt response to CETIFARMA's requirements.

7.3 According to the seriousness of the infringement CETIFARMA will decide from the imposition of an admonition to monetary sanctions.

7.4 CANIFARMA will execute the imposed sanctions and will abstain from participating in the proceedings undertaken by CETIFARMA for this purpose. CANIFARMA may decide, if appropriate, to notify to the Health Authorities a member's recurrence of serious or very serious breaches. This will be decided by the General Assembly. In case of contempt to a resolution, CETIFARMA will notify CANIFARMA's Board of Directors, which will proceed according to its regulations. The separation of this affiliate from CANIFARMA will be decided in General Assembly.



8. ADMISSION PROCEDURES OF COMPLAINTS AND RULING OF INFRINGEMENTS

8.1 ON THE ADMISSION OF COMPLAINTS

8.1.1. Reception and admission of complaints due to infringements to this Code will take place in conformity with the provisions stipulated in Chapter VII, PROCEDURE FOR THE ENFORCEMENT OF SANCTIONS, articles 13 to 16, of the Code of Ethics and Transparency.

8.1.2 When a complaint has been admitted by CETIFARMA, the complainant must make a deposit to cover the administration fees which amount will be determined annually by CETIFARMA.

8.1.3 Once CETIFARMA has been notified of a potential infringement the examination procedures will proceed. In compliance with the provisions of CETIFARMA's internal regulations and depending on the complexity of the case an examination group will be designated.

8.2 ON INFRINGEMENT RULING

8.2.1 Once the examination group's submits a resolution, CETIFARMA will make an evaluation of the conduct, in order to determine the seriousness of the breach.

8.2.2 As established in Paragraph 7.1 of the Code of Good Promotional Practices of The Pharmaceutical Industry Established in Mexico, breaches may be minor, serious or very serious.

8.2.3 Minor breaches are those that affect the relation of affiliates and/or adherents.

8.2.4 Serious breaches are those that lead to a practice of unfair competition and affect the industry's reputation.

8.2.5 Very serious breaches are those where conducts may imply a potential risk to the patient's health, or affect the performance of the health care professionals, and the scientific credibility of the resulting practice.

8.2.6 Recurrence of any conduct will be considered, per se, as a very serious breach.

8.2.7 In the case of a minor breach, a financial sanction will be imposed that can attain from the equivalent of two thousand times to the equivalent of five thousand five hundred times the current minimum daily wage of the economic area involved.

8.2.8 In the case of a serious breach, a financial sanction will be imposed that can attain from the equivalent of five thousand five hundred times to the equivalent of ten thousand times the current minimum daily wage of the economic area involved.

8.2.9 In the case of a very serious breach, a financial sanction will be imposed that can attain from the equivalent of ten thousand times to the equivalent of twenty thousand times the current minimum daily wage of the economic area involved.

The Council of Ethics and Transparency of the Pharmaceutical Industry established in Mexico (CETIFARMA) approved the modifications to this Code on September 23, 2009.





CODE OF GOOD INTERACTION PRACTICES OF THE PHARMACEUTICAL INDUSTRY WITH **PATIENT** ORGANIZATIONS



In order to ensure and regulate an ethical, transparent and respectful relationship between the Pharmaceutical Industry and the Patient Organizations (PO), codes of good practices have been adopted, in the international sphere, since 2007. The Codes of the EFPIA, of Germany, Spain and Ireland were taken as reference.

The Pharmaceutical Industry established in Mexico recognizes the effort of organizations that support the patient's needs, and the potential of common work to improve health. The need of a behavioral framework to encourage transparency in the interaction with these organizations has also been acknowledged.

In this context, and in order to ensure a positive, constructive and mutually beneficial interaction with patient organizations, the Council of Ethics and Transparency of the Pharmaceutical Industry developed this Code with the purpose of establishing the ethic principles and guidelines that pharmaceutical industries, conforming CANIFARMA and adhering to CETIFARMA, are committed to comply.



The following principles must be applied in the relationship between the Pharmaceutical Industry and Patient Organizations.

- 1. Respect to the Patient Organizations autonomy and independence in the establishment of their policies and work programs.
- In all collaboration with patient organizations, diversity must be respected, exclusion practices must be avoided and work strategies mutually accorded.
- **3**. Supports from the Pharmaceutical Industry to PO must not be conditioned and promotion of medicines will not permitted.
- **4.** Objectives, scope and supports granted to PO must always be transparent and have to be disclosed on an annual basis.
- PO must not be used to induce prescription and incorporation or exclusion of medicines in official product catalogs and equivalent catalogs in the private sector.



This Code defines the guidelines to regulate relationships between the Pharmaceutical Industry established in Mexico and the patient organizations. Its content is based on universal ethical principles and respect of human dignity.



The Code covers the activities undertaken by pharmaceutical companies or their subsidiaries, foundations, associations, institutes, agencies or third parties linked to them, and from which collaboration of any kind may result in a direct or indirect manner.

PO are non profit institutions, representing and responding to the patients' needs, through different activities, such as supporting the care of the sick; searching therapeutical options; contributing to the formulation of health policies, and developing health information and promotion programs.



1. NO PROMOTION OF PRESCRIPTION MEDICINES

Based on the General Health Law (Ley General de Salud) and the Code of Good Promotional Practices of Medicines of the Pharmaceutical Industry established in Mexico (CBPP), promotion of prescription medicines directed to Patient Organizations is prohibited.

2. FORMALIZATION OF AGREEMENTS

2.1 Collaboration between pharmaceutical industries and PO must have in place a written agreement which will include, at least: the activities to be undertaken, cost, source and destination of funding; direct and indirect support and any other relevant non-financial aid.

2.2 Pharmaceutical companies comply to set forth criteria and procedures for the approval and implementation of this kind of collaborations.

2.3 In the formalization of agreements, companies will abide by their applicable guidelines, their codes of ethics and conduct, their transparent practices and the deontological instruments approved by CETIFARMA and CANIFARMA.

2.4 Any other kind of sponsorship provided by social, governmental or private sector organizations should not be excluded.

3. TRANSPARENCY

3.1 Pharmaceutical Industries, when required, must make available to CETIFARMA a list of the PO to which they provide financial or any other kind of support. This should include a short description of the scope and the nature of the rendered supports. CETIFARMA may confirm that these abide by the provisions of this Code if considered necessary.

3.2 Companies must ensure the implementation and application of supports granted and, in case an infringement is identified, they should proceed to correct it and notify CETIFARMA.

3.3 Companies shall adopt the necessary measures to ensure the accountability of the offered sponsorship.

3.4 Companies shall abstain from requesting to participate as sole sponsors of a Patients Organization.

4. EDITORIAL GUIDELINES

4.1 Pharmaceutical Industries sponsoring the elaboration and/or publication of Patient Organizations' material must not seek to influence the text in a manner favorable to their own commercial interests.

4.2 This guideline does not exclude the possibility of correcting eventual inaccuracies or material errors.

4.3 Sponsors must be clearly acknowledged in every publication supported partially or completely by one or several Pharmaceutical Industries.

5. USE OF LOGOS AND PATIENT ORGANIZATIONS PROPRIETARY MATERIALS

5.1 The use of a logo, insignia or proprietary material of a Patients Organization requires an explicit authorization from that organization.

5.2 Pharmaceutical companies seeking such permission must make a precise written request indicating the specific purpose and the way this material will be used as ell as the temporality agreed with the Patients Organization.

6. HOSPITALITY AND MEETINGS

6.1 Events sponsored or organized indirectly or directly by a company must be held in a proper venue that is conductive to the purpose of the event, avoiding those that are renowned for their entertainment facilities or considered ostentatious.

6.2 All forms of hospitality provided by the Pharmaceutical Industry to Patient Organizations shall be reasonable. The concept of reasonable hospitality is understood as the payment of round-trip travel expenses, lodging, meals, and eventual registration fees.

6.3 Companies must fund or defray these expenses only through Patient Organization and never to patients in an individual manner.

6.4 International events organized or sponsored in Mexico must comply with this Code.

7. CONSULTANCY

7.1 Companies abiding by this Code may ask CETIFARMA for guidance on its proper application.

7.2 Consults must be addressed to the Executive Secretariat of the Council of Ethics and Transparency (CETIFARMA) according with the procedure established in CETIFARMA's internal regulations.

8. APPLICATION OF THE CODE

8.1 Adhering companies complying with the Code of Ethics and other deontological instruments issued by CETIFARMA, are bound to respect this Code's principles and guidelines within their activities.

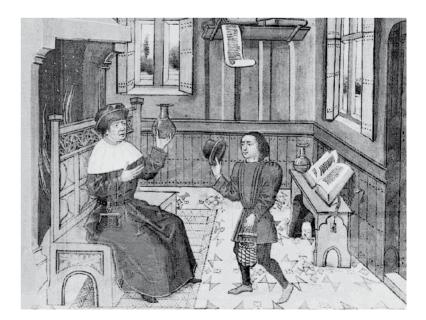
9. ENFORCEMENT

9.1 CETIFARMA will be responsible for the enforcement of the provisions established in this Code.

9.2 Therefore, companies abiding with the provisions of the Code are committed to denounce before CETIFARMA all contravening practices and abide by the corresponding rulings.

9.3 CETIFARMA's constituents, as well as the complainant and the defendant, commit themselves to preserve confidentiality during the complaint's examination procedures, avoiding any information disclosure on the matter of concern.

The Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) approved this Code on September 23, 2009.







PRESIDENT DR. Carlos Campillo Serrano

VICEPRESIDENT ING. Jaime Uribe de la Mora

EXECUTIVE SECRETARY DR. Juan Francisco Millán Soberanes

COUNCIL MEMBERS

ING. Benito Bucay Faradji SR. Oswaldo Gola ING. Rafael Gual Cosío ING. Julio Gutiérrez Trujillo LIC. Bruno J. Newman ING. Alfredo Rimoch Lewinberg DR. Manuel Ruiz de Chávez DR. Sergio Ulloa Lugo

MEMBER AD HONOREM sr. Rubén Aguilar Monteverde

ADVISOR DR. Juan Pablo Llamas Galaz

AV. CUAUHTÉMOC 1481, 3er. PISO, COL. SANTA CRUZ ATOYAC, DELEGACIÓN BENITO JUÁREZ, MÉXICO 03310 D.F. TEL/FAX (52-55) 5601-2865 cetifarma@canifarma.org.mx