National Association of Pharmaceutical Laboratories

Code of Ethics

ALAFARPE

2016

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Introduction

The regulation and promotion of ethical principles of the pharmaceutical industry were the basis for the founding of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) in 1968. The purpose of the IFPMA Code, published in 1981, was to present a global self-regulatory approach for the pharmaceutical industry, mainly focusing on the correct and legitimate promotion of pharmaceutical products. In the following years, the Code has been adopted by different pharmaceutical companies and associations around the world; being subject to a permanent update process in order to reflect the new challenges facing the industry at the global level. Progressively, the scope of application of the Code has expanded to the interactions of the industry with health professionals, medical institutions and patient organizations.

The National Association of Pharmaceutical Laboratories (ALAFARPE) is a member association of the IFPMA and, as such, is subject to compliance with the IFPMA Code and to ensure that its Member Companies are subject to regulations and principles oriented to the fair and legal promotion of medications, as well as to ensure that the interaction between the pharmaceutical industry and health professionals; public officials; medical or scientific institutions, or institutions with a scientific background; individual patients; patient organizations and all those participating in the health sector takes place within the framework of ethics and transparency.

The well-being of patients is the supreme goal of the pharmaceutical industry. In order to ensure that the promotion and sale activity of medications is performed within the strictest ethical principles, the Member Companies of ALAFARPE are subject to this Code pursuant to the following provisions:

1 Definitions

Health Sector Player: It generally refers to all those in charge of the prescription, recommendation, application, supply, purchase, sale or distribution of drugs, either public or private, including, among others: health professionals, payers, distributors, logistics and sales operators, pharmacy or drugstore sales persons, pharmaceutical chemists, health institutions, hospitals, clinics, foundations, universities, academic institutions, medical and scientific associations. For the purposes provided herein, the term also comprises patients, caregivers and patient organizations.

Auspice: It refers to any legitimate contribution of goods or services provided by a Member Company in favor of a Medical Institution or Patient Organization which purpose is necessarily to promote the formation or dissemination related to the health sector with medical, scientific, non-promotional purposes and/or a legitimate promotional purpose; and in which, the Medical Institution or Patient Organization also provides, in favor of the Member Company, a legitimate good or service as a retribution.

Donation or Contribution: Act of liberality by which a Member Company (donor or contributor) provides, free of charge, and without expecting a remuneration or benefit in return, a pecuniary amount or good or service in favor of a third party (donee) that accepts it with the legitimate purpose of fostering the health-related formation, dissemination or research, or related to patients' support or health sector.

Member Company/Firm: Company associated under ALAFARPE that develops, produces and/or commercializes medications in the territory of the Republic of Peru and/or any other entity under its control, such as a subsidiary, foundation, association, institute, agency, as well as companies that are part of its economic group operating in Peru and that are exclusively engaged in the commercialization of pharmaceutical products. The term also refers to an individual or legal entity not associated under ALAFARPE

that expressly and voluntarily complies with this Code of Ethics. The terms “company,” laboratory” or “Member Company” in singular or plural has the same meaning described herein.

Clinical trials: Any and all research performed in human beings in order to determine or confirm clinical and/or pharmacological effects, and/or identify adverse reactions, and/or study pharmacokinetic of one or several medications under investigation with the purpose of determining their safety, effectiveness and/or efficacy.

Event: Any promotional, scientific meeting, congress, conference, symposium, workshop, classroom or distance training course, or any other type of similar activity, including but not limited to: advisory boards meetings; lectures; visits to manufacturing plants or research premises; planning, teaching or research meetings related to the performance of clinical trials, non-interventional studies and post-authorization studies; preceptorships, activities with patients, either organized or sponsored, directly or indirectly, by a Health Sector Player.

Public Official/Employee: Individual, employee (either full-time or part-time) or contractor rendering services to an entity from, controlled by or operated at any level by the Peruvian State, or a partially and publicly-financed one. This definition includes, among other things, health professionals and administrative personnel from public hospitals.

Undue Incentive: Any benefit, in cash or in kind, offered or delivered, directly or indirectly (including commercial bonuses and/or incentive programs for pharmacy or drugstore sales persons) contrary to ethical and legitimate commercial practices, which purpose and/or consequence is to induce or encourage the recommendation, prescription, purchase, distribution, supply, dispensing or administration of drugs.

Interrelation: Any activity in which a company where any Health Sector Player is involved participates, or any activity performed, organized or sponsored thereby, and from which interaction a contribution, support or valuable consideration of any kind in favor of any of the parties can be directly or indirectly derived.

Medical Institution: Any organization which purpose is to provide health care-related services, offer medical training to Health Professionals and/or perform medical research.

Market Research: Collection and interpretation of information regarding persons or organizations through the use of statistical and/or analytical methods and techniques of applied sciences in order to obtain new insights or search for support elements during the decision making.

Patient Organization: Generally, a non-profit institution representing the interests and needs of patients, their families and/or any other person in charge of the patient’s health care.

Patient: Person that acquires or that could acquire a pharmaceutical product commercialized by a Member Company either directly or through third parties.

Research Process: Process through which the Court of Ethics of ALAFARPE shall collect evidence regarding the alleged infractions of this Code of Ethics by a Member Company, and which shall end with a decision by virtue of which the Member Company shall be sanctioned or exempted from liability.

Pharmaceutical Product: It refers to any pharmaceutical or biological product (notwithstanding the status of its patent and/or the fact that it has a registered trademark) intended to be used under prescription from a health professional or under his supervision, and also intended to be used in the diagnosis, treatment or prevention of diseases in human beings, or to have an influence in the structure or any other function of the human body and includes, for the purposes of this paragraph, medical devices.

Patient support program: Program conducted or organized by a Member Company and/or by a third party acting by and through a Member Company, addressed to Patients.

Health Professional: Professional medical member ~~or student~~ in any of its fields, specialties and professional (sic), such as: dentistry, optometry, bacteriology, pharmaceutical chemistry, nursing, nutrition, physical therapy, respiratory therapy, psychology, podiatry, among others, that in the exercise of their profession, and in a legitimate matter, could carry out and condition activities such as the prescription, recommendation, purchase, supply, dispensation or administration or drugs. Moreover, this category includes pharmaceutical dependents.

Promotion: Any activity performed, organized and/or sponsored, directly or indirectly (through third parties) by a member company intended to promote, directly or indirectly, the prescription, dispensation, recommendation, supply, sale or consumption of drugs of human use.

Value transfer: Any direct or indirect payment, benefit, or valuable consideration, in cash or in kind, by any mean, performed by a Member Company in favor of a beneficiary, regardless of its purpose. Value transfers that are part of commercial operations between laboratories and distributors, pharmacies or health organizations are excluded from this concept.

Visitor or Medical representative: Technically trained personnel working for a Member Company, whose function is to advertise, promote and provide information from Pharmaceutical Products, directly to Health Professionals.

2 Companies' Purpose and Responsibility

2.1 The responsible and participative social action of the business sector plays a key role in the development of society and there is global consensus as to the need for private enterprise to move forward towards increasingly stricter ethical environments. Those who uphold the provisions of this Code agree to foster greater transparency in business decisions driven by the leaders of the entrepreneurial community and to contribute to the development of a scenario of healthy and free competition.

2.2 This Code of Ethics represents, together with its corporate policies, the rules by which, exercising its self-regulation powers, the pharmaceutical companies associated to ALAFARPE have agreed to be governed both in the field of promotion of drugs and in the interrelation with the different players of the Health Sector, seeking that all activities in the furtherance of their corporate purpose are undertaken upholding the highest ethical principles of professionalism and responsibility.

2.3 Complying with the principles under this Code ensures that the information provided within the framework of drug promotion is complete and accurate for the sake of protecting and improving public health and in line with the interests of health administration, as well as those of the pharmaceutical trade itself. The activities or materials related to the promotion, as well as the interrelations with the Health System Players, must contribute, by content or nature, to

strengthening the confidence in the pharmaceutical trade.

2.4 This Code has been prepared following the Peruvian regulations in force and the IFPMA Code and applies, without exceptions, to all ALAFARPE associates and Member Companies and to the individuals or companies that voluntarily adhere to it.

2.5 This Code regulates the ethical standards of the Member Companies in their interrelations with the different Health Sector Players, directly or through third parties, without prejudice to the internal regulations of each Member Company and to the applicable law.

2.6 The guidelines contained in this Code do not seek to restrain the legitimate exchange of medical and scientific information during the development stage of a drug or the interrelation between Member Companies and Health Professionals and/or Medical Institutions and/or Patient Organizations, but to frame such interactions within ethical standards and transparency criteria that the companies agree to uphold.

2.7 The responsibility of the Member Companies with regard to the provisions in this Code extends to the activities involving training, enforcement and surveillance of the personnel in their charge, regarding the provisions herein established. Companies are responsible for ensuring that all their personnel involved in activities concerning promotion and establishment of relationships of any kind, whether it is a direct employee, external personnel under contract, distributors and service providers in general, are in conditions to comply strictly with the provisions of this Code.

2.8 The companies must comply with this Code, keeping the same behavior standards in their interactions with the different stakeholders, including third parties acting in representation of Member Companies.

2.9 This Code does not seek to replace or substitute any legal provisions in force, or the internal Codes of Conduct of pharmaceutical companies associated under ALAFARPE, but to be used as a complement and as interpretation criteria thereof. In case of conflict between the provisions of this Code and the national laws and/or Code of Conduct of a company, the members must apply the most restrictive rule.

3 Scope

3.1 This Code of Ethics covers all forms of interrelation of the companies with health system players in educational or promotional activities performed in furtherance of their corporate purpose related to drugs, regardless of whether they are prescription drugs, through any means, including the digital platform.

3.2 This Code does not regulate:

i. The advertising/promotion of over-the-counter drugs to the public. Notwithstanding, this Code does regulate the promotion of over-the-counter drugs aimed at health sector players and in general, any interaction of Member Companies with such players regarding these products.

ii. The commercial transactions of the companies with the corresponding health system players.

4 *Governing principles regarding ethical behavior and promotion*

The companies associated under ALAFARPE conduct medical, pharmaceutical and bio-pharmaceutical researches for the benefit of patients and to provide support for high-quality medical care: they promote, sell and distribute their drugs in an ethical manner and in line with the norms and regulations in force concerning medicines and health care.

The governing principles below establish the basic standards of the Code of Ethics of ALAFARPE applicable to the behavior of the Member Companies and of their agents, thus contributing to ensure proper interrelations with the different health system players.

4.1 The main priority of the pharmaceutical companies associated under ALAFARPE is to contribute to the health care and well-being of patients. Their relations with the health system players must always pursue the benefit of patients, seek to provide support to a healthy practice of medicine and other sciences related to the health of all Peruvians, and foster research, science and development.

4.2 The companies shall uphold the highest standards in all activities concerning research, development and promotion of their drugs.

4.3 The companies shall always act within an ethical and legal framework, strictly respecting the regulations in force and the endorsed codes of ethics of the trade.

4.4 The companies shall uphold the highest safety and efficacy standards determined by the regulatory authorities and shall guarantee quality in the production of medicines that shall be fully supported by scientific evidence and comply with all the research stages required under international standards.

4.5 The companies shall have an internal pharmaceutical surveillance program to monitor and control their drugs in line with applicable laws and international standards on the matter. Furthermore, it is their responsibility to notify the competent national authority promptly and clearly, any changes in the safety information to be prescribed, resulting from pharmaceutical surveillance programs or from decisions emanated from regulatory authorities of other countries.

4.6 The companies' interaction with their different counterparts must at all times be ethical, proper and professional and must respect the autonomy and independence of all health system players. No company must offer or supply anything in such a way or in such conditions that it may have an inadequate influence.

4.7 Companies are responsible for the technical and scientific information or data related to clinical studies that are communicated or presented to health professionals regarding their drugs, and shall make sure they provide valid, truthful, accurate and balanced data, supported by scientific evidence.

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

4.9 The companies shall strictly adhere to the prohibition of promotion of prescription drugs aimed at the general public. Health-related education and prevention campaigns and materials are not considered promotion activities.

4.10 The promotion of drugs must be based on accurate and balanced information and must not be misleading. Information in advertising materials must support a proper assessment of risks and benefits of the drug and of its proper use.

4.11 Drug promotion must be transparent. The promotional material related to the drugs and their use must clearly indicate the sponsor. Payments made for promotional activities must be duly documented and properly supervised to ensure they are used for the intended purposes.

4.12 The companies must respect the privacy, confidentiality and safety of third parties' personal information to which they may have access. To that end, they undertake to comply with applicable regulations regarding personal data protection and must have in place the corresponding policies, internal mechanisms and authorizations to ensure compliance of provisions in Law 29733 - Law on the Protection of Personal Data and the Regulations thereof, approved by Supreme Decree 003-2013-JUS, or the provisions that may amend, complement or replace them. The companies shall guarantee that all personal data shall be treated in accordance with the purpose for which they were gathered and shall take special care in the protection of patients' personal information.

4.13 The companies are aware that the transgression of the ethical guidelines established in this Code has a negative impact on the entire sector and; therefore, they undertake to adopt all measures on their side to guarantee that the provisions contained herein shall be observed and in line with their corporate policies and applicable laws.

5 General interrelation guidelines

The ethical and transparent behavior of the Member Companies in their interactions with the different players of the health system with power to influence or decide regarding the prescription, distribution, recommendation, sale, consumption or use of drugs for human use or who have decisive or regulatory power on these matters, whether they are health professionals, payers, patient organizations, patients, health system officials or control and surveillance entities, must adhere to the following fundamental, basic guidelines:

5.1 Ethical Conduct

5.1.1 Companies are precluded from offering or delivering to a health system player, directly or indirectly, any benefit, in cash or in kind, which contrary to honest commercial practices, may induce or encourage the recommendation, prescription, purchase, distribution, supply, dispensing or administration of a drug. Any benefit constitutes an undue incentive in the terms of this Code.

5.1.2 Undue incentives considered include, among others:

i. Any type of drug promotion or marketing activity under an award in cash or in kind, such as raffles, accumulation or awarding of points or the like, which may essentially entail that the option to participate in such activity or awarding of the benefit for the third party may depend on the prescription, dispensing, recommendation, sale, disposition, consumption or use of a drug. This includes any commercial benefit and/or bonus granted to pharmacy and/or drugstore sales persons.

ii. The inappropriate hospitality offering that exceeds the necessary, reasonable and moderate means in the terms outlined in this Code.

iii. The granting of any article that exceeds the maximum limits established in the next paragraph or which may not comply with the conditions to be exempted from the prohibition.

5.1.3 The following conducts do not constitute undue incentives:

i. The exceptional condolence expressions aimed at health professionals and/or their relatives on account of the decease of a first degree blood relative or first degree kinship, provided that their value is equal to or less than fifty percent (50%) of the minimum salary (RMV) in force.

ii. The exceptional congratulation expressions aimed at health institutions or entities related to the health system on account of an anniversary or relevant milestone and history, such as a flower arrangement or commemorative plaque, if their value is equal to or less than fifty percent (50%) of the RMV. Such expressions in no case may consist in personal gifts or in the sponsorship of social activities with a commercial value, related to the celebration, such as alcoholic or non-alcoholic beverages, music, food or the like and/or entertainment.

iii. The general congratulation expressions to commemorate the day of the different health professionals (physician, nurse, etc.) consisting in a press release or the like, with a value equal to or less than fifty percent (50%) of the RMV.

5.1.4 The Companies agree to exhibit an ethical conduct that may guarantee and preserve the guidelines expressed in this Code in the contractual processes they participate in, respecting the following:

i. Not to offer, directly and/or through third parties, payments, favors, prerogatives, rewards or bonuses to influence the decisions of, among others, health system officials, health professionals or health institutions, patients, providers, foundations or patient organizations, whether they are legal entities or individuals, seeking to obtain or maintain a benefit and/or to secure an unjustified advantage. This includes direct or indirect payments as bonuses or incentives to pharmaceutical chemists and/or pharmacy sales persons, owners and/or administrative personnel of drugstores or hospitals to recommend and/or dispense specific products.

ii. Report any offers or requests contrary to honest practices, concerning payments, favors, gifts, prerogatives, rewards or bonuses, according to the compliance control procedure provided in this Code, their corporate policies and the applicable laws.

iii. Not to agree with other competitors with respect to the procuring and/or public or private bidding processes to which they may present themselves or agree with other proponents on the terms to be submitted at a procuring and/or bidding process, unless they participate jointly as a consortium according to the Law or if the proponents form part of one same business group.

iv. Abstain from carrying out operations with third parties whose resources are generated by illegal activities. Therefore, they will demand from the third parties with whom they hold business relations the confirmation that they have not incurred in sanctions or investigations for corruption or asset laundering. If it should be verified that the suppliers' statements are false, they shall terminate the corresponding business relationship immediately and without the requirement of a legal statement, notice or indemnity, to which end they will include in the corresponding contracts or agreements a unilateral termination provision for this reason.

5.1.5 The companies agree to adopt strict measures to correct and/or sanction according to their corporate policies and applicable laws, any employees who fail to report conducts that may attempt against the principles of this Code or who may breach these provisions. In addition, they shall create internal communication channels to encourage employees to report conducts that attempt against the principles of this Code, establishing, as well, that no employee shall be subject to admonishing, suspension, dismissal, fine or sanctions of any nature for reporting violating conducts. In this respect, the companies shall engage all necessary efforts to inform and ensure compliance of this Code among their employees.

5.1.6 The companies may not manage, perform or finance legal actions through third parties (for example, patient organizations, NGOs, etc.) who may seek to force the access to drugs. The legal actions that ALAFARPE may initiate are not included in this scope.

5.1.7 When interpreting this Code, the internal codes of conduct of the Member Companies and the applicable laws, the strictest provision shall prevail.

5.2 Transparency

5.2.1 All promotional materials related to the drugs and their use, prepared or sponsored by a company, must clearly indicate the sponsor. The company logo shall suffice to that end.

5.2.2 The companies may distribute scientific material provided it complies with the requirements established in this Code and in their own companies and that it may be guaranteed. When a company finances, carries out or orders in any other way the publication of promotional material in scientific journals, such promotional material may not be presented as an independent editorial content and must clearly indicate who sponsors it.

5.2.3 When companies organize or sponsor events, this will be clearly stated in all documents related to the invitation, as well as in any other work, paper or document that is published related thereto.

5.2.4 Companies must duly document any and all transfers of value that they may perform directly or indirectly to players in the health system according to their internal procedures and the applicable laws. This includes fees paid for service provision, collaboration provided for the execution of scientific and professional events, hospitality expenses offered for an event, including transportation, registration, accommodations and meals and the registration or delivery of medical-scientific publications, among others. In addition, the obligation to document covers all donations, sponsorships or contributions that companies may deliver, directly or indirectly, to players of the health system. This documentation shall not be disseminated or transmitted to competitors and shall be compiled and preserved according to the companies' own accounting and filing policies. In order to comply with the provisions in this paragraph, Member Companies shall have an adjustment term of 6 months, counted as of the effective date of this Code.

5.2.5 The obligation to document value transfers as described in the foregoing paragraph does not apply to payments made to health professionals who have a work relationship with the company for the furtherance of their corporate purpose (that is, health professionals who are employees of the company and who have a relationship that involves subordination) medication samples delivered in compliance with the provisions of this Code or the printed promotional material furnished to health professionals.

5.2.6 Companies shall submit to ALAFARPE on an annual basis and on the date that the Executive President's Office may establish, for publication, the list of patient organizations to which they may have granted support, directly or indirectly, in cash or in kind, including a description of the support provided, the amount or value, the purpose thereof and the identification details of the beneficiary organization. When submitting such information to ALAFARPE, the companies must guarantee that they hold the corresponding authorizations to share it and that they are not in breach of any previously acquired confidentiality duties or obligations.

5.2.7 Companies express their commitment with transparency of clinical trials and other research initiatives they may undertake or sponsor. Clinical trials shall be conducted following the guidelines of the Regulations on Clinical Trials of Peru, approved by Supreme Decree 017-2006-SA as amended and complemented. It is hereby recognized that there are significant benefits for public health associated to having the information of clinical trials made publicly available to health professionals, patients and interested third parties, guaranteeing, however, the protection of personal data and contractual rights, as well as compliance with the legal provisions in force regarding industrial property. No clinical trial may be performed on a patient without the patient's previous informed and signed consent, containing acceptance of all potential risks and benefits entailed in the participation in a clinical trial.

5.3 Events

5.3.1 Companies may organize, sponsor or support scientific or professional events related to educational or complementary or refresher courses within the Peruvian territory, aimed at the different actors of the health system, to expand their knowledge level in matters concerning health care, improvement of patients' quality of life, health service provision and system sustainability, among others.

5.3.2 The objective and approach in symposiums, conferences and other scientific or professional events aimed at health system actors, organized, sponsored or supported by the companies should be to provide scientific or educational information and/or inform about drugs, seeking improvement of health and patient care.

5.3.3 It is against the ethical guidelines provided in this Code to offer or deliver any sponsorship in return for hospitality that may take place independently of a scientific or professional event. Hospitality must always be accessory to the main scientific or professional event and must be restricted to the provision of the means required for attendance and participation of the Health Professionals in the event. Furthermore, hospitality arrangements and expenses incurred by the companies must always be reasonable, meaning that hotels selected for accommodation of Health Professionals with the support of the companies may not and shall not be considered luxurious or extravagant, and may not offer entertainment activities (dancing, shows, casinos, etc.) The following considerations must be taken into account:

i. Events organized by member companies must not be conducted in touristic destinations, considering, for such purpose, the attending audience, unless most of the attendees belong to the locality where the event is taking place.

ii. The events may take place at hotels where business meetings are usually conducted, preferably four stars hotels. Exceptionally, due to logistic reasons, events may take place at a higher category hotel, for which each company shall establish the internal approval procedures.

iii. Hotel reservations may be made maximum from one day before to one day after the event.

iv. It is possible to establish a different criterion for the foregoing cases, provided there is a reasonable justification, for which member companies shall establish the corresponding internal approval procedures.

5.3.4 An event invitation in no case shall be subordinated to an obligation or commitment to prescribe, recommend, purchase, provide, administer or promote a drug.

5.3.5 In no case may a value transfer be offered or made to an event guest in compensation for the time taken to attend the event, unless it is the case of event participants under contract for the provision of professional services (speakers, advisors, etc.)

5.3.6 Companies are not allowed to organize or sponsor own or third-party events containing in their agendas entertainment or ludic elements or activities, parties, raffles, prizes, or other games of chance and/or tours. The foregoing restriction does not include activities such as welcome reception and closing dinner that are usually part of the official activities program in a congress, symposium and the like, provided that altogether they result reasonable, moderate and do not contain leisure, entertainment, ludic or chance activities. Companies shall refrain from participating in events organized by third parties that announce any entertainment activity as part of the program. These restrictions do not include entertainment activities that event organizers may offer as "optional" activities. In no case may these be directly or indirectly assumed by the company (including travel tickets and/or hotel reservation extensions).

5.3.7 Companies shall not organize events away from Peru, unless most of the participants or the relevant expertise resource of the event are located abroad, that is, an economic-geographic efficiency criterion shall prevail to select the venue location.

5.3.8 In no case shall companies organize or sponsor events in venues especially designed for leisure, in exclusively touristic places and/or places that may be considered extravagant or linked to mainly ludic, recreational or sport activities. As a general rule, the selection of a location shall be that where most of the attendees live.

5.3.9 Events organized or sponsored by the companies shall comply with the following requirements:

i. Have a program with relevant medical, scientific or professional content so that the main aspect of interest is the quality of the scientific or professional program. The agenda must be predominantly scientific or academic (not less than 70% of the event time.) It is not allowed to conduct independent entertainment events within the context of the organization of a scientific and/or academic event.

ii. Guest selection shall be the result of a careful evaluation of their capacities, education and experience that evidence their suitability to benefit from the training offered by the event subjects. The Companies shall set up internal screening mechanisms to ensure guest suitability for the event, and must be able to properly support the selection of the health professionals invited.

iii. Invitations to the event must clearly and expressly identify the purpose, sponsorship, scope and concepts that will be covered. In addition, and in the case of health professionals who work in hospitals or State offices, an authorization from the Health Professional's

immediate supervisor or any other person concerned shall be required in case there is a value transfer (for example: travel tickets, accommodation, transfers, etc.)

iv. Hospitality sponsorship may only cover the actual travel expenses, enrollment, accommodations (up to four stars hotels) and meals (excluding fancy restaurants) which must be moderate and reasonable, and may only be offered for the days covered by the scientific or professional activity. The following must be taken into consideration:

- ✓ Airline tickets for health professionals invited shall be of in tourist / coach class.
- ✓ Airline tickets and hotel reservations must be maximum from one day before to one day after the event, except for justified logistic exceptions.
- ✓ Health professionals invited may not participate directly or indirectly in the coordination of airlines tickets and hotel selection.

v. Snacks and meals offered during the event shall be moderate, reasonable and accessory to the main objective of the event.

vi. Local background music may be allowed. No musicians, dancers or any other artistic act shall be hired as accompaniment or activity of a scientific or professional event.

vii. Invitations shall not be extended to persons other than the beneficiaries, for whom the medical-scientific or professional content of the meeting may or may not be relevant for the development of their practice or profession, including, without restrictions, relatives, friends or spouses. Companies shall not assume any companion expenses.

viii. Companies shall cover directly all accommodation expenses and may make use of intermediary agencies which will have to strictly observe the conduct guidelines provided herein.

5.3.10 Events organized by third parties that are supported by the companies must be organized by a legally incorporated entity and must comply with all requirements indicated in the foregoing paragraph. The companies must have procedures in place to allow verification of guests' attendance to the meeting or event in question.

5.3.11 Companies must have an internal process in place to document that sponsorships granted for event accommodations comply with the requirements provided herein, providing among others, amount, purpose, date, recipient, agenda and any other required information to prove the legitimate need of the sponsorship and that sponsorship objectives are being complied with.

5.3.12 Hospitality-related sponsorships for patients and patient organizations shall strictly observe the following special requirements:

- ✓ Hospitality for patient organizations shall only be covered or funded through the patient organizations and never directly through patients individually.
- ✓ Sponsored events for patients may not have a promotional nature, and no incentives may be offered for attending the event, which may not be used to collect patients' data. Furthermore, the scientific information submitted to patient organizations must be presented by a health professional and must have an objective, cautious, balanced and impartial nature, taking special care that the information is not perceived as excessively encouraging and hopeful.

5.4 Donations, Contributions and Auspices

5.4.1 Donations or contributions made by the companies to health-related institutions shall comply with the following requirements:

i. They must respond to charitable, scientific, professional, humanitarian or social benefit reasons;

ii. They shall be granted without any valuable consideration in favor of the donor, whether direct or indirect, in cash or in kind;

iii. The donation shall not pursue the personal benefit of the donation beneficiary's employees or officials;

iv. The donation shall not constitute an incentive for the recommendation, prescription, purchase, supply, sale or administration of drugs;

v. The donation shall be transparent and formally documented by contract or acceptance letter signed by duly authorized representatives, which copies must be kept by the company, and the corresponding donation certificate.

5.4.2 Auspices provided by the companies to health care institutions shall meet the following requirements:

i. They must respond to legitimate commercial, promotional or scientific purposes;

ii. They must be granted against consideration from receiver that must be proportional to the contribution made;

iii. They must not seek the personal benefit of the auspice receiver's employees or officials;

iv. They must not be granted on condition that receiver recommends, prescribes, purchases, supplies, sells or administers drugs from the company;

v. They must be transparent and formally documented by contract or acceptance letter signed by duly authorized representatives, which copies must be kept by the company.

5.4.3 Companies are not allowed to grant donations to actors of the health system on an individual basis, but to duly incorporated legal entities. Not included in this restriction is the invitation to or the sponsorship of events in moderate and reasonable circumstances as described in chapter 5.3 of this Code.

5.4.4 Companies may support the logistic organization of scientific events through the donation of snacks. Without prejudice to the foregoing, the donation of snacks shall follow the criteria for donations herein established, as well as the internal channels and requirements of each company for the granting of donations.

5.4.5 Companies may make contributions in the form of academic recognition, provided that:

i. Value payment shall be directly made to the educational institution or scientific association and not to the beneficiary.

ii. The Company shall have no control or decisive influence in the selection of beneficiary.

iii. The present or future use, recommendation or prescription shall not be used as criterion for candidate selection.

5.4.6 Companies shall not make direct or indirect contributions, donations or auspices to political parties.

5.5 *Digital Environment*

5.5.1 The continuous development of technology and the use of new communication means, platforms and channels by pharmaceutical companies to promote their products and interact with the different health system actors shall not preclude the development of ethical business conduct. The nature of communication means, platform or channel used does not exempt laboratories from their obligation to comply with the ethical guidelines provided in this Code, corporate policies and applicable law. Companies must refrain from using means which because of their characteristics, technical limitations or conditions of use, may hinder compliance of the guidelines provided herein.

5.5.2 Among other things, the use of digital communication technologies allows providing information to the public in general regarding pathologies, their implications for health, health care and non-pharmaceutical options for their treatment, such as multidisciplinary and palliative treatments.

5.5.3 Each company may employ digital environment devises to train health professionals on pharmaceutical options of their own products. The use of digital environment means to promote prescription drugs shall be exclusively aimed at health professionals qualified to prescribe drugs, within an academic and technical-scientific framework. These activities must include the following measures to distribute such information exclusively among professionals :

i. A clearly legible warning stating information is exclusively addressed to health professionals qualified to prescribe or provide drugs, hence a specialized education is required for its proper interpretation, or

ii. Companies shall guarantee that persons accessing the content have the capacity as health professionals qualified to prescribe or provide drugs.

5.5.4 Companies shall abstain from making available to the public in general the promotional contents of prescription drugs, whether directly or indirectly, through links, comments, markers, or any other practice that may facilitate repetition or forwarding thereof.

5.5.5 Companies are responsible for the contents released through communication means, platforms and channels that they directly or indirectly control or fund, as well as for the implementation of user guides that set conduct standards and regular operating procedures to control the contents of the digital environment they give access to, host, copy or link to. Such procedure must consider the obligation to immediately and diligently rectify any irregularity.

5.5.6 Companies must have responsible behavior guidelines for their employees in the digital environment to establish consequences derived from their non-compliance both when submitting information regarding or in the name of the company and when using any means, platform or channel provided by the company.

5.5.7 Comply with the applicable law.

6 *Interaction with health professionals*

6.1 *Drug promotion*

6.1.1 No drug or therapeutic indication shall be promoted without prior approval by the General Directorate of Medicines, Supplies and Drugs (DIGEMID).

6.1.2 The following do not constitute promotion of drugs or therapeutic indications:

i. Reply, by the medical department of a member company, to spontaneous requests from health professionals in relation with non-approved drugs or indications, where there is specific written warning that such drug or therapeutic indication has not been approved in the country;

ii. Proper disclosure of scientific data related to non-approved active ingredients or indications, in scientific events not sponsored by the companies, such as conferences on research findings organized or conducted by medical-scientific associations, where such proviso is expressed.

iii. Public disclosure of information related to non-approved drugs or indications, to shareholders and other stakeholders, as required by the applicable regulations.

iv. Printed information or documents that in compliance with the applicable regulations, companies deliver to health professionals so that they may hand them out to patients related to approved drugs that because of their posology complexity, route of administration, etc. require additional information, provided that the purpose of this information is to improve treatment and that it complies with the requirements of Peruvian laws.

6.1.3 Promotional information must be clear, legible, accurate, balanced, honest and complete in order to allow the receiver to form his own opinion regarding the therapeutic value of the drug. The therapeutic information must be based on the updated evaluation of all relevant evidence and must reflect it clearly. It must not cause confusion due to distortion, exaggeration, improper emphasis, omission or in any other way. Ambiguity must be avoided by all means. Absolute statements such as "unique" or "no other" must not be used unless adequately supported and based on scientific grounds.

6.1.4 Information offered must be complete, based on scientific evidence, and must comply with requirements based on the applicable law.

6.1.5 Companies shall not suggest or promote substitution of the medical formula, or adopt any measure to attempt against the autonomy of health professionals.

6.1.6 Companies shall ensure that representatives responsible for the promotion of their drugs are properly educated and trained, and that they have sufficient medical and technical knowledge to convey true information regarding the drugs of the companies they represent. They shall:

i. Keep a professional relationship with interlocutors receiving their visit.

ii. Report the health professional's comments regarding visit results, including adverse events, which shall be reported to the companies and health authorities in accordance with the applicable law.

iii. Carry out visits, preferably to health system actors' offices or practices. In case the actor of the health system is a public official, the visit must be conducted in accordance with the applicable law.

6.1.7 The medical visit or promotional activity to payers or other actors responsible for decision making regarding drug prescription or purchase in no case may be subordinated to the payment, in cash or in kind, as direct or indirect valuable consideration or compensation for the time invested in such activity. Furthermore, neither medical representatives nor any other company representatives shall make any appointment or shall pay for a consultation visit to be received by a health professional. Exceptionally and when required by the situation, medical representatives of the companies may conduct one-on-one meetings offering modest hospitality (for

example, a soft drink and/or low-cost snack) but shall not offer or conduct meetings in restaurants, hotels or entertainment centers.

6.1.8 In the case of one-on-one meetings conducted by other positions, meetings may include breakfast, lunch, dinner or a light meal, provided the purpose of this meeting is legitimately of a business nature. The purpose of the meeting and the need for the invitation must be documented in the expense account. The place must be suitable and not sumptuous.

6.2 Educational Activities

6.2.1 Pharmaceutical companies associated under ALAFARPE give support or conduct educational and training activities that contribute ensuring that health system players obtain more updated and accurate information and understanding to improve patient care and the health system in general. The main purpose of a training event is to improve the knowledge of physicians and other players of the health system to help in the provision of optimum healthcare and to improve patient treatment.

6.2.2 When companies provide content to medical education activities and programs, such material must refer to use approved by the corresponding authorities, it must be honest, balanced and objective, as well as designed to allow expression of the diverse recognized opinions. Content must consider medical, scientific or professional information that may contribute to improve patient care.

6.2.3 Events that involve the participation of health professionals must adhere to the provisions set forth by this Code, the corporate policies of each Member Company and the applicable law.

6.2.4 In the case of one-on-one academic or scientific meetings, same may include breakfast, lunch, dinner or light meals, provided they take place within the context of meetings with predominant scientific purpose (not less than 70% of the total time taken). The purpose of the meeting and the need for the invitation must be documented in the expense account. The place must be proper and not sumptuous.

6.3. Promotional Material

6.3.1. Drug promotion must be based on scientific data and must include information regarding precautions, contradictions, warnings, interactions and secondary effects of the promoted drugs. The applicable law, corporate policies and provisions contained in this code must be observed.

6.3.2. It is possible to make a comparison provided there are objective and verifiable grounds and it does not affect the good standing of third parties or their products.

6.4. Promotional Products and Products of Medical Use

6.4.1. Promotional products and/or products of medical use are intended to serve as a trademark reminder.

6.4.2. Promotional products are non-monetary products distributed with promotional purpose. They must be related to the work of the health professional that receives them. Promotional products must not exceed individually an amount equivalent to five percent (5%) of the minimum vital salary (RMV).

6.4.3. Products of medical use are items physicians may require for medical care of patients in their practice, such as an anatomic model, gowns, surgical gloves, tongue depressors, among others. These may not exceed individually an amount equivalent to twenty percent (20%) of the minimum vital salary. Furthermore, total value of products delivered to each physician per year (calendar) may not exceed 50 percent (50%) of the RMV.

6.4.4. It is expressly, explicitly and categorically prohibited for products to consist of gifts, cash or its equivalent for the personal benefit of the health professional, whether directly or indirectly delivered.

6.4.5. It is not permitted the delivery of products not related with the medical practice to health professionals on the occasion of relevant national, cultural or religious celebrations.

~~*6.4.6.* The limit for each of these products is 7% of the RMV and may be delivered maximum twice per year to each health professional.~~

~~*6.4.7.* Such products may have the company logo but not the trademark of any of their products.~~

6.5. Medication Samples

6.5.1. Medication samples may be provided to health professionals only so that they may become acquainted with a medicine, its indications and recently authorized administration route or to improve patient care.

6.5.2. Samples may not be provided with the intention to induce prescription, recommendation, acquisition, supply or administration of a medicine or for the treatment of patients as sole purpose.

6.5.3. Samples must be furnished to physicians using an adequate control and monitoring system, which must comply with the regulations issued by the tax authorities (SUNAT) in relation with activities involved in the delivery of medication samples.

6.5.4. Only a limited number of medication samples of each drug may be provided to each health professional, the number to be established by each company according to the characteristics of the product in a reasonable manner. Samples may not be larger than the smallest commercial presentation of the product and must be clearly marked as "medication sample" so as to prevent the undue re-selling or use thereof.

6.5.5. Companies shall keep a medication sample control system, including monitoring of samples while they are in the hands of their sales representatives.

6.6. Professional Services

6.6.1. Contracting of health professionals, directly or through companies pertaining to economic groups of the Member Companies is allowed, as consultants/advisors, lecturers or presenters in events, researchers in market/clinical/scientific studies and/or to provide their services in educational activities when such participation implies the payment of compensation.

6.6.2. The agreements with health professionals or with entities of which they form part shall comply with the following conditions:

- ✓ The need of the services to be contracted shall be expressly documented.
- ✓ Prior to the service provision, a written agreement must be executed, identifying the following: services to be provided, amount of compensation, deliverables and term for the service provision.
- ✓ The agreement shall include a clause under which the health professional agrees to represent expressly that he is providing a service to the company, every time he speaks publicly about any matter related to the purpose of his agreement with the company.

- ✓ The selection criteria for contractors must be objective (not commercial) and must be directly related to the identified need and the contractor must have the education, experience and recognitions required for the provision of the services.

- ✓ The total number of health professionals to be contracted must be related to the need to reach the established requirement.

- ✓ The compensation for the agreed service provision shall respond to the fair market value and must be documented. It must be in cash and paid through bank channels. No loss of profit shall be paid to the health professional for activities not performed during the service provision. Notwithstanding, it is feasible to pay a reasonably higher differentiated rate when the services are provided outside the place of residence of the contracted professional.

- ✓ The contracting of a health professional must not be intended as an incentive to prescribe, recommend, acquire and/or administer a medication. In this respect, the respective agreements must establish the purpose for which the health professional is being hired.

- ✓ Travel expenses and costs of accommodations and meals related to the services contracted may be agreed, however, they must be reasonable and meet the requirements and conditions established in this Code, except in justified cases concerning logistic matters.

- ✓ For the hiring of foreign health professionals, payment shall consider the fair market value of the country of origin of the hired health professional or the country where he exercises his profession.

- ✓ When contracting the services of health professionals, Member Companies must ensure an adequate management of conflicts of interest through the inclusion of pertinent clauses in their contracts, an analysis of the health professional's career, among others.

- ✓ When contracting health professionals or health sector actors working in public sector entities, Member Companies may not contract their services for advisory or consultancy matters that involve aspects concerning the institution where these health professionals work. The contract must include the health professional's obligation to inform about his hiring to the Entity where he works. The hiring of health professionals as researchers in clinical studies conducted in the Entity where they work is permitted, bearing in mind to avoid conflicts of interest.

- ✓ The indirect hiring of health professionals (for example through companies where they work) must comply with all the rules contained in this Code.

6.7. *Clinical Research*

6.7.1. Research activities must be conducted observing the research protocols and in line with national and international rules.

6.7.2. Every clinical research sponsored by Member Companies shall be conducted according to the Helsinki Declaration, the Code of Nuremberg, the Universal Declaration on Bioethics and Human Rights of UNESCO and the Peruvian and international legal provisions in force, available to that end. This implies the existence of:

- ✓ Research protocols ethically and scientifically valid.

- ✓ Election of research centers and researchers suitable and certified on the subjects to be researched

and on the clinical research methodology, knowledgeable of their rights and obligations.

- ✓ Informed consent, which must be complete, real and clear, and which must include accurate information about the risks and benefits entailed in participating in the study. They must be read, understood and signed in acceptance by the participating subject or his/her legal representative prior to any intervention and/or procedure included in the study, in strict observance of the applicable habeas data laws.

- ✓ Submission of the protocol to the relevant internal approvals prior to any intervention and/or procedure included in the protocol.

- ✓ Submission of the protocol, letter of approval of the institutional ethics committees, personal record of researchers and co-researchers and letter of commitment of the researchers and the sponsoring company, among other documents required, to the competent national authority for approval, prior to any procedure and/or intervention included in the protocol.

- ✓ Transparent and clear statement of the financial conditions that link the companies to the Research Center and the Researchers.

- ✓ Pharmaceutical surveillance program for the reporting of events and adverse reactions of the companies, according to the regulations issued by the local health authorities.

- ✓ Respect for privacy and the confidential information and strict compliance of the applicable regulations on data protection.

- ✓ Transparency in the formation of study groups, avoiding moral pressure actions or undue material compensation to obtain the consent of the study subjects.

- ✓ The companies are in the obligation to keep proper evidence that validates compliance with all the requirements described in this chapter.

6.7.3. Non-interventional and Phase IV post-approval studies must not exert undue formulation influence on the health professionals.

6.7.4. All studies with prospective pharmacological intervention must observe the legal provisions in force. The so-called "seeding trials," "clinical experiences" or the like, the purpose of which is to expand the physicians' prescription habit, are forbidden.

6.7.5. Patients' or disease records shall not be used for the promotion of drugs or to exert undue influence on health professionals for their recommendation or prescription.

6.7.6. Payments made for the different services provided by the health professionals in relation with the clinical research shall be subject to the fair market value determined by the medical area of each Member Company.

6.8. *Market Research*

6.8.1. In order to obtain information related to their business, companies may conduct paid market research studies, which must comply with the following:

- ✓ The research must have a previously defined need;

- ✓ Confidentiality of participants must be maintained at all times;

- ✓ The research activities must not be conducted directly by personnel from the sales work force of the company;

- ✓ The hiring of health professionals and/or entities through which the research is to be conducted must be formalized through a written agreement;
- ✓ In the case of research studies commissioned by more than one company, the results analysis shall be individual;
- ✓ The companies must guarantee that the conduction of the research shall not constitute an incentive for anti-competitive agreements or practices;

6.8.2. Market research studies must not be a mechanism to encourage drug consumption or prescription.

6.8.3. The results of market research studies commissioned by the companies may be used in the promotional material provided they indicate that they are the result of a market research commissioned by the company.

6.8.4. The companies shall be responsible for the handling, treatment, storage and elimination of the personal contact data obtained during the market research studies commissioned.

7 Interrelation with patients

7.1 Interrelation with Patient Organizations

7.1.1 Having in mind the common interests of the Member Companies and Patient Organizations, it is necessary to define ethical guidelines to guarantee the respect and commitment towards these organizations.

7.1.2 The principles for an adequate interrelation with patient organizations are:

i. The Independence and autonomy of patient organizations must be guaranteed;

ii. It is expressly forbidden for companies to request patient organizations the specific promotion of a drug;

iii. The support to patient organizations shall not be used in any case whatsoever, to induce drug prescription or promotion;

iv. The funding of patient organizations must have several sources. Nevertheless, there may be exceptional situations where only one company is willing to support a certain patient organization or an activity thereof, which would be acceptable as long as the company does not condition such support to being the exclusive supplier of funds.

v. Patient organizations may not be used by Member Companies as vehicles to file legal actions by funding those actions.

7.1.3 All collaboration between companies and patient organizations must be documented in writing so as to comply with the obligation concerning transparency.

7.1.4 No company may use the logotype, trademark, distinctive sign or material that identifies a patient organization, except in the case of joint activities with the patient organization. Companies may not demand that their logos be used as a condition to provide support. If a company logo is to be used, there must be a spontaneous written request from the patient organization to use same.

7.1.5 Companies may not make contributions to patient organizations that refuse to disclose the source of the funds.

7.1.6 When a company sponsors a publication from a patient organization, the name of the sponsoring company

must be expressly mentioned. It is important that companies do not exert influence on such publications to favor their own commercial interests.

7.1.7 It is possible to enter into agreements with patient organizations for the provision of advisory or consulting services, provided that such services are rendered to collaborate with health care assistance, research and/or for educational purposes. It should be guaranteed that the agreement does not respond to an incentive to recommend a drug.

7.2 *Patient Support Programs*

7.2.1 The purpose of patient support programs is to provide support to patients and caregivers in their illness, as well as in proper drug use. This includes programs aimed at educating towards improving life quality.

7.2.2 Among the contributions of patient support programs, it is possible to provide support to patients who are unable to afford their medication or who cannot interrupt their treatment or who may require an initial or continuity dose. In these events, the cases must be duly documented within the support programs managed by each company.

7.2.3 Only patients duly enrolled in patient support programs are eligible for the benefits of such programs. In order to join a patient support program, applicants must submit, at least, the following, depending on the type of program: physician's report indicating the disease and treatment and/or drug prescription, a document evidencing that the drug is not covered by a private or public insurance. Medication samples may not be given directly to patients through these programs. Furthermore, a patient support program may not be used for indications of drugs not approved by the competent national authority.

7.2.4 Patient support programs may include the delivery of articles related to the activities implemented in the program, provided the value of such articles does not exceed 5% of the minimum salary (RMV).

7.2.5 Companies must not contract or in any way finance health professionals in the support programs to make recommendations or prescribe the drugs.

7.2.6 Patient support programs may have a commercial and it is forbidden to establish a patient support program with the purpose of promoting products.

7.2.7 Support programs may not suggest recommendations to replace the treatment established by the treating physician. In this respect, the physician providing the service to the patient within the support program may in no case be the prescribing physician.

7.2.8 Companies may not use patient support programs to encourage, manage, execute or finance legal actions that seek to force access to drugs.

7.2.9 Patients that form part of a support program must sign a previous informed consent to the company. The handling of this information must meet the requirements established in the applicable laws.

7.2.10 The individual information of the patients of a support program shall not be disclosed to the commercial areas. Only statistical information may be disclosed to the commercial areas.

7.2.11 Patient support programs must guarantee an adequate channel for reporting adverse events that may arise in the course of these programs.

7.3 *Interaction with patients and caregivers*

7.3.1 Patient data used by the companies to comply with the Peruvian legal provisions in data privacy, as well as the prohibition of direct promotion of drugs to consumers that require them.

7.3.2 If a company should require to interact with patients in order to obtain information about their experience related to their disease, it must comply with the following requirements:

i. Initial contact with the patient must be through a patient organization or through a health professional, before whom the patient grants authorization to share his data with the company.

ii. The patient´s testimony must be contributed for free and must not be subject to any compensation whatsoever, in cash or in kind, except for the payment of any costs that may be incurred for transportation, accommodations and/or meals required for the rendering of the testimony and which must be paid directly by the company.

iii. It is expressly forbidden to provide medication samples or to supply drugs in exchange for a patient's testimony.

iv. All interaction with patient to obtain their testimony must be previously documented through a written agreement with the company, which must include the corresponding confidentiality clauses.

v. The extent of hospitality for a patient must be accessory and must comply with the requirements defined in chapter 5.3 of this Code.

7.4 Diagnostic Support

Companies may provide support through diagnostic trials that may cover needs within the patient support programs, under the following guidelines:

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

ii. Health professionals may prescribe these trials to any patient without it implying the previous condition to prescribe the products of the company providing the support for the diagnostic trials.

iii. The value of the diagnostic trials shall be paid directly by the company to the institution performing the trial and in no case to the prescribing physician or to the patient.

iv. The company shall not have access to the personal identification data of patients referred for the sponsored diagnostic trials. Only statistical data on trial results shall be made available to the company.

v. The selection of the institution that will perform the diagnostic trials must be based on objective criteria that guarantee their suitability and Independence.

8 Interrelation with public health system officials

8.1 Scope of application

8.1.1 The provisions contained in this chapter with regard to the interrelation of companies with public health system officials are applicable to individuals, regardless of whether they are full-time or part-time employees or contractors (physicians, administrative personnel, etc.) who provide their services to an entity owned, controlled or operated by any level of the Peruvian State or which may be financed, even partially, with public funds.

8.1.2 The guidelines established in this code for the interrelation with public health system officials shall apply

without prejudice to the legal provisions. In case of conflict between the provisions of this Code and the applicable legal provisions, the strictest rule shall prevail.

8.2 *Fundamental principles in the interrelation with public Health System officials*

The interrelation of companies with public health system officials must comply with the highest ethical and transparency standards, upholding the following principles:

8.2.1 Absence of inappropriate influences: Companies shall not participate in any interaction that may constitute or may be perceived as an undue influence on a public health system official. In particular, companies shall not:

i. Offer, promise or pay any valuables, directly or indirectly, to a public health system official, a member of their family, a legal entity of their property or under control of their family, to ensure an undue commercial benefit or to obtain, retain or guide business deals towards the company. In this respect, Member Companies may only perform the following actions through their representatives, in one-to-one meetings:

- In the case of medical representatives: offer the health professional a beverage and/or non-expensive snack within the context of a scientific or commercial conversation in the Institution's cafeteria (not outside the Institution) provided it takes place within the context of a meeting with scientific or academic purposes. These meetings may take place in institutional cafeterias provided that the hospital or health center allows such meetings in such premises.
- In the case of other positions: Exceptionally and sporadically (due to the health professional's agenda) meet in the Institution's cafeteria (never outside the Institution) and, if deemed convenient, assume the breakfast, lunch, supper or dinner cost in the cafeteria, provided the meeting takes place with legitimate predominantly scientific purposes (at least 70% of the time involved) or with commercial purposes. The reason for the meeting and for the invitation must be duly documented.
- The following rules shall apply in such cases where the public health official works in the public and private sector at the same time:
  - ✓ If the purpose of the interaction is to discuss issues concerning the Public Entity, the rules detailed in the preceding paragraphs shall apply.
  - ✓ If the purpose of the interaction is to discuss issues concerning the Private Entity, the rules detailed in item 6.1.7 of this Code.
  - ✓ If the purpose of the interaction is to discuss issues concerning both Entities (Public and Private), the rules for interaction with Public Sector Health Professionals shall apply (the strictest Rule).
- Provide promotional articles and/or materials for medical use.
- Give Corporate Agendas or Calendar (on special dates).
- Send invitations to scientific or academic events - conferences, etc. through a formal written invitation addressed to the institution, with the express authorization of the invited health professional's immediate superior.
- Send greeting cards on birthdays or other special dates.

ii. Offer, promise or make any payment, directly or indirectly, to a public health system official to facilitate or expedite government actions.

iii. Send individual breakfast, lunch or dinner invitations to Public Health System Officials outside the context of a meeting with scientific or academic purposes.

8.2.2 Ethical conduct in the course of commercial transactions: companies shall abstain from any of the following

actions:

i. Discuss with purchasing/acquisitions/logistics or regulatory personnel the possibility of offering any kind of opportunities related to the company for the employee or any of his relatives;

ii. Request or obtain non-public information of the purchasing entity or of possible competitors that may generate an illegal competitive advantage;

iii. Offer or grant any kind of benefit for a public official of the health system or for a related third party.

8.23 Conflicts of interest: Companies shall avoid establishing relationships with public health system officials, which may generate a conflict of interest for any of the parties, or which may be perceived as such. To that end, companies must document all their interactions with health system officials transparently and reflecting the real situation, so that they are able to clarify any accusation with regard to the existence of an improper handling of a conflict of interest.

8.24 Honesty and Integrity: In their interactions with public health system officials, companies must adopt the necessary mechanisms to ensure the veracity and accuracy of all the information provided by their employees or any third parties acting in their name. There must be service agreements previously executed with public officials of the health sector, detailing the scope of services and the compensation paid for such services.

8.25 Transparency: Employees and third parties acting in the name of a company in its interrelations with public health system officials must present themselves clearly as representatives of the corresponding company.

8.26 Respect and Independence: Companies shall respect the Independence and fairness of public health system officials in the discharge of their duties. Abuse of any position must be avoided by all the parties involved.

8.27 Legality: Some health system officials, because of their nature or the work they perform, may be subject to special regulations (for example, EsSalud) more restrictive than the provisions established in this Code. Companies must guarantee strict compliance of the regulations applicable to health system officials in their interrelation with them.

8.28 Confidentiality: Companies must respect the rules and regulations that govern the provision of confidential or privileged information by public health system officials.

9 Compliance control

9.1 Overview

9.1.1 Member companies, as well as non-member third parties who may adhere to this Code, shall adopt internal procedures in their companies to ensure full compliance thereof, regardless of the mechanisms provided in this chapter and/or the provisions established in the laws in force.

9.1.2 The Ethics Committee of ALAFARPE will be the body in charge of disseminating, informing and enforcing this Code, and will ensure that its website provides direct access to this document and that it offers a consulting mechanism to the associated companies regarding the provisions contained herein.

9.2 Control Bodies

9.2.1 The competent control bodies for compliance control and the management of claims concerning alleged violations of this Code are: the Ethics Committee of ALAFARPE, the External Ethics Panel and the Higher

Appellate Panel.

9.2.2 The duties of the Ethics Committee of ALAFARPE are:

i. Safeguard compliance of the provisions of this Code by its members.

ii. Propose to the Board of Directors of ALAFARPE the measures it deems convenient for the implementation, dissemination and enforcement of the provisions of this Code.

iii. Periodically revise and update the provisions of this Code.

iv. Interpret the provisions of this Code and clarify its scope, with exception of inquiries concerning possible violations.

The Ethics Committee may delegate the functions it may deem pertinent to a work group designated by it on a temporary or permanent basis.

9.2.3. The External Ethics Panel is the first instance in claim proceedings regarding violations to the Ethics Code and shall consist of three (3) members and their respective alternate members, having no conflicts of interest with ALAFARPE associates, who shall be appointed annually by the Board of Directors of ALAFARPE. To that end, the Board shall prepare a list of nine (9) persons as eligible members for the External Ethics Panel that will hear the claims. In order to prepare such list, the Executive Director of the Association will receive candidates presented by the member companies or companies endorsing the Code. The following criteria shall be considered in the preparation of the list:

i. Professionals with at least ten years exercising the profession.

ii. The members must not be related as employees or permanent advisors of companies in the pharmaceutical sector or of ALAFARPE, at least during the two years previous to their presentation as eligible members.

iii. They must be knowledgeable or experienced in ethical matters, compliance programs, self-regulation and/or corporate governance.

iv. Knowledge or experience in the pharmaceutical sector.

v. In the event an impediment should arise at the time the External Ethics Panel is established or during the processing of a claim, the interested party shall inform the Executive Director of ALAFARPE so that new panel members may be appointed pursuant to this Code.

9.2.4 The decisions of the External Ethics Panel may be contested before the Higher Appellate Panel, which shall be formed by one member proposed by each of the parties of the proceeding and one proposed by ALAFARPE from a list of eligible members prepared and published by ALAFARPE on an annual basis.

9.3. Sanction Categories

9.3.1. Violation to the Code of Ethics shall be categorized as minor, serious and major, based on the following evaluation criteria:

9.3.1.1. Nature of the violation and, in particular, the possible risk for patients' health.

9.3.1.2. Damage to the medical or scientific profession or the society in general, generated by the violation.

9.3.1.3. Repeated violation.

9.3.1.4. Damage to the pharmaceutical trade image.

9.3.1.5. Economic benefit for the company resulting from the violation.

9.3.2. Once the violation has been classified as minor, serious or major based on the previously mentioned criteria, aggravating factors may concur, which shall be evaluated and considered by the competent body when imposing the corresponding sanctions. The accumulation of aggravating factors may modify the initial classification from "minor" to "serious" or from "serious" to "major". Aggravating factors are:

9.3.2.1. Degree of intent.

9.3.2.2. Disregard of previous warnings.

9.3.2.3. Concurrence of several violations in the same event or activity.

9.3.2.4. Major amount of economic benefit estimated for the company resulting from the activity involved in the violation.

9.3.3. Repeated acts in violation of this Code shall entitle the Board of Directors of ALAFARPE to consider the viability of the permanence of the repeat offender in the Association.

9.3.4. Based on the criteria previously mentioned, the sanctions to be imposed by the External Ethics Panel or by the Higher Appellate Panel may have a moral, monetary, participative or legal nature.

9.3.4.1. Moral sanctions:

- Obligation to perform new training course
- Written admonishment, with copy to governing bodies or head office, depending on seriousness of violation.
- Reporting to Head Office and/or their governing body in the event of repeated misconduct, concurrence of two (2) or more minor and/or serious violations and in the case of major violations.
- Publication in the page of ALAFARPE of the resolutions adopted in the case of serious violations.

9.3.4.2. Monetary sanctions:

- For minor violations: imposition of fines from 10 to 20 Tax Units (UIT).
- For serious violations: imposition of fines from 21 to 50 UIT.
- For major violations: imposition of fines from 51 to 100 UIT.

9.3.4.3. Participative sanctions are applicable to companies associated under ALAFARPE and consist in suspending the breaching company's participation in deliberative activities of the committees and/or work groups of ALAFARPE and/or in Board meetings for up to three (3) months and/or suspending voting in right in the Board of Directors for up to three (3) sessions, without prejudice to considering removal from the Association.

9.3.4.4. Legal sanctions: If the final decision indicates that there was a violation of the Code of Ethics that constitutes a violation of legal provisions in force, the claimant may evaluate reporting the case to the competent authority.

9.4. Settlement of Disputes Procedure

9.4.1. If a member of ALAFARPE should consider that another member is allegedly violating this Code of Ethics, it must contact such member to clarify the facts before submitting a complaint.

9.4.2. Any person and, in the case of members of ALAFARPE and of companies that adhere to this Code, may submit a formal complaint to ALAFARPE through their legal representative regarding conducts that violate the provisions of this Code of Ethics. Such complaint must be submitted in writing and must be addressed to the Board of Directors of ALAFARPE, detailing the facts known to the complainant, accompanied with the evidence to prove the accuracy of the alleged facts.

9.4.3. Upon receipt of the complaint, the Board of Directors must validate it, verifying that:

v. The reported conduct attributed to the alleged offender violates a provision of this Code of Ethics;

vi. There is sufficient objective information to process the claim and the complainant has furnished specific proof or data to enable processing;

vii. The complaint has been submitted in good faith, based on real facts.

If the complaint cannot be validated due to the absence of any of the above requirements, it may not be processed according to the procedure for settlement of disputes of this Code and complainant must be informed accordingly by ALAFARPE.

Within fifteen (15) business days after the complaint for alleged violations to the Code of Ethics has been received and validated, the Executive President of the Association shall call the External Ethics Panel.

9.4.4. In the case of anonymous complaints, three delegates of the Board of Directors shall conduct a preliminary investigation and decide if they should be submitted to the External Ethics Panel.

9.4.5. The External Ethics Panel shall initiate the process within thirty (30) business days after being established. ALAFARPE shall notify the complainant and the alleged offender in writing.

9.4.6. The External Ethics Panel shall issue a resolution within thirty (30) business days after having received documentation and notify the parties and the Executive President of ALAFARPE within the next five (5) business days. The parties may submit to this same authority a motion to reconsider within fifteen (15) business days after being notified. The External Ethics Panel shall decide on such motion to reconsider within fifteen (15) business days and shall notify the parties and the Executive President of ALAFARPE within the next five (5) business days through any means.

9.4.7. The decisions of the External Ethics Panel, including the reconsideration decision, may be appealed before the Higher Appellate Panel. To that end, appellant must notify the Board of Directors of the Association within five (5) business days after receiving notification of the External Ethics Panel's award, its decision to appeal. If no intention to appeal is expressed, the award of the External Ethics Panel shall be firm.

9.4.8. Upon having the intention to appeal been established, the Board of Directors of ALAFARPE shall notify the parties within the next five (5) business days the need to form the Higher Appellate Panel to which end there will be a maximum term of fifteen (15) business days for the designation and establishment of the panel. The Higher Appellate Panel shall issue its decision within a maximum term of thirty (30) business days, which shall be final.

9.4.9. Once the decision of the External Ethics Panel or of the Higher Appellate Panel, as the case may be, is rendered firm, indicating the existence of a violation to the Code of Ethics, the Board of Directors shall enforce the determined sanction or sanctions, prior notification to the parties through any means.

9.4.10. The resolution or decision on sanctions for minor violations to the Code of Ethics shall be informed to all members and in the case of violations determined as serious and major copy shall be sent to the General Manager of the sanctioned company.

9.4.11. If the last instance resolution, whether it is the External Ethics Panel or the Higher Appellate Panel, should determine that there was no violation to the Code of Ethics, the alleged offender may request to make the situation public.

9.5 Expenses

9.5.1 The cost of each instance shall include the fees of the External Ethics Panel and/or the Higher Appellate Panel and the operating expenses they may require. The fees of the External Ethics Panel and/or the Higher Appellate Panel, as the case may be, shall be set by ALAFARPE, taking as reference the rates framework in force of the Lima Chamber of Commerce.

9.5.2 Upon completion of the process, the total amount of fees and expenses shall be paid by the losing party provided that the decision is supported. In the event that the final decision is unsupported, the total amount of fees and expenses related to the process shall be paid by the complaining party.

10. Effectiveness

This code shall enter into full force and effect on September 1, 2016. Member Companies shall have until December 31, 2016 to adapt their internal processes to the scopes of this Code. If a Member Company should require additional time, it shall submit justification to the Board of Directors of ALAFARPE.