

AGREEMENT FOR TRANSPARENCY IN THE RELATIONSHIP BETWEEN PHYSICIANS AND HEALTH CARE INSTITUTIONS WITH THE PHARMACEUTICAL INDUSTRY

PURPOSE

To establish a consensual framework of principles and actions in order to promote ethical relations between the pharmaceutical industry, physicians, healthcare institutions and sanitary authorities, thus contributing to the development of transparency for the benefit of patients, the medical profession, pharmaceutical development and research, and health in general.

SCOPE OF ACTION

This agreement defines, in the following four chapters, the main guidelines for the interaction between physicians and the pharmaceutical industry both on a private and a public level.

- i. Promotion and dissemination of information regarding authorized medicines.
- ii. Training and continuing education for physicians sponsored by the pharmaceutical industry
- iii. Studies and clinical research.
- iv. Appropriate use of medicines and respect to medical prescriptions.

ASSUMPTIONS

- Human beings are the main concern regarding health. Relations between the pharmaceutical industry and physicians should focus on security, treatment efficiency and financial protection of the patient.
- Cooperation between the medical profession and the pharmaceutical industry has always been essential to the different stages of development, appropriate use and prescription of medicines.
- Besides complying with the prevailing laws, the relationship between these two groups must be regulated by: ethical principles, a humanistic approach in the service to the patient, accuracy and scientific substantiation, professional independence, transparency, cooperation and social responsibility towards health as a universal value.
- The liberty to prescribe is related to the physician's responsibility and expertise, which implies that the use of therapeutic or diagnostic means must be preceded by the consideration of its scientific validity, its efficiency and its suitability for a specific patient, including considerations on the cost-benefit for the patient himself.

AGREEMENTS

i. **Medicine promotion and dissemination of information**

The pharmaceutical industry has the right to promote its products within the medical community. However, the independence of the physician to take decisions regarding the treatment must be guaranteed. Likewise, the content of promotional and information materials must be reliable, accurate and in strict accordance with the truth.

Hence all parties commit themselves to respect the following purposes:

Industry

- To expressly adhere to the Code of Ethics and Transparency of the Pharmaceutical Industry Established in Mexico and the Code of Good Practices in the Promotion of the Pharmaceutical Industry established in Mexico. As well as to support the activities assumed by the Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) and to comply with the provisions of its internal regulations.
- Provide honest and updated information regarding their products, with an accurate description of their advantages, disadvantages and counter indications, based on available scientific evidence.
- If a medicine is withdrawn from the market, it is the responsibility of the pharmaceutical company to provide reliable information of the motives this action to interested parties.
- Ensure that the medical representatives have appropriate qualifications and training.
- Refrain from promoting their products before obtaining the sanitary registration and the corresponding authorization.
- Abstain from offering gifts or benefits to physicians when not related to their medical practice. These are only allowed provided their cost does not exceed the limits established by the Codes of Ethics and Promotion of the Pharmaceutical Industry.
- Refrain from offering any kind of economic compensation to the healthcare institutions or medical associations, in order to facilitate the promotion of their medicines.

- Avoid misleading promotional strategies.
- Medical samples of authorized products may be supplied to physicians in strict compliance with the laws, regulations and self-regulating codes.
- Promptly update and disseminate relevant information concerning the pharmaco-vigilance of a product once it has entered the market.
- Encourage coordination with sanitary authorities in order to facilitate and increase efficiency in the pharmaco-vigilance operating system.
- Promote prescriptions of medicines by their generic denomination for the benefit of the patients.

Physicians

- No compensation from the industry shall be requested or accepted in order to favor the promotion, prescription or recommendation of a specific product.
- No promotional aids or expensive benefits shall be accepted if they are not related to their professional practice.

Public and private healthcare institutions

- Every institution, in accordance with its own laws, as well as the provisions presented in this document, shall establish regulations defining the framework for the promotional activities of the medical representatives in their facilities.
- Healthcare institutions that authorize promotional activities of medical representatives to their premises, shall refrain from claiming fees or any kind of support from the pharmaceutical industry as a condition to grant the access to their facilities.
- Promote coordination with the industry to help disseminate information, among the physicians, about the proper use of medicines according to institutional needs.

ii. Training and continuing education for physicians sponsored by the pharmaceutical industry

The pharmaceutical industry may organize and sponsor meetings for the healthcare professionals. These events must clearly respond to ongoing training purposes, or scientific actualization and dissemination, and must be authorized by the corresponding institutions. The pharmaceutical industry's participation in training and continuing education events for physicians must be transparent and grounded on the use of reliable scientific information.

Under no circumstances, physicians shall be compelled to prescribe the sponsor company's medicines by accepting funding to participate in an event for academic, scientific actualization or dissemination, or any other purpose.

The dissemination of information or support materials for such events must clearly express if their purpose relies on promotional or educational motives. In the case of educational events, their content must be endorsed by an academic institution.

Industry

- The industry may sponsor fees to speakers, material aids and facilities where an event takes place. Furthermore, travel expenses may be provided to the participants but shall not be extended to persons uninvolved with the meeting's topic.
- The context of the event must be consistent with its academic, scientific or informative purpose and payment of unjustified travel expenses must be avoided.
- Sponsorship during these trips must be strictly related to the meeting's purpose. Funding should not be extended to other kind of activities such as leisure or sports.
- Physicians that have been sponsored by the industry to participate in an event must have a practical and professional interest in the topic of the event.
- Event facilities must ensure a proper learning environment.

Physicians

- Industry sponsorship of travel companions expenses or those derived from sport or leisure activities must not be accepted.
- Funding of travel expenses beyond the programmed schedule should not be accepted.
- Invitations to events that are not related to their professional practice should not be accepted.

Public and private healthcare institutions

- Encourage their medical staff to participate in the training and continuing education events organized by the industry, provided these invitations are for meetings aimed at the development of knowledge and research.

iii. Studies and clinical research

Cooperation between physicians and the pharmaceutical industry is essential both in the generation process of new products and in the pharmaco-epidemiological research.

Clinical research studies must be formulated properly in the corresponding protocols and submitted for evaluation by a research committee and a research ethics committee, and, if required, by a biosecurity committee; they cannot be undertaken unless authorized by both of them and by the Federal Commission for the Protection from Sanitary Risks (*Comisión Federal para la Protección contra Riesgos Sanitarios*) COFEPRIS.

The institution's Research Committee is responsible of verifying the protocol is based on updated data of the problem to be solved, and that the proposed procedure is viable to obtain the desired outcome.

The Research Ethics Committee is responsible of verifying that the rights and well-being of the research participants are respected, and that the protocol is acceptable from an ethical perspective, which includes, among others, its social relevance, risk-benefit ratio, informed consent, confidentiality, damage repair and access to the researchs' benefits once it is completed.

The Biosecurity Committee is responsible of monitoring the security that is provided during the studies, in order to protect individuals (patients, healthcare staff), the community and the environment from accidental contact with potentially harmful substances.

Industry

- Clinical studies must adhere to the ethical research principles and protocols provided in the latest version of the Declaration of Helsinki, the International Guidelines for Ethical Review of Epidemiological Studies of the Council for International Organizations of Medical Sciences CIOMS, the International Code of Medical Ethics of the World Medical Association, the Belmont Report and the Guidelines of Good Clinical Practices (*Guías para Buenas Prácticas Clínicas*) and General Health Law (*Ley General de Salud*).
- The purpose of these research protocols is to meet scientific and therapeutic objectives. Studies with mere promotional purposes must not be developed.
- All study participants, including physicians and patients, must be informed of the identity of the sponsor company.

- It is mandatory for clinic research studies to obtain the informed consent of all participants, with a clear statement that their participation is willful and not subject to any kind of economic support.
- Clinical research studies must comply with all preclinical experimental phases before any human application.
- Payments to the staff in charge of the development of the research protocol must be reasonable and subject to the responsibility level of each participant. In order to avoid any conflict of interest derived from research remunerations, the amount of the payments must be transparent and should be included in the research protocol.
- The nature, amount and duration of the benefits for the patients participating in the research must be defined from the beginning of the project's planning and accorded among the sponsor and the institution (Authorities and Ethics and Research Committees) involved in the research. These agreements must be included in the research protocol and submitted to the Ethics and Research Committee's evaluation.
- If the results of the research provide more efficiency and security of a medicine, a compromise shall be established in order to maintain the treatment to the participants in the study, under their authorization, until the medicine is available on the market.
- Once approved, and before any clinical study begins, notice has to be given in order to obtain its registration in the National Registry of Clinical Studies, once it starts its operation.
- Every action that discloses study results, whether in print media or in scientific events, must mention the name of the company sponsoring the event.
- All research results must be honestly published even if their content is adverse to the sponsors' interests.
- The company in charge of the study must compensate the institution for the cost of the expenses that were used during the project implementation process.

Physicians

- No payment or other benefits shall be received by the mere fact of referring patients to be recruited in a study.
- Participation in studies that does not involve their area of experience or practice is not permitted.
- Participation is permitted only in studies previously authorized by the institutional Ethics Committees and the Health Authorities.

Public and private healthcare institutions

- Compensations shall not be requested or accepted in exchange of the referral or admission of patients of the institution in the studies.
- It is their responsibility to verify that research studies comply with the research standards accepted at the national or international levels.

iv. Appropriate use of medicines and respect for medical prescriptions

The process involved from the moment of prescription until the medicines dispensation in the pharmacy, must protect the patients' interests, respect the liberty of the physicians to prescribe and strictly adhere to their indications. For this reason:

Industry

- Medicine packaging shall be designed to facilitate the patient's adherence to the complete treatment.
- Pharmacies must not be pressured to substitute a prescribed medicine for a similar product, even if it contains the same active substance.

Physicians

- The physician's therapeutic indications must take into account the therapeutic efficiency of the prescribed medicine, an optimum cost-benefit ratio as well as the patient's free will.
- Medicine prescription must comply with the provisions of articles 31 and 32 of the Health Supplies Regulation (*Ley de Insumos para la Salud*).
- Side-effects must be promptly reported and the pharmaco-vigilance system must be supported.

Public and private healthcare institutions

- Undertake actions to facilitate the physicians' access to information and training related to the rational use of medicines.
- Promote coordination and inform the industry of medicine packaging that does not encourage the patients' adherence to complete the treatment.

- The pharmacy that supplies the medicine must strictly respect the indications defined by the physician.
- Side-effects must be promptly reported and the pharmaco-vigilance system must be supported.

FOLLOW-UP COMMITTEE

In order to guarantee the implementation and dissemination of this agreement, a Follow-Up Committee has been established by the General Health Council (*Comité de Seguimiento del Consejo de Salubridad General*), integrated by a representative of each of those institutions and companies that signed, who will be in charge of promoting compliance, identifying deviations and suggesting appropriate measures to correct them.

A 90 days period, starting in the date of the signature, was given to present the dissemination strategy and the operating guidelines of the Follow-up Committee.

The Committee will make a report to the General Health Council every six months regarding transparency within the relationship between physicians, healthcare institutions and the pharmaceutical industry.

CONCLUSION

Ethical and transparent relations between the pharmaceutical industry, physicians, patients, and healthcare institutions is of vital importance to guarantee on the one hand the security, adherence and efficiency in a medical treatment, and on the other to respect the patients' interests.

The existence of a mutual agreement based on an ethical conduct must be a fundamental pillar for the enhancement of healthcare resource management, the improvement of population's health and the development of scientific knowledge.

PARTICIPATING INSTITUTIONS

The following institutions commit themselves to fully comply with the Agreement for Transparency in the Relationship between Physicians, and Health Care Institutions and the Pharmaceutical Industry, signed on October 24th, 2007, at, the Official Presidential Residence of Mexico *Los Pinos*, in Mexico City.

**NATIONAL ACADEMY OF
MEDICINE OF MEXICO**
*(Academia Nacional de Medicina de
México)*

Emilio García Procel

**NATIONAL CHAMBER OF THE
PHARMACEUTICAL INDUSTRY**
*(Cámara Nacional de la Industria
Farmacéutica)*

Carlos Abelleira

**NATIONAL BIOETHICS
COMMISSION**
(Comisión Nacional de Bioética)

**COUNCIL OF ETHICS AND
TRANSPARENCY OF THE
PHARMACEUTICAL INDUSTRY**
*(Consejo de Ética y Transparencia de la
Industria Farmacéutica)*

Guillermo Soberón Acevedo
MEXICAN ACADEMY OF SURGERY
(Academia Mexicana de Cirugía)

Benito Bucay Faradji
**MEXICAN ACADEMY OF
PEDIATRICS**
(Academia Mexicana de Pediatría)

José Antonio Carrasco Rojas

Gabriel Cortés Gallo

MEDICAL COLLEGE OF MEXICO
(Colegio Médico de México)

**NATIONAL ASSOCIATION OF
PRIVATE HOSPITALS**
*(Asociación Nacional de Hospitales
Privados)*

Reynaldo Cantú Mata

Alejandro Alfonso Díaz

**SCHOOL OF MEDICINE
NATIONAL AUTONOMOUS
UNIVERSITY OF MEXICO**
*(Facultad de Medicina - Universidad
Autónoma de México)*

**GRADUATE SCHOOL OF MEDICINE
NATIONAL POLITECHNIC
INSTITUTE**
*(Escuela Superior de Medicina- Instituto
Politécnico Nacional)*

José Narro Robles

Ricardo García Cavazos

**MEXICAN INSTITUTE OF SOCIAL
SECURITY**
(Instituto Mexicano del Seguro Social)

Juan Francisco Molinar Horcasitas

MINISTRY OF HEALTH
(Secretaría De Salud)

Maki Esther Ortíz Domínguez

**INSTITUTE OF SOCIAL SERVICES
AND SECURITY FOR STATE
WORKERS**
*(Instituto de Seguridad y Servicios
Sociales de los Trabajadores del
Estado)*

Miguel Ángel Yunes Linares