Code of Ethics
AFIDRO
2015

Whereby, Good Practices for Pharmaceutical Industry, represented by the Association of Pharmaceutical Laboratories for Research and Development, AFIDRO, are set.

Bogotá D.C., Colombia
PRESENTATION

The mission of the pharmaceutical industry for research and development is the improvement of the quality of life and health of mankind, through the study of new molecules and the creation of innovative medicines with high quality and reliability, consistent with the highest standards of manufacturing. This commitment has been reflected in self-regulatory policies adopted by the industry as it pertains to management and promotion processes of its products, for more than three decades.

The Code of Ethics of AFIDRO emerges as a tool for self-regulation that establishes guidelines and criteria on which basis the associated companies develop their relationships with stakeholders in the health sector, always looking for priority to the patient benefit. The text has been updated four times in response to changing needs: April 2005, June 2007, December 2010 and this version that takes effect on January 1, 2015.

This Code provides guidelines for ethical conduct of the pharmaceutical associates of AFIDRO, regarding their interrelationships with all stakeholders in the Colombian health system. The scope of regulated conduct extends to the interrelationships of those associates with health professionals, payers, pharmacists, druggists, intermediaries in the supply chain, patients and patient organizations, caregivers, patients at support programs, participants in clinical research trials and market research, users of the health system in general, government officials, institutions and entities of control and surveillance, among others. The code also looks after stressing that ethical behavior guidelines shall also be guaranteed in the digital environment.

Additional to the launch of this Code, AFIDRO creates a Specialized Deontological Unit, as a sign of its great commitment to ethical principles and guidelines of conduct contained herein, which is exclusively in charge of monitoring and developing the guidelines of this Code, ensuring its proper implementation and advocating for the fulfillment of its purposes.

The Code of Ethics of AFIDRO 2015 confirms the commitment of the industry it represents, which is managed in Colombia under the highest international standards. We appreciate the generosity of the Spanish Association FARMAINDUSTRIA to authorize the use of its Code of Good Practice for the Pharmaceutical Industry 2014 as a benchmark, thus contributing significantly to the careful effort led by the Ethics Committee of AFIDRO, in which all members of the Association participated in a committed and devoted way, resulting in the present document.

High standards adopted in this Code demonstrate the unambiguous intention of the associates of AFIDRO to strengthen confidence in their relationships with their interlocutors. The companies recognize that a violation of the provisions contained herein reflects negatively on the entire sector, therefore, fully aware of the impact of their actions, they pledge to increase measures to ensure its strict fulfillment, being always attentive to any practices that could endanger compliance with the ethical principles set forth herein.

This standard of voluntary self-regulation could become an excellent parameter for action throughout the pharmaceutical industry in Colombia, unifying criteria in front of sensitive ethical issues for society. Strict compliance of the partners of AFIDRO with this Code, as well as third parties that voluntarily adopt it, promotes an atmosphere of healthy competition and development of promotional strategies consistent with unified ethical criteria.

The Code of Ethics of AFIDRO 2015 shall be used as a tool of conduct and good practice, in line with the laws of the country, the own codes of conduct of the companies and the international standards in this matter.
We trust this tool will be a key element in the fundamental mission of the pharmaceutical industry to ensure the welfare of patients, advocating for the advancement of society and the development of a responsible industry with its environment.

Bogotá, December 2014

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INTRODUCTION

The Code of Ethics of AFIDRO constitutes the basis for action of the pharmaceutical companies which are members of the Association of Pharmaceutical Laboratories for Research and Development, AFIDRO, in Colombia, through the promotion of an ethical culture, the commitment to transparency and the fight against corruption, the preservation of the integrity of users and the protection of the general interest of society.

This Code reflects the decision of the associates of AFIDRO to self-regulate, by accepting to submit their performances to ethical standards more stringent than those of the current Colombian legal system are, in order to help develop a better health system in Colombia.

AFIDRO is very committed to promoting that the marketing practices of the pharmaceutical industry in Colombia aimed at the health professionals and payers, the distribution chain, the patients in the case of OTC medications, and the users in general, meet the highest international ethical standards, encouraging a responsible, honest and transparent industry, very attentive to any unfair practice.

The ethical principles set out in this Code reflect an industry aware of its environment, the country's priorities, and the challenges of the health system, which acts accordingly.

To ensure full implementation of the above, we proceeded to review and update the Code of Ethics of AFIDRO, which reflects the commitment of the pharmaceutical industry for research and development, represented here, with the highest international standards.

The associates of AFIDRO and the moral persons or the legal entities adhering to this Code voluntarily assume the obligation to adjust all their activities to the spirit of the following provisions:
1. DEFINITIONS

Health system stakeholder: It refers generally to everyone in charge of the prescribing, recommendation, implementation, supply, purchase, sale or distribution of drugs, whether of public or private nature, including, among others: health professionals, payers, suppliers, logistics and procurement operators, pharmacists, druggists, health institutions, hospitals, clinics, foundations, universities, academic institutions, medical associations and scientific associations. For purposes of the provisions of this Code the term also includes patients, caregivers and patient organizations.

Company: Pharmaceutical associate of AFIDRO that develops manufactures and / or sells drugs in the territory of Colombia and / or any entity under its control such as a subsidiary, foundation, association, institution, agency, or third party service provider. The term also includes the moral or legal person that is not a member of AFIDRO, and expressly and voluntarily adheres to this Code of Ethics. The terms "pharmaceutical company", "laboratory" or "business" in the singular or plural have the same meaning as described here.

Caregiver: Person who provides care to a sick or disabled person of any age, generally in the home environment.

Gift or prebend: Any benefits in kind or in cash given directly or indirectly, in a manner contrary to honest commercial practices, which have the ability to induce or encourage the recommendation, prescribing, purchase, distribution, supply, dispensing or administration of medications.

Donation: Act of generosity by which a company (donor) freely provides a sum of money or a good or service (donation in kind) in favor of a third party (donee), who accepts it.

Clinical Trials: Any investigations in humans to determine or verify the clinical, pharmacological and / or other pharmacodynamic effects and / or to identify any adverse reactions and / or to study the pharmacokinetics of one or more investigational medicinal product to determine its safety, effectiveness and / or efficacy.

Event: Any promotional or scientific-professional meetings, congresses, conferences, symposia, distance or face training courses, or any other similar activities including, but not limited to: expert meeting, visit to manufacturing or research facility, researchers training meeting in relation to the conducting of clinical trials and post-approval surveys, organized or sponsored by a company.

Health system official: Natural person, employee (full or part-time) or contractor that provides services to an entity that is owned, controlled or operated at any level by the Colombian state, funded even partially with public money.

Interrelationship: Any activities performed, organized, sponsored or involving the participation of a company, in which a stakeholder of the health system gets involved and whose interaction can be derived in a direct or indirect collaboration, support or compensation of some kind to either party.

Health sector institution: Any entities having decision-making responsibility or capacity on the purchase or use of drugs, such as: Health Service Providing Institutions (IPS by its initials in Spanish), Health Maintenance Organizations (EPS by its initials in Spanish), Compensation Funds, Entities with special health regimes or territorial entities, among others.

Market research: Collecting and interpreting information about individuals or organizations through the use of methods and statistical and / or analytical techniques of applied sciences, to gain new perceptions or search for support elements in decision-making.

Medicament / Medicine / Drug: Pharmaceutical preparation obtained from active ingredients, with or without adjuvants, presented under pharmaceutical form, which is used for the prevention, relief, diagnosis, treatment,
cure or rehabilitation of the disease, including its package, lettering, label and packaging. The term medicament / medicine / drug in singular or plural in the context of this Code applies to any substance or combination of substances regardless of their origin (chemical synthesis, biological, biotechnological, radiopharmaceutical or other) intended to be used by prescribing, recommendation or under supervision of a health professional, for diagnosis, treatment or prevention of disease in humans or to affect the structure or any function of the human body, and for purposes of the provisions herein, includes medical devices.

**Patient Organization:** Non-profit institution, legally constituted, which represents the interests and needs of patients, their families and caregivers.

**Patient:** Person receiving health cares, i.e., requiring a service to promote, maintain, monitor or restore his/her health.

**Payer:** Natural or legal person who has interference or empowered to recommend or perform acquisition for valuable consideration of medicaments, and/or disbursement of the related resources, whether public or private resources. This term includes, but is not limited to, HMOs, HSPIs, compensation funds, distributors, logistics/procurement operators and druggists.

**Patient Support Program:** Program organized by a pharmaceutical company and aimed at patients properly formulated by a health professional with a drug manufactured or marketed by that company, or, aimed at caregivers of these patients too.

**Health Professional:** Member of the medical profession in any of its fields or specialties or professional in any field of health sciences such as dentistry, optometry, bacteriology, nursing, nutrition, physical therapy, respiratory therapy, psychology, podiatry, among others, who in the exercise of his/her profession could carry out or condition the activities of prescribe, purchase, supply, dispense or administer drugs. The term includes anyone in charge of prescribing, recommendation, application, supply, purchase, sale or distribution of drugs, whether public or private, including distributors, logistics and procurement operators of the general system of social security in health, collective purchase organizations, pharmacists, druggists and payers in general.

**Promotion:** Any activities undertaken, organized or sponsored by a pharmaceutical company, intended to promote, directly or indirectly, the prescribing, dispensing, recommendation, sale or consumption of medicinal products for human use.

**Transfers of value:** Any in cash or in kind payments, benefits or compensations, performed by any means, by a company or entity under its control in favor of a recipient, directly or indirectly, regardless of its purpose. This concept excludes transfers of value that are part of the commercial transactions between laboratories and distributors, pharmacies or health organizations.
2. PURPOSE AND RESPONSIBILITY OF THE COMPANIES

2.1 The responsible and participatory social action of the business sector plays a key role in the development of society and there is global consensus on the need that private enterprise moves towards increasingly stringent ethical environments. Those who welcome the provisions of this Code are committed to promoting greater transparency about business decisions driven by leaders of the business community and contributing to the development of a healthy competitive environment.

2.2 This Code of Ethics is a set of rules by which, the pharmaceutical associates of AFIDRO, making use of their self-regulation powers, have agreed to be bound both in the field of drug promotion as in the interrelationship with the different stakeholders in the health system, in order to ensure that their activities in development of the company object are carried out in compliance with the highest ethical standards of professionalism and responsibility.

2.3 The compliance with the principles stated in this Code ensures that the information provided in the context of drug promotion is complete and accurate, in order to protect and improve public health, and in line with the interests of the health administration as well as those of the pharmaceutical industry itself. The activities or materials related to the promotion as well as interrelationships with the stakeholders of the health system shall contribute by their content or nature, to enhance trust in the pharmaceutical industry.

2.4 This Code has been prepared in accordance with the current Colombian regulations and applies without exception to all the associates of AFIDRO and the moral or legal persons who voluntarily adhere to it.

2.5 This Code regulates the ethical standards of the associates of AFIDRO in their relationships with the various stakeholders in the health system directly or through entities under its control.

2.6 The guidelines contained in this Code does not seek to restrict the exchange of medical and scientific information during the development stage of a drug or the relationship between pharmaceutical companies and health professionals and / or patient organizations, but framing such interactions within ethical standards and transparency criteria that companies undertake to comply with.

2.7 The responsibility of the companies with regard to the provisions of this Code extends to activities to train, implement and monitor their human staff, about compliance with the provisions set forth herein. The companies are responsible for ensuring that all personnel involved in their promotional activities and relationships of any kinds, either direct employees or external staff contracted, are able to enforce the provisions of this Code strictly.

2.8 The companies will be responsible for correcting breaches of this Code resulting from the inappropriate behavior of any representative thereof. This obligation shall extend to the sales forces of third parties that are used for drug promotion.

2.9 The companies shall comply with the spirit and letter of this Code, maintaining the same standards of conduct in their interactions with various stakeholders.

2.10 This Code is not intended to replace or supersede the legal regulations in force or the internal codes of conduct of the pharmaceutical associates of AFIDRO. In case of conflict between the provisions of this Code and the national law and / or the Code of Conduct of the company, the partners must apply the most restrictive standard.
3. SCOPE

3.1 This Code of Ethics covers all forms of interrelationship of the companies with the stakeholders of the health system in educational or promotional activities related to drugs carried out, by any means, in development of its company object, including digital environment.

3.2 This Code of Ethics does not regulate:

i. Regulation of advertising of OTC medicines.

ii. Business transactions of the companies with the relevant stakeholders of the health system.
4. GUIDING PRINCIPLES ON ETHICAL CONDUCT AND PROMOTION

The associates of AFIDRO perform medical, pharmaceutical and biopharmaceutical research in order to benefit patients and provide support to high quality medical care; they promote, sell and distribute their medicines in an ethical manner and in accordance with the rules and regulations in force on medicines and healthcare.

Guiding principles listed below establish the basic standards that make up the Code of Ethics of AFIDRO that apply to the conduct of the associates of AFIDRO and their agents, helping to ensure that their relationships with the various stakeholders in the health system are suitable.

4.1 The main priority of the pharmaceutical associates of AFIDRO is the healthcare and welfare of patients. Their relationships with stakeholders of the health system must always be intended for the benefit of the patient, for supporting a healthy practice of medicine and other sciences related to the health of Colombians as well as for promoting research, science and development.

4.2 The companies shall comply with the respect of the highest standards in all activities of research, development and promotion of their drugs.

4.3 The companies shall always act in a legal framework in strict accordance with current regulations.

4.4 The companies shall comply with the highest standards of safety and efficacy, determined by the regulatory authorities and ensure quality in the production of medicines that have full support of scientific evidence and have complied with all phases of research required, according to international standards.

4.5 The companies shall have an internal pharmacovigilance program that allows monitoring and control of their medicines, these programs must be in accordance with international standards in this matter. It is also their responsibility to notify immediately and clearly to the national competent authority of any changes in the safety information to prescribe, derivative from pharmacovigilance programs or decisions of regulatory authorities in other countries.

4.6 The interactions of companies with various partners must be ethical at all times, adequate and professional and shall respect the autonomy and independence. No company shall offer or give anything in a manner or conditions that could have an improper influence.

4.7 The companies are responsible for the technical and scientific information or related to clinical studies about their medications to be communicated or presented to health professionals, making sure to provide valid, truthful, accurate and balanced data and supported by scientific evidence.

4.8 The companies consider that ethical promotion of prescription medicines to health professionals is a vital element for health promotion and the prevention and treatment of diseases.

4.9 The companies will adhere strictly to the ban on promotion of prescription medicines aimed at the general public. Education and prevention campaigns on health are not considered promotional activities.

4.10 The drug promotion shall be based on accurate and balanced information and must not be misleading. The information in promotional materials must support an appropriate assessment of the risks and benefits of the drug and its proper use.

4.11 The drug promotion shall be transparent. The promotional material relating to medicines and their use shall clearly indicate who sponsors. Payments made in the development of promotional activities must be properly documented and there must be adequate supervision to ensure their use for the purposes intended.

4.12 The companies shall respect the privacy, confidentiality and security of personal information of third parties that they can access. To this end, they undertake to comply with the applicable rules on personal data
protection, and must have relevant policies, internal mechanisms and authorizations to ensure compliance with the provisions of Law 1581 of 2012 and Decree 1377 of 2013, or rules that modify, complement or replace. The companies ensure that all personal information will be treated in accordance with the purposes for which it was collected and they will take special care to protect the personal data of patients.

4.13 The companies are aware that the transgression of ethical guidelines established in this Code negatively impacts the entire sector, so they undertake to adopt all measures incumbent upon them to ensure observance of the provisions contained herein.
5. INTERRELATIONSHIP GENERAL GUIDELINES

The ethical and transparent conduct of pharmaceutical companies in their interactions with the various stakeholders in the health system, who have the power to influence or decide on the prescribing, dispensing, recommendation, sale, consumption or use of medicinal products for human use, or have a decision-making or regulatory power over these matters, whether health professionals, payers, patient organizations or patients, health system officials or control and surveillance entities, must meet the following basic guidelines:

5.1 Ethical Behavior

5.1.1 The companies are forbidden from offering or giving directly or indirectly any benefit in cash or in kind, to a stakeholder of the health system, which, contrary to honest commercial practices, has the ability to induce or encourage the recommendation, prescribing, purchase, distribution, supply, dispensing or administration of a drug. Any such benefits constitute a gift or prebend in the terms of this Code.

5.1.2 Gifts or prebends shall include, among others:

i. Any promotional or marketing activities of medicines under the system of rewards in cash or in kind, such as raffles, accumulation or sum of points or any other similar modality that essentially assumes that the option to participate in such activity or delivery of such benefit to the third depends on prescribing, dispensing, recommendation, purchase, sale, disposal, consumption or use of a drug.

ii. Inappropriate offering of hospitality that exceeds the necessary, reasonable and moderate logistic means, in the terms set forth in the chapter 5. 3 of this Code.

iii. Delivery of any items exceeding maximum limits established in the following paragraph or fails to comply with the conditions to be exempted from the prohibition.

5.1.3 Not constitute gifts or prebends, among others:

i. Exceptional demonstrations of sympathy addressed to health professionals and / or their families for the death of a relative in first degree of consanguinity or first civil, provided that its value is equal to or less than fifty percent (50%) of a current legal monthly minimum wage (SMMLV by its initials in Spanish).

ii. Exceptional demonstrations of congratulation addressed to health institutions or entities related to the health system for an anniversary or milestone of significance and history, such as a newspaper ad or a commemorative plaque, whose value is equal to or less than fifty percent (50%) of a current legal monthly minimum wage (SMMLV by its initials in Spanish). Such demonstrations in no case may consist of personal gifts or sponsorship of social activities with commercial value, related to the celebration, such as drinks, music or entertainment.

iii. General demonstrations of congratulation to mark the day of different health professionals, consisting of a newspaper ad or similar whose value is equal to or less than fifty percent (50%) of a current legal monthly minimum wage (SMMLV by its initials in Spanish). Such demonstrations in no case may be individualized or consist of personal gifts or sponsorship of social activities with commercial value, related to the celebration, such as drinks, music or entertainment.

iv. Delivery of medical-scientific publications or subscriptions of modest value to healthcare professionals twice a year at most and whose commercial unit value in the country does not exceed fifty percent (50%) of a current legal monthly minimum wage (SMMLV by its initials in Spanish), which does not compensate trading practices and meets an educational purpose for the benefit of the patients care.
v. Storage devices for technical or scientific information aimed at health professionals’ practice, consisting of CD, DVD or USB sticks or other of modest value not exceeding ten percent (10%) of a current legal monthly minimum wage (SMMLV by its initials in Spanish).

vi. Promotional items whose value may not exceed an amount equal to ten percent (10%) of a current legal monthly minimum wage (SMMLV by its initials in Spanish), delivered in small quantities and that have relationship with the work of the recipient. Such promotional items can be marked in compliance with prescribed by law.

vii. Items delivered by companies in the development of their internal programs to support patients, whose value does not exceed a value of ten percent (10%) of a current legal monthly minimum wage (SMMLV by its initials in Spanish) and where the item delivered is related to the activities implemented in the support program.

viii. Fees for services that meet conditions set out in section 6.5 of this Code.

ix. Activities of scientific research, pharmacoconomics or non-interventional, which are addressed to or involving health professionals, and developed in accordance with protocols of research, international and national standards and approval of the corresponding Ethics committees.

x. Sponsorship and development of the own events of the companies or support for third-party that meet all the requirements of chapter 5.3 of this Code.

5.1.4 The companies are obliged to observe ethical behavior to ensure and preserve the guidelines established in this Code in contractual processes involving them, respecting the following:

i. No offer or make payments, favors, privileges, rewards or perks with the ability to influence making-decisions of, health system officials, health professionals or institutions, patients, providers, foundations or leagues of patients, among others, whether legal or natural persons, with the purpose of obtaining or keeping any benefit and / or secure an unjustified advantage.

ii. Report immediately any offer or request for payments, favors, gifts, privileges, rewards or perks, contrary to honest practices, in accordance with the procedure for monitoring compliance set forth in this Code.

iii. Not agree with other competitors on contracting processes and / or public or private tenders in which they will participate, neither agree with other proponents on the terms to be submitted to a contracting or bid process except if they participate under the modality of consortium or temporary bonding, or if the proponents are part of a business group.

iv. Refrain from conducting transactions with third parties whose resources come from illegal activities. To this end, they shall require such third parties with whom they maintain business relationships, confirmation that they are not subject to sanctions or investigations by corruption or money laundering; so they will use the due diligence of a good business man to verify such information on the available databases. In the event that they verify that the claims of suppliers are false, they will terminate immediately the relevant business, without judicial statement, notice or compensation, for which they will include a provision for unilateral termination for this reason, in the relevant contracts or agreements.

5.1.5 The companies undertake to adopt strict measures to correct and / or punish employees who do not report any behavior that threatens the principles of this Code or violate the provisions herein. Additionally, they must make explicit that no employee will be subject to retaliation for reporting a behavior that threatens the principles of this Code. In this sense, companies shall review, within a period of one year from the entry into
force of this Code, the contracts subscribed with their employees to ensure that these refer to their obligation to ethical behavior under the provisions of the Code of Ethics of AFIDRO 2015.

5.1.6 The companies cannot motivate, manage, conduct or fund legal actions seeking to force access to medicines, such as tutela actions.

5.2 Transparency

5.2.1 All promotional material related to drugs and their use, sponsored by a company, shall clearly indicate who sponsors.

5.2.2 The companies can deliver scientific material that meets requirements of Article 6.3 and that can be backed up. When a company finances, conducts or orders otherwise the publication of promotional material in scientific journals, such promotional material cannot arise as an independent editorial content and shall clearly indicate who is sponsoring.

5.2.3 When the companies organize or sponsor events, this fact shall be stated in all documents relating to the invitation, as well as any work or presentation or document to be published in connection with the event.

5.2.4 The companies shall properly document, in accordance with its internal procedures, any transfer of value directly or indirectly made to the stakeholders of the health system. This includes, among others, fees paid for services rendered, collaboration granted for the completion of scientific and professional events, hospitality expenses offered on account of an event, including transport charges, registration or enrolment, accommodation and meals and the registrations or deliveries of medical-scientific publications. Likewise, the duty of documentation covers all donations or contributions that companies deliver, directly or indirectly, to the stakeholders of the health system. This documentation will not be disseminated or transmitted to competitors; it will be compiled and maintained in accordance with their own policies on accounting and filing of each company.

5.2.5 The duty of documentation described in the preceding paragraph does not apply to payments made to health professionals with whom the company has a working relationship for the development of its company object, to medical samples submitted in compliance with the provisions of this Code or the printed promotional information to be delivered to health professionals.

5.2.6 The Companies shall make available to AFIDRO, intended for publication, the list of patient organizations that have been granted direct or indirect financial support in cash or kind, including a description of the granted support and its amount, its purpose and the identification data of the beneficiary organization, annually on the date on which the Executive Presidency provides. When making this information available to AFIDRO, the companies must ensure that they have the necessary authorizations to share it and are not violating confidentiality obligations and duties previously acquired. AFIDRO shall publish the information reported and may contract an external audit firm to corroborate the veracity of it.

5.2.7 The companies expressed their commitment to transparency of clinical trials and other research initiatives to develop or support. It is recognized that there are important public health benefits linked to make publicly available to health professionals, patients and third parties, information about clinical trials, while ensuring the protection of personal data and safety thereof and compliance with the existing rules on data protection and contractual rights as well as the compliance with applicable laws on industrial property.

5.3 Events

5.3.1 The companies can organize, sponsor or support scientific or professional events on education, complementation or updating of vocational training, aimed at various stakeholders in the health system, in order to improve their knowledge in matters related to health care, improving the quality of life of patients, the provision of health services or the sustainability of the system, among others.
5.3.2 The objective and focus of the symposia, congresses and other scientific or professional events aimed at health system stakeholders organized, sponsored or supported by the companies shall be to provide scientific or educational information and/or report on drugs to advocate for improving healthcare and patient care.

5.3.3 It is contrary to ethical guidelines established in this Code offering or delivery of any sponsorships under the concept of hospitality to occur independently of a scientific or professional event. The hospitality must always be secondary to the main purpose of the event and must be limited to provide the means necessary for attendance and participation in it.

5.3.4 The invitation to an event may not be in any case conditioned to an obligation or commitment to prescribe, recommend, purchase, provide, manage or promote a drug.

5.3.5 In no case may it be offered or made, any transfers of value to the guest to an event to compensate for his/her time spent in attending the same, except for persons under contract for professional services.

5.3.6 It is not allowed to organize or sponsor companies own events, or supporting or sponsoring events of others, containing within its agenda, entertainment or recreational items or activities, parties, raffles, prizes or other gambling activities. Not included in the previous ban, activities such as the welcome reception and closing luncheon that usually form part of the official program of congresses, symposia and similar, provided that together are reasonable and moderate and do not contain leisure, entertainment or recreational elements or gambling activities. The companies shall refrain from participating in events to announce aforementioned items on its agenda.

5.3.7 The companies will not be able to organize or sponsor national events taking place outside Colombia, except that most of the participants or the relevant resource or expertise, being the main purpose of the event, is located abroad.

5.3.8 In no case the companies will perform or sponsor any event in places specially designed for recreation, in exclusively tourist places or places associated predominantly with leisure, recreational or sporting activities.

5.3.9 Events organized or sponsored by companies must meet the following requirements:

i. Have a program with relevant medical, scientific or professional contents, so that the quality of the scientific or professional program is the main focus of interest.

ii. The selection of the guests must be the result of a careful assessment of their abilities, training and experience, evidencing their suitability to benefit from the training in topics covered by the event.

iii. The invitation to the event shall be clearly and specifically identified in terms of its purpose, it must state clearly and expressly who performs sponsorship and its scope.

iv. Sponsorship of hospitality may cover only actual expenses related to travel, registration, accommodation and food of the guest, which must be moderate and reasonable, and may only be offered during the duration of scientific or professional activity.

v. Snacks and meals offered during the course of the event shall be moderate, reasonable and secondary to the main purpose of the event.

vi. Own background music of the place where the event is held may be permitted, provided it is not paid by the company.

vii. Invitation cannot be extended to persons other than beneficiaries for whom the medical-scientific or professional meeting content is relevant to the development of their practice or profession.
companies cannot pay any accompanying person expenses even when the spouse / husband or partner of the health professional guest is to turn a health professional, but where there are no legitimate reasons of suitability to be also invited to the event in question.

viii. The companies will be directly responsible for the payment of hospitality expenses and may use intermediary agencies, who will in turn strictly comply with the guidelines of conduct set forth herein.

5.3.10 Events organized by third parties supported by companies shall be organized by a legally constituted institution, and must comply with all the requirements mentioned above. The companies shall establish procedures that allow the verification of attendance of those invited to the meeting or event in question.

5.3.11 The companies shall have an internal process for documenting that the sponsorships given to hospitality in the events meet all requirements set forth herein, it shall record among others, the amount, purpose, date, recipient, the agenda and all documentation necessary to prove a legitimate need to sponsor and that objectives of the sponsorship were met.

5.3.12 Sponsorships related to hospitality to patients and patient organizations strictly will observe the following special requirements:

i. The hospitality to patient organizations could only be paid or financed through the patient organization and never directly to patients individually.

ii. The sponsored events for patients cannot be promotional in nature, cannot generate any incentive for attending and they cannot collect patient data.

iii. The invitation to patients can be extended exceptionally for health reasons to a companion to attend as caretaker.

5.4 Donations and Contributions

5.4.1 The donations or contributions made by the companies to institutions related to health care, must meet the following requirements:

i. To obey charitable, humanitarian or social benefit reasons.

ii. It is granted without any compensation in cash or in kind, directly or indirectly in favor of the donor.

iii. Donation will not seek the personal benefit of the employees or officials of the beneficiary of the donation

iv. Donation is not an inducement to recommend, prescribe, purchase, supply, sale or administer drugs

v. Donation be formalized with documents, and the company keeps copies of such documents.

5.4.2 The companies are not allowed to make donations to health system stakeholders individually, but to legal entities properly constituted. Not included in this ban, invitation to, or sponsorship of events, in the circumstances of moderation and reasonableness described in section 5.3 of this Code.

5.4.3 The companies can make contributions under form of scholarships or academic awards provided that:

i. The value payment is made directly to the educational institution or scientific association and not the beneficiary.

ii. The company has no control or influence in determining the choice of the beneficiary.
iii. The use, recommendation or prescribing of drugs, in the present or future, is not used as a criterion for selecting of candidates.

5.4.4 The companies shall not make direct or indirect contributions to political parties in order to gain advantage in commercial transactions or with the State. Contributions to political campaigns must be disclosed in accordance with applicable disclosure laws.

5.5 Digital Environment

5.5.1 The continuous development of technology and the use of new media, supports and communication channels by pharmaceutical companies to promote their products and their interaction with the different stakeholders in the health system shall not prevent the development of ethical business conduct. The nature of the media, support or communication channel used does not exempt the laboratories from their obligation to comply with the ethical guidelines established in this Code. The companies shall refrain from using media that by its nature, technical limitations or conditions of use, do not enable compliance with the guidelines set forth herein.

5.5.2 The use of digital communication technologies allows the companies, among others, to provide academic information to the public in general about pathologies, their implications for health care and non-pharmacological options for its care, such as multidisciplinary care and palliative care.

5.5.3 Each company may employ digital environment mechanism to educate health care professionals about pharmacological options of their own products. The use of digital environment media for the promotion of prescription drugs will be addressed exclusively to health care professionals authorized to prescribe medications, within an academic and technical-scientific framework. To ensure that the information is disseminated only to these professional groups, these activities shall include measures such as:

i. A clearly legible warning that the information is intended exclusively for health professionals authorized to prescribe or dispense drugs, so that a specialized training is required for proper interpretation

ii. The condition that persons having access to content declare their status of health professional authorized to prescribe or dispense drugs.

5.5.4 The companies shall refrain from making promotional content of prescription medicines available to the general public, directly or indirectly through links, comments, bookmarks, or any other practice that involves its replay or forwarding.

5.5.5 The companies are responsible for the content disseminated through the media, supports and communication channels that control or finance directly or indirectly, and for the implementation of the usage guidelines that establish rules of behavior and a standard operating procedure for checking the content of the digital environment to give access, hosting, copying or linking. This procedure shall include the obligation to correct hastily and diligently any irregularities.

5.5.6 The companies shall have guidelines for responsible action in the digital environment for its employees, which establish consequences of the non-compliance, both in presenting information about or on behalf of the company and when using media support or channel provided by the same company.
6. INTERACTIONS WITH HEALTH PROFESSIONALS

6.1 Educational Activities

6.1.1 The pharmaceutical associates of AFIDRO support or conduct educational and training activities that contribute to ensuring that stakeholders of the health system obtain most updated and accurate information and understanding to improve patient care and the health system in general. The main objective of a training event is to improve knowledge of medical professionals and other stakeholders in the health system to help provide optimal health care and improve patient care.

6.1.2 When the companies provide contents to the activities and medical education programs, such material shall be honest, balanced and objective and designed to allow the expression of diverse recognized opinions. The content shall consist of medical, scientific or professional information that can help to improve patient care.

6.1.3 Training or education events must adhere to the provisions of Chapter 5.3 of this Code.

6.2 Promotion of Medicines

6.2.1 No person may promote any drug or therapeutic indication that has not been officially approved by the competent national authority.

6.2.2 Not constitute promotion of drugs or therapeutic indications:

i. The answer, of the medical department of a laboratory to spontaneous requests made by a health professional, related to unapproved drugs or indications, whose response is warned in writing that the drug or therapeutic indication in question is not approved in the country.

ii. Proper dissemination of scientific data regarding active ingredients or unapproved indications, in scientific events not sponsored by companies, such as conferences on discovery of research, organized or conducted by medical and scientific societies, where this proviso is expressed.

iii. Public dissemination of information related to drugs or indications not approved, to shareholders and other stakeholders, as required by current regulations.

iv. The information or printed documentation provided by companies to health care professionals, in compliance with current regulations, so that he / she, in turn, can hand it to the patient, for certain approved drugs, that, for the complexity of their dosage, route of administration, etc., require the provision of additional information, provided that this information is intended to improve treatment compliance and is in line with the requirements of Colombian law.

6.2.3 Promotional information shall be clear, legible, accurate, balanced, fair and complete to allow the receiver to form his own opinion on the therapeutic value of the drug in question.

The promotional information shall be based on an updated assessment of all relevant evidence, which shall be reflected clearly. It shall not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. Any ambiguities shall be avoided at all costs. The absolute statements such as "unique..." or "no/any ..." shall only be used when they are properly supported and are scientifically substantiated.

6.2.4 The information provided must be complete, based on scientific evidence, and must include the active ingredient, mechanism of action, approved indications, therapeutic uses, contraindications, cautions, warnings, reported side effects, dosage, administering risk, risk of drug dependence, presentations and drug interactions, without omitting any of the information that appear in the scientific literature or known by the manufacturers, in accordance with the legal provisions.
6.2.5 The companies cannot suggest or promote the replacement of medical prescription or take any action that threatens the autonomy of health professionals.

6.2.6 The companies shall ensure that representatives in charge of promoting their drugs are adequately trained and have sufficient medical and technical knowledge to disseminate accurate information about drugs of the companies they represent. They must:

i. Maintain a professional relationship with partners visited.

ii. Report comments of the healthcare professionals, as a result of the visits, including adverse events, which must be informed to companies and health authorities in accordance with applicable law.

6.2.7 The development of medical visits or promotional activity to payers and other stakeholders responsible for making decisions about buying or prescription of drugs, in no case may be conditional upon the payment in cash or in kind as a direct or indirect way of compensation or consideration for their time invested in this activity.

6.3 Promotional Material

6.3.1 The drug promotion shall be based solely on arguments, facts and scientific data.

6.3.2 The companies shall keep in mind when designing promotion of their drugs that first thing is the safety and life of patients, keeping balance between therapeutic and beneficial features of their drugs, and information about cautions, contraindications, warnings, interactions and side effects, within their promotional campaigns.

6.3.3 The companies must ensure that any material or activity developed and performed by health professionals for the promotion and prescription of drugs, is in line with the provisions of this Code, complies with the internal requirements of the company, the universally accepted standards and the legal regulations in force. The above requirements will apply to all electronic materials, including audiovisual material.

6.3.4 The laboratories shall have clear written policies for design, review and approval processes of promotional material and / or activities, and an appropriate medical department that endorses, supports and approves them. Each company will be responsible for:

i. The scientific endorsement of the content, both materials and promotional activities related to their drugs.

ii. The procedures for obtaining, printing, dissemination and appropriate use of scientific references.

iii. The monitoring, control and harmony of the promotional message and the prescribing information, in force and approved by the competent authority in Colombia.

6.3.5 It is the responsibility of companies that the different elements of support required by law and other regulation in force in Colombia are consigned in the materials being promoted to healthcare professionals.

6.3.6 The promotion shall be supported on scientific studies and the qualities of the drug and not on the weaknesses of competitors. The comparison will be acceptable provided that it is objective, truthful and not containing statements that affect the good name of others. The comparisons must about similar or comparable ends and shall have scientific backing in a publication.

6.3.7 All promotional materials must conform to regulations.

6.4 Promotional Items and Medical Samples

6.4.1 Promotional and / or medical useful items, must not individually exceed a sum equal to ten percent (10%) of a current legal monthly minimum wage (SMMLV by its initials in Spanish), may be marked in accordance
with the provisions of the law and may be delivered in minimum quantity, if it relates to the work of the healthcare professional who receives it. In no case these items may consist of gifts, cash or its equivalent for the personal benefit of the healthcare professional, and shall not exceed on the whole, on an annual basis, the amount of fifty percent (50%) of the current legal monthly minimum wage (SMMLV by its initials in Spanish).

6.4.2 The free samples of a drug may be delivered to health professionals able to prescribe drugs under the provisions of existing laws, meeting the following requirements:

i. Delivery of samples must be made with the sole purpose of improving patient care.

ii. They shall be marked as samples, so they cannot be sold or used improperly.

iii. They must be delivered to health professionals able to prescribe, in modest and reasonable quantity according to their purpose.

iv. They shall be subject to appropriate systems of control and monitoring, including monitoring of samples in the possession of sales representatives.

v. They cannot be offered or delivered as an incentive or reward for prescribing, administration, recommendation, payment or providing of any drug or company service or for obtaining any improper advantage or for personal use of the health professional recipient.

6.5 Professional Services

6.5.1 It is permitted to hire healthcare professionals as consultants and advisors in activities, as: speakers, discussants, moderators or presenters in events, researchers in market, clinical or scientific searches, pharmacoeconomics or non-interventional activities, and / or to provide their services in training, as advisers in meetings of advisory bodies, or participating in market research, where such participation involves remuneration.

6.5.2 The agreements with health professionals or entities to which they attend (institutions, foundations, scientific societies, professional organizations or associations, etc.) and cover legitimate provision of such services, must meet the following conditions:

i. The company must identify and clearly document, in advance, the legitimate need for the services to be procured.

ii. Prior to the provision of services, the company must subscribe a written contract that identifies the services to be rendered, the payment amount, the deliverables by the consultant, how to verify delivery and the deadline for providing the services.

iii. The contract shall include a clause whereby the contractor undertakes to declare expressly and clearly that he / she is serving the company whenever he / she publicly states with respect to any matter under his / her agreement with the company.

iv. The criteria for selecting contractors shall be directly related to the identified need; they must have the training, experience, expertise and recognitions necessary to provide the service. The responsible for carrying out the selection within the company must have the training and experience necessary to assess whether the candidate meets the selection criteria.

v. The number of contracted consultants must not exceed the quantity reasonably required to accomplish the intended target.

vi. The remuneration for the agreed performance must obey market criteria, be commensurate with the time spent, the work done and the responsibilities assumed and must be properly documented and
The remuneration must be monetary and not in kind and they shall not make cash payments. The total annual fees received by a stakeholder of the health system from a company for services shall be reasonable.

vii. The hiring of a health professional to provide the relevant service shall not be an incentive to prescribe, recommend, purchase, provide and / or administer a drug.

viii. The contracts of service shall not be used to justify compensation for time spent during the event, accommodation and other expenses related to hospitality.

ix. It may be agreed to pay travel, accommodation and food expenses related to contracted services that are reasonable and properly supported and comply with the requirements and conditions set out in section 5.3 of this Code.

x. The contracting company must keep dossiers with documentary support of services provided and give these services the use that it was intended.

xi. The place and the circumstances in which any meeting with consultants is held, is conducive to the services contracted; and that all activities with consultants have a primary focus on the contracted services.

xii. All meetings of the companies with service providers must comply with the terms and conditions provided in Chapter 5.3 of this Code.

6.6 Clinical Research

6.6.1 The companies carry out research activities in which both health professionals and volunteer patients are involved in conducting clinical trials; these activities are developed according to research protocols, international and national standards and approval of the relevant ethics committee.

6.6.2 All clinical research sponsored by member companies of AFIDRO who adopt provisions of this Code, will be developed in accordance with the Guidelines for Good Clinical Practice, the Declaration of Helsinki, the Nuremberg Code, the Universal Declaration on Bioethics and Human Rights UNESCO and other Colombian and international regulations available for this purpose. This implies the existence of:

i. Research protocols ethically and scientifically valid.

ii. Choosing of validated and suitable research centers and researchers, regarding research topics and methodology of clinical research, aware of their rights and obligations.

iii. Informed consents that must be complete, true and clear, including accurate information about the risks and benefits involved in participating in the study. They shall be read, understood and signed in acceptance by the individual participating in the study or his / her legal representative, prior to any intervention and / or procedure included in the study, in strict compliance with applicable laws on habeas data.

iv. Submission of protocol to institutional ethics committees for approval prior to any intervention and / or procedure included in the protocol.

v. Submission of the protocol, the approval letter from the institutional ethics committees, the resumes of researchers and co-researchers and the letter of commitment of the researchers and the sponsoring company to the competent national authority for approval prior to any procedure and / or intervention included in the protocol; in order to comply with Colombian current legislation relating to research.
vi. Monitors, auditors, statisticians, coordinators and medical writers, for the proper handling of data.

vii. Transparent and clear stipulation of financial conditions linking companies with the Centre for Research and Researchers.

viii. Pharmacovigilance program to report adverse events and reactions, under the regulations of the local health authorities.

ix. Absolute respect for privacy, respect of confidential information and strict compliance with the regulations applicable on data protection of individuals participating in the studies.

x. Absolute respect for the integrity of individuals participating in the study, and the existing highest health care standards.

xi. Transparency in the formation of study groups to prevent measures of moral pressure or undue material compensation to obtain the consent of the individuals participating in the study.

xii. The associated or attached laboratories are obliged to maintain appropriate evidence to validate compliance with all the requirements described in this chapter.

6.6.3 The non-interventional post-approval and Phase IV studies shall not exercise undue influence of formulation on health professionals.

6.6.4 All studies with prospective pharmacological intervention must comply with current regulations. The so-called "seeding studies", "clinical experience" or similar, which aims to expand the habit of prescribing of physicians, are forbidden.

6.6.5 Patient or illness records cannot be used to promote drug or to exercise undue influence on health professionals for recommendation or prescription.

6.7 Market Research

6.7.1 The companies can anticipate market research to gain new insights or seek support elements in decision making because of their business, which shall preserve the following conditions:

i. The legitimate need for research shall be previously and clearly established.

ii. It shall be guaranteed anonymity and respect for confidentiality of participants in the report of the information collected.

iii. The activities of research development shall not be performed directly by staff of the sales force or marketing of the company.

iv. The participants will receive a moderate and reasonable compensation for their participation, representing the fair market value and being proportional to the time spent, the work performed and the responsibilities assumed. The payment must be made in cash or its equivalent (not in kind) and properly documented.

v. The recruitment of health professionals and / or entities through which the research is conducted, shall be formalized through a written agreement with the company sponsoring the study. Such agreements must be approved before implementation; they shall specify the nature of the services to be provided, the objectives, the conditions of participation and the remuneration of professionals, the population to recruit and the collection methods.

vi. The person who develops research must be trained on the mandatory report of adverse events.
vii. The information obtained from such research shall be treated fairly and lawfully, and can only be used for specific and legitimate purposes for which it was obtained.

viii. The behavior of the survey takers shall be ethical so that no competing company or product be disparaged or discredited.

ix. Must have a written protocol previously approved by the company, which clearly establishes objectives, methodology, expected results and their use.

x. In the case of research commissioned or sponsored by more than one company, the analysis of the results will be individual as well as actions taken based on that information.

xi. Companies shall ensure that the conducting of the research does not constitute an incentive to agreements or practices anti-competitive.

6.7.2 The market research shall not be a mechanism to encourage consumption or prescription of drugs. The surveys with promotional purposes shall not be presented as market research. Notwithstanding the foregoing, subsequent to the realization of market research activities, it is legitimate to use the information collected for supporting in making decisions about the design of promotional activities.

6.7.3 The interaction with health professionals during market research cannot be used to influence their individual prescribing habits.

6.7.4 The outcome data of market research sponsored by companies shall not be used in promotional material unless it can be demonstrated that such information complies strictly with the requirements of Chapter 6.3 of this Code. In case of use of these data in promotional material, it must state that they result from a market research sponsored by the company.

6.7.5 All market research shall safeguard the rights of respondents and ensure the protection and integrity of personal data, in compliance with current legislation, by observing the following:

i. The respondents shall be able to voluntarily provide informed consent to the collection and use of their data, based on a clear understanding of the purpose of the collection and the use (s) to be given to such information and shall be informed of their right to inquire about the handling of their data and how they can request that these be modified or destroyed.

ii. In no way an unauthorized or illegal use of personal data will be made.

iii. The identity of respondents shall not be disclosed to the companies without their explicit consent.

iv. Personal data may only be transferred if these are adequately protected.

v. Personal data shall not be kept beyond the time necessary to meet the immediate purposes of the research.

6.7.6 The companies will be responsible for the handling, the treatment, the storage and the disposal of personal contact details obtained during the market research sponsored by them.
7. INTERACTION WITH PATIENTS

7.1 Interaction with Patient Organizations

7.1.1 The pharmaceutical industry has many common interests with patient organizations, which advocate or support the needs of patients and caregivers. The ethical guidelines established herein advocate to ensure respect and commitment of industry to strengthen these organizations to become a group of greater social and institutional recognition.

7.1.2 The agreed principles on which the direct or indirect interrelation of companies with patient organizations is based are:

i. The independence and autonomy of patient organizations in terms of positioning, action policies and activities, must be ensured.

ii. Any cooperation between patient organizations and companies shall be based on mutual respect, giving equal weight to the points of view and decisions of each party.

iii. The companies shall not seek that patient organizations assume the specific promotion of a prescription drug; nor will patient organizations assume it.

iv. Supports to patient organizations will not be used for inducing drugs promotion or prescription.

v. Any supports, financial or any other type, paid by a company to a patient organization as well as the objectives and scope of such collaboration will always be clearly recognized.

vi. The funding of patient organizations shall ideally be wide and proceed from various sources. No company may request to be exclusive provider of funds of the patient organization or any of its programs. However, there may be exceptional situations in which only one company want to support a particular patient organization or any of its activities, which would be acceptable as long as it does not condition its support to being the sole provider of funds.

7.1.3 All cooperation between pharmaceutical companies and patient organizations shall be documented in writing such a way that allow companies to comply with the obligation on transparency established in section 5.2.6 of this Code.

7.1.4 The companies undertake to establish internal procedures and criteria for approving and monitoring collaborations with patient organizations.

7.1.5 No pharmaceutical company may use the logo, the mark, the distinctive sign or material that identifies a patient organization, except in joint activities with the patient organization. The pharmaceutical companies may not require the use of logos of the companies as a condition of support to be granted.

7.1.6 The companies will require patient organizations requesting their contributions, the obligation to inform the origin of the sponsorship as an essential and inherent condition to the delivery of any support. No company can make contributions to a patient organization that refuses to make the disclosure of origin of funds.

7.1.7 Any partial or totally sponsored publications, by one or more companies, must unequivocally mention the sponsors. When companies sponsor a material or publication of patient organizations, shall not seek to influence
its content so that it can favor their own commercial interests. This does not prevent the possibility of correcting any inaccuracies or errors in the materials.

7.1.8 The agreements with patient organizations for the provision of advisory or consulting services to companies, such as presentations at events as a speaker or moderator or expert meetings, shall be allowed only if such services are provided for the purpose of collaborating with the healthcare and/or the research. The agreements that cover the legitimate provision of such services, with patient organizations that have the ability to provide such services within their company object, must meet the following conditions:

i. Identify clearly the legitimate need thereof, before requesting these services.

ii. Ensure that the recruitment of the patient organization for the provision of such services does not constitute an inducement to recommend a drug.

iii. Verify the existence of a written agreement, which specifies at least the nature of the services to be provided and the criteria as a basis for calculating the amount to be paid for their provision, prior to the provision of these services. The agreement must include a transparency clause under which the patient organization undertakes to demonstrate that it provides paid consulting services to the laboratory, when publicly expressed regarding the matters covered in the agreement.

iv. Verify that the criteria used for selecting the patient organization are directly related to the identified need and that the person responsible for the selection has the experience and training necessary to assess whether the selected organization meets these criteria.

v. Verify that contracted services do not exceed the amount that would be reasonably necessary to accomplish the intended purpose.

vi. The contracting company must maintain documentary support for services provided by the organization and give these services the use that was expected.

vii. The remuneration for the provision of these services must be monetary and not in kind and obey market criteria, must be commensurate with the time spent, the work performed and the responsibilities assumed.

7.1.9 The companies shall take the measures required to follow up the implementation of the supports by the patient organization, and in case of identifying deviations, implement appropriate action.

7.2 Patient Support Programs

7.2.1 The companies can offer support programs for patients properly diagnosed and formulated by their treating physician, without prejudice to the diagnoses support referred to in Section 7.4 of this Code.

7.2.2 The patient support programs must be formally described and its contents must have been carefully prepared and approved by the companies.

7.2.3 The patient support programs are intended to help patients and caregivers in managing their disease and appropriate use of the medication, including programs and services focused on support to the adherence, education in improving quality of life, live with the disease and rational drug use. The programs may not take steps that undermine medical autonomy.
7.2.4 Within the patient support programs it may be provided support for patients who cannot afford or cannot discontinue their medication and require a start or continuity dose. Such cases must be properly documented in the program, ensuring the existence of a previous prescription by a prescribing physician.

7.2.5 The patient support programs cannot be used to perform the delivery of drugs without the prior existence of a medical prescription, or to make delivery of medical samples or carry out drug replacement programs.

7.2.6 It is not possible to provide patient support programs for indications of drugs not approved by the competent national authority.

7.2.7 The patient support programs may include the delivery of items of modest value, which do not individually exceed a cost of 10% of one current legal monthly minimum wage (SMMLV by its initials in Spanish), where the item delivered is directly related to the activities implemented in the program and contains no drug promotion.

7.2.8 Support programs cannot have a purpose of drug promotion. The provision of any program or activity related to patient support programs shall be kept clearly separate from the promotional activities of pharmaceutical drugs.

7.2.9 Pharmaceutical companies shall not involve or finance the participation of health professionals within the patient support programs so that these professionals carry out activities related to the recommendation or prescription of drugs or pharmaceutical drugs of the sponsor.

7.2.10 In no way, the laboratory can offer or deliver a payment in cash or in kind to the health care professional by the referral of patients to a patient support program, nor shall offer support programs to some health professionals exclusively for their personal or financial benefit.

7.2.11 The information provided to patients or caregivers enrolled in the patient support programs, shall not try to promote drug promotion or guide the patient to the self-prescription thereof. The materials to be delivered to patients must first be reviewed and approved by the medical area of the companies.

7.2.12 The patient support programs cannot be promoted directly to patients or patient organizations. The health professionals will be the exclusive channel for dissemination of support programs for formulated patients. Sales representatives of the companies can provide general information regarding the programs, but shall not offer, give, show or participate in specific activities of these programs. Such programs can be promoted to professionals so that they may know the benefits that the laboratory offers to patients.

7.2.13 The patient support programs can provide health care services, assistance and support to the patient, ordered by their treating doctor, without taking behaviors that undermine or replace the doctor-patient relationship. It shall be clear that all clinical decisions, including the selection of drugs and the management development of the treatment plans are the responsibility of the treating physicians, who shall act at all times with full professional independence. All the above services shall be implemented by accredited persons or institutions legally authorized to develop such services. In no case the professional who provides patient support service will be the same prescriber.

7.2.14 The companies cannot in no context, including patient support programs, encourage, manage, conduct or fund legal action seeking to force access to medicines.
7.2.15 Every patient admitted to a support program must provide his / her previous consent informed to the company. The company handling personal information provided by the patient, must meet the criteria of data privacy handling defined under Colombian law. The company cannot ask for any sensitive data that affects or could affect the patient's privacy, or use patient information for own ends different from the program objective. The information related to the identification data and the status of patients must be maintained at all times under the applicable requirements of preservation and confidentiality.

7.2.16 The individual information of the patient collected in the course of the providing a patient support program must not be shared with the sales department of the companies for promotional purposes or to plan promotional activity. However, this does not exempt the possibility that this department accesses statistical information of the program. This information and the inclusion of patients in the programs shall not be a factor for the calculation and granting of incentives or bonuses.

7.2.17 The laboratories that implement patient support programs, directly or through third parties, shall ensure the reporting of adverse events generated during the development of such programs.

7.3 Interaction with patients and caregivers

7.3.1 All interaction with patients as a source of information must comply with the guidelines of the Colombian legislation on data privacy and prohibition of direct promotion to consumer of prescription drugs.

7.3.2 In the event that a laboratory requires interact with patients as a source of information on their experience coping with the disease, it must meet the following requirements:

i. The initial contact with the patient cannot be done directly by the laboratory, but through a patient organization or a health professional, to whom the patient gives permission to share his / her data with the laboratory.

ii. The contribution of the testimony of the patient shall be free of charge and shall not be subject to any compensation in cash or in kind, except the payment of the costs involved in transport, accommodation and / or food on the occasion of the submission of that testimony, which must be paid directly by the company.

iii. By no means, a payment may be made in kind, by delivering medical samples or supply of drugs in exchange for the testimony of a patient.

iv. The patient must have experience in managing with the disease.

v. Prior to the activity, the interaction must be documented by a written agreement with the company, where the type of testimony to be submitted by the patient and the confidentiality clauses, are defined.

vi. The hospitality to the patient shall be complementary and moderate and meet the requirements defined in section 5.3 of this Code

7.3.3 The laboratories must have, defined procedures to ensure the proper handling of patient spontaneous applications, ensuring compliance with the guidelines of the Colombian legislation on the ban of direct promotion to consumer and the reporting of adverse events. Any request from a patient related to the clarification of medical issues shall be rejected and the patient shall be advised to consult his / her physician.
7.4 Diagnoses Support

The companies support the provision of diagnostic tests that meet needs within health programs and comply with the following guidelines:

i. The diagnosis support programs will be offered exclusively to health professionals and in no case to patients.

ii. These tests may be prescribed by the healthcare professional to any patient, without conditions in the case of a possible formulation of the medicament produced by the company.

iii. The prescription of sponsored diagnostic tests cannot be the subject of consideration or any benefit to the health care professional who prescribes.

iv. The value of diagnostic tests will be paid by the Company directly to the institution that made it, and in no case to the professional who prescribes or the patient.

v. The company shall not have access to information identifying patients referred for diagnostic tests sponsored.

vi. The choice of the institution that conducts the diagnostic tests shall be based on objective criteria for ensuring its suitability and independence. In exceptional cases in which the diagnostic test must be performed direct or indirectly by a prescribing physician, the compensation shall reflect the fair market value, and the sponsorship of this service shall not be conditional to future drug prescribing.
8. INTERRELATIONSHIP WITH OFFICIALS OF THE HEALTH SYSTEM

8.1 Scope

8.1.1 The provisions contained herein concerning the interrelationship of the companies with officials of the health system, defined as natural persons employed full or part time, or contractors who provide services to an entity that is owned, controlled by, or operated by any level of the Colombian state or, even partially financed with public money, do not replace the guidelines for the interrelationships of the companies with health professionals from public institutions in their role of treating physicians, established in chapter six (6) of this Code.

8.1.2 The guidelines for interrelationship with officials of the health system shall apply without prejudice to the legal, national or foreign standards, applicable to companies; in case of conflict between the provisions of this chapter and the applicable legal rules or provisions of its own Code of Conduct, the most stringent standard shall apply.

8.2 Fundamental principles in the interrelationship with officials of the Health System

The interrelationship of the companies with officials of the health system must meet the highest ethical and transparency standards, respecting the following principles:

8.2.1 Absence of improper influences. The companies shall not engage in any interrelationship that constitutes or that may be perceived as undue influence to an officer of the health system. In particular, no company shall:

   i. Offer, promise or pay anything of value, directly or indirectly, to an officer of the health system, to a family member, to a legal entity of his / her property or under his / her control or that of his / her family, to ensure an improper commercial advantage or for obtaining, retaining or directing business to the company.

   ii. Offer, promise or make any payment directly or indirectly to an official of the health system, to facilitate or expedite government actions.

8.2.2 Ethical Conduct in the development of commercial transactions. Companies shall refrain from:

   i. Discuss with staff of purchasing / procurement or regulatory, the possibility of the company-related opportunities for officials or family member.

   ii. Request or obtain information on potential competitors, or that it is the exclusive property of the purchasing entity.

   iii. Offer or give any type of benefit to the official of the health system, or a third party related to him / her.

8.2.3 Conflict of interests. The companies shall avoid establishing relations with officials of the health system that may create a conflict of interest for any of the parties, or give the perception that such a conflict is created. The companies shall properly document all interactions with officials of the health system, so that they are in a position to refute any allegation regarding the existence of a potential conflict of interest with an official of the health system.
8.2.4 *Honesty and Integrity.* In their interactions with officials of the health system, the companies will take all necessary measures to ensure the veracity and accuracy of all information provided by their employees or third parties acting on their behalf.

8.2.5 *Transparency.* Employees and third parties acting on behalf of the companies in relationships with officials of the health system shall be presented clearly as representatives of the company concerned.

8.2.6 *Respect and Independence.* The companies shall work toward and respect the independence and impartiality of officials of the health system in developing their functions. The abuse of any position shall be avoided by all involved.

8.2.7 *Legality.* Some officials of the health system by their nature or their function may be subject to special rules or regulations, more restrictive than the provisions of this Code. The companies shall ensure strict observance of the provisions, of the standards or the regulations of particular relevance to officials of the health system in their interrelationship with them.

8.2.8 *Confidentiality.* The companies shall respect the standards and regulations governing the release of confidential or privileged information by officials of the health system.
9. CONTROL OF COMPLIANCE

9.1 Overview

9.1.2 The associates of AFIDRO as well as non-members third parties, who adhere to this Code, shall implement procedures to ensure compliance, regardless of the legal or regulatory mechanisms in force that are applicable to the relevant subject.

9.1.3 AFIDRO will create a Deontological Unit with functions exclusively related to socialization, training and compliance with this Code, also making sure that its website contains direct access to this document, as well as providing a consultation mechanism for associated companies on provisions contained herein.

9.1.4 The presentation of legitimate claims for breaches of the Code of Ethics will come by the designated authorities and following the procedure established in this chapter.

9.1.5 AFIDRO is responsible for administering claims for breaches of this Code of Ethics to ensure they are processed as required by this procedure. This includes the validation of the claim, the preparation of documents for the decision groups and informing the parties of the outcome. AFIDRO does not participate nor voice nor vote in making decisions about the existence of violations of the Code.

9.2 Control Bodies

9.2.1 The competent bodies for monitoring compliance and processing of complaints arising from alleged violations of this Code are: Ethics Committee of AFIDRO, the External Court of Ethics and the High Court of Appeal.

9.2.2 The functions of the Ethics Committee of AFIDRO are:

i. Advocate for compliance with the provisions of this Code by the partners.

ii. Propose to the Board of AFIDRO the measures it deems necessary to the implementation, dissemination and fulfillment of the provisions of this Code.

iii. Perform regular review and updating of the provisions of this Code, to propose to the General Assembly of AFIDRO

iv. Interpret the provisions of this Code and clarify their scope.

The Ethics Committee may delegate temporarily or permanently functions that it considers relevant, to a working group of their choice.

9.2.3 The External Court of Ethics is the first instance in the processes of allegations of breaches of the Code of Ethics and shall consist of three (3) members and their respective alternates, without conflict of interest in relation to the associates of AFIDRO, who shall be appointed annually by the Board of Directors of the Association.

9.2.4 Decisions of the External Court of Ethics may be appealed to the High Court of Appeal, consisting of a member proposed by each of the parts of the process and another member proposed by AFIDRO, from a list of eligible, annually composed and published by AFIDRO.
9.3 Categorization of Sanctions

9.3.1 Violations of the Code of Ethics are categorized as minor, serious and very serious, based on the following assessment criteria:

i. Nature of the infringement and, in particular, the possible risk for patient health.

ii. Prejudice to the scientific or medical profession or society generally generated by the infringement.

iii. Generalization and / or recurrence of the infringement.

iv. Detriment to the image of the pharmaceutical industry.

v. Economic benefit to the laboratory derived from the infringement

9.3.2 Once the infringement qualified as minor, serious or very serious, according to the above criteria, there may be aggravating factors that must be taken into account by the competent authority when imposing appropriate sanctions. The accumulation of aggravating factors can modify the initial rating of "minor" to "serious" or "serious" to "very serious". These aggravating factors are:

i. Degree of intentionality.

ii. Failure to comply with previous warnings.

iii. Concurrence of several infringements in the same fact or activity.

iv. Greater amount of the estimated economic benefit for the laboratory, derivative of the infringing activity.

9.3.3 The reiteration of the behaviors contrary to the provisions of this Code empowers the Board of Directors of AFIDRO to consider the feasibility of stay of the recurrent associate, in the Association, according to the provisions of the Statutes of the Association.

9.3.4 Based on the above criteria, the sanctions to be imposed by the External Court of Ethics or the High Court of Appeal will be moral, pecuniary, participative and legal nature.

i. Moral sanctions:

a) Written admonition.

b) Imposition of the obligation to perform retraining for minor infringements.

c) Report to hierarchical superiors in the event of reiterative behaviors, concurrence of two (2) or more minor and / or serious infringements and in the case of very serious violations of this Code.

ii. Pecuniary sanctions:

a) For minor infringements: fines of 10-20 times the current legal monthly minimum wage (SMMLV by its initials in Spanish).

b) For serious infringements: fines of 21-50 times the current legal monthly minimum wage (SMMLV by its initials in Spanish).
c) For very serious infringements: fines of 51-100 times the current legal monthly minimum wage (SMMLV by its initials in Spanish).

iii. The participation sanctions apply to associates of AFIDRO and consist of the suspension of the infringing company participation in deliberative activities of committees and / or working groups of AFIDRO and / or meetings of the Board of Directors for up to three (3) sessions, and / or suspension of vote at meetings of the Board of Directors and Assembly for up to three (3) sessions, without prejudice to consider expulsion of the Association in accordance with the provisions of the Statutes of AFIDRO.

iv. Legal sanctions: If the final decision indicates that there was an infringement of the Code of Ethics, which constitutes a violation of national current laws, the last instance to know the process will ask the Board of Directors of AFIDRO to report the case to the regulatory health authority or other competent legal instance.

9.3.5 The penalty will be determined in a reasoned manner. Pecuniary sums collected under payment of penalties for violations of the Code of Ethics of AFIDRO will be made available to the Ethics Committee of AFIDRO, who may use them to support social responsibility projects.

9.4 Dispute Resolution Procedure

9.4.1 In the event that, an associate of AFIDRO considers that another associate was allegedly in violation of this Code of Ethics, it shall contact the infringing company in order to clarify the facts, prior to filing a complaint with AFIDRO.

9.4.2 Any person, in the case of the associates of AFIDRO and the companies adhering to this Code, through their legal representative, may file a formal complaint with AFIDRO for conduct that violate the provisions of this Code of Ethics. Such complaint shall be in writing, addressed to the Executive Presidency of AFIDRO and shall contain a detailed statement of the facts known to the complainant, with evidence to prove the veracity of the alleged fact.

9.4.3 Upon receipt of the complaint, it must be validated by AFIDRO, verifying that:

i. The complainant has met the prerequisite to contact the alleged infringer, as established in section 9.4.1 of this Code.

ii. The alleged conduct attributed to the alleged infringer violates a provision of this Code of Ethics.

iii. There is sufficient objective information to process the complaint and the complainant provides concrete evidence or data to prosecute the claim.

iv. Apparently the complaint is filed in good faith, motivated by factual.

If, for the absence of any of the above requirements, the complaint cannot be validated, this shall not be processed according to the Dispute Resolution Procedure of this Code; this situation shall be informed by AFIDRO to the complainant.
9.4.4 Upon receipt and validation of the complaint for alleged violations of the Code of Ethics of AFIDRO, the Executive Chairman of the Association shall convene the External Court of Ethics within the next fifteen (15) working days.

9.4.5 In the case of anonymous complaints, three delegates from the Ethics Committee shall carry out the preliminary investigation and, in the opinion of such Committee it will be established if applicable the submission to the External Court of Ethics.

9.4.6 The External Court of Ethics will initiate the process within thirty (30) working days after its constitution. AFIDRO shall notify this fact in writing to the complainant and the defendant.

9.4.7 The External Court of Ethics will issue a decision, without prejudice to the waiver of the terms by the parties, within thirty (30) working days after receipt of the documentation submitted by the Executive Chairman of AFIDRO. Such decision shall be notified, by any means, to the parties and the Executive Presidency of AFIDRO, by the External Court of Ethics, within the next five (5) working days; against this decision it may be presented an appeal for reversal, which must be brought with the same authority within the fifteen (15) working days after the notification of the decision. The External Court of Ethics shall have a maximum term of fifteen (15) working days to rule on the application. Such decision shall be notified, by any means, to the parties and the Executive Presidency of AFIDRO, by the External Court of Ethics, within the next five (5) working days.

9.4.8 The decisions of the External Court of Ethics, including the verdict on the appeal for reversal, may be appealed to the High Court of Appeal. To this end, the appellant shall notify the Executive Chairman of the Association, about his / her decision to appeal, within the five (5) working days after the notification of the External Court of Ethics’ decision. If the intention to appeal is not expressed, the decision of the External Court of Ethics will be final.

9.4.9 Once established the intention to appeal, the Executive Chairman of AFIDRO shall notify the parties about the need to conform High Court of Appeal, within the next five (5) working days; there will be a term of no more than fifteen (15) working days for the appointment of its members and its conformation may not exceed five (5) working days. The High Court of Appeal shall have a maximum term of thirty (30) days to issue a decision, without prejudice to the waiver of the terms by the parties. No appeal proceeds against decisions of the High Court of Appeal.

9.4.10 Once the decision of the External Court of Ethics or High Court of Appeal is final, as the case, the Executive Chairman of AFIDRO, indicating that there was a violation of the Code of Ethics, shall proceed to enforce the penalty or penalties determined, after notice to the parties by any means.

9.4.11 The decision or judgment of punishment for minor infractions of the Code of Ethics shall be informed to all associates; in the case of infringements qualified as serious, additional to the copy sent to all the associates of AFIDRO, a further copy will be sent to the Regional Superior of the sanctioned laboratory. For behaviors qualified as very serious, a copy will also be forwarded to the headquarters of the sanctioned laboratory.

9.4.12 If the last resort decision, headed by the External Court of Ethics or the High Court of Appeal determined that there was no violation of the Code of Ethics, this situation may be made public, upon request of the defendant.
9.5 Expenses

9.5.1 To start the process and/or to process the appeal for reversal or the remedy of appeal, as the case, the part that drives the process shall pay AFIDRO 25% of the value of each instance. The judicial proceedings will not initiate while this amount has not been paid, nor will the terms come into effect.

9.5.2 The value of each instance shall consist of the fees of the members of the External Court of Ethics and/or the High Court of Appeal and all operating expenditure required. The fees of the members of the External Court of Ethics and the High Court of Appeal, if any, shall be set by AFIDRO, for which it may take the existing rate framework at the Arbitration and Conciliation Center of the Chamber of Commerce Bogota, as a reference.

9.5.3 After the procedural steps, all bills for fees and expenses must be cancelled to AFIDRO, by the defendant or who has driven the process in the event that the defendant is not sanctioned, as the case.
AFIDRO

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