

## **CODE OF CONDUCT**

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### **PREAMBLE**

The pharmaceutical industry constantly renews its quest for innovative therapies that transform themselves into alternatives for the growing challenges of public health, bringing dynamism to a sector that is constantly recycling its concepts and opening new horizons to patients and healthcare professionals. The ethical promotion of medicines is the lawful way employed by the industry to interrelate with people who directly and/or indirectly need to be aware of these innovations and, therefore, must have fast and effective access to information about suitable treatments for their specific needs.

Interfarma's Associate Companies and those that spontaneously agree to adhere to the terms of this Code of Conduct (referred to as "Companies") acknowledge the importance of medicine promotions and agree to conduct their promotional activities within uniform, ethical and transparent standards and consistent with the autonomy of healthcare professionals.

This Code of Conduct reflects the industries' commitment in contributing to the consolidation in Brazil of a pharmaceutical market conscious of their responsibilities towards patients, consumers, doctors and all healthcare professionals whom they are connected with

### **CODE OF CONDUCT**

#### **Definitions**

The following definitions are applicable to this Code of Conduct:

**Healthcare Professional:** Any member of the medical, dental or pharmaceutical profession who may prescribe or dispense medicines.

**Related Healthcare Professionals:** Any person who can influence the prescription, dispensation, or recommendation of medicines, both in private and public sectors when acting as Public Agents, including nurses, physiotherapists, speech therapists; medical, pharmacy, nursing, physiotherapy and phonology students; drugstore and pharmacy over-the-counter attendants, product standard commissioners, public and private hospitals agents and employees, and other entities and clinics connected with patients or Institutions, Bodies, Associations and Healthcare Companies.

**Institutions, Bodies, Associations and Healthcare Companies:** Are all those that directly or indirectly, in the private sector or as part of public administration, take part in or support the healthcare sector, including those medical, pharmaceutical and patient representative classes, regulatory agencies, Ministry of Health and Secretaries of Health at municipal and state levels, or any other private entity or public administration body that directly or indirectly purchase medicines.

**Public Agent:** any individual who, permanently or temporarily, with or without pay, holds, directly or indirectly a position, job or public service at any body or entity from public administration;

**Promotional Material:** All and any materials produced by the Companies aimed at promoting their products, independent of any other support or media used.

**Free Samples:** all non-chargeable medicines distributed to Healthcare Professionals.

## Code Structure

In order to better systemize the rules hereunder, the dispositions of this Code were divided as follows:

- Chapter 1 – General rules for the pharmaceutical sector;
- Chapter 2 – Rules related to medicines subject to medical prescriptions;
- Chapter 3 – Rules related to medicines exempt of medical prescriptions;
- Chapter 4 – Procedures for dealing with complaints.

## CHAPTER 1 – General Rules for the Pharmaceutical Sector

### Section 1 – General Principles

1.1. Companies will observe the following ethical principles when promoting their medicines:

- 1.1.1. **Basis of Interaction:** Companies' relationship with Healthcare Professionals, Related Healthcare Professionals and Institutions must be based on the exchange of information as a means of improving the permanent development of medical and pharmaceutical practices, contributing to patient's access to more and more efficient and reliable therapies.
- 1.1.2. **Information about Products:** The information about products must be balanced, trustworthy, complete, up-to-date and, when appropriate, supported by scientific evidences. The promotion of medicines based on controversial information or without solid foundation is against the principles of this Code.
- 1.1.3. **Independence of Healthcare Professional:** Companies cannot, directly or indirectly, offer, promise or grant bonuses, gratifications or any other economic advantages to Healthcare Professionals as an inducement to prescribe, use, promote, recommend, indicate or endorse medicines. Any action that may be perceived as an undue interference in the autonomy of Healthcare Professionals or Related Healthcare Professionals should be interrupted immediately, without prejudice to possible responsibility inquiry in accordance with the rules of this Code and the Legislation in force.
- 1.1.4. **Appropriate use of Medicines:** Promotional activities must serve to disseminate the appropriate use of medicines and recommendations that are not strictly in accordance with those previously approved by the Brazilian Sanitary Authorities are prohibited.

- 1.1.5. **Transparency in Relationship:** Companies are not allowed to maintain veiled relationship with Healthcare Professionals, Related Healthcare Professionals or Institutions, Bodies, Associations or Companies connected with the Healthcare sector. Actions involving donations or the hiring of professionals for specialized services, evaluations, researches or studies must be always motivated by clearly identified social, scientific or educational necessities and with solid justification.
- 1.1.6. **Responsibility:** Companies will be responsible for the faithful application of this Code of Conduct in every activity that they undertake, directly or indirectly, with Healthcare Professionals and Related Healthcare Professionals. Companies will be also responsible for distributors and other contracted companies whenever acting on their behalf.
- 1.1.7. **Established Legislation:** In addition to the rules of this Code, all laws, decrees, regulations, resolutions and norms from competent authorities concerning this subject shall apply to medicine promotions.

## **Section 2 – Adherence to the Code and Application to Healthcare Correlated Areas**

- 2.1. Companies bound to this Code of Conduct will sign a declaration whereby they commit themselves to respect the norms hereby established and subject themselves to the rulings of disciplinary bodies established to evaluate conducts and apply sanctions for any proven infractions to current rules, in accordance with Chapter 4 outlined below.
- 2.2. The application of this Code can be also extended to interested companies that operate in areas connected to the defense and protection of health, as for instance, nutritional and medical-hospital products. The peculiarities of such connected activities shall be considered when applying the rules of this Code of Conduct.

## **Section 3 – Contracting Healthcare Specialized Services**

- 3.1. Companies can contract Healthcare Professionals or Related Healthcare Professionals to provide specialized services in accordance with their specialization or graduation areas. Companies are allowed to remunerate those Professionals in accordance with the complexity and importance of the professional services provided, in addition to out-of-pocket expenses, provided that they are within reason, for transportation, accommodation and meals incurred during the period those Professionals are working on behalf of the Companies.
- 3.2. Contracting of Healthcare Professionals or Related Healthcare Professionals must comply with transparency principles and ethical limits established in this Code, observing, when applicable, the following:
- a) The existence of an agreement in writing specifying the nature of the services to be provided and the criteria to remunerate these services;
  - b) The existence of a legitimate interest in contracted services clearly and previously identified;
  - c) The adoption of standardized criteria for the selection of required professionals, assuring that those people responsible to select have the knowledge needed to evaluate if the selected professionals meet established requirements;
  - d) The number of professionals hired is compatible to the complexity of the services to be provided;

- e) The maintenance of pertinent records and ensure that services provided have been effectively undertaken;
- f) Meetings with contracted professionals must always be made in venues compatible with the level of services provided. The main objective of such meetings must always be related to contracted services. The social and entertaining events are secondary in comparison to the main event, considering the time and relevance dedicated to social and entertainment activities, and
- g) The reimbursement of transportation, accommodation and meals expenses are compatible to the circumstances. Expenses effectively reimbursed have to be supported by invoices (or equivalent) and must not include any expenses or payments incurred in benefit of relatives, companions or people invited by the contracted Professional.

3.3. Contracting of Healthcare Professional or Related Healthcare Professional that hold, or held, a Public Agent function shall follow pertinent norms, observing permanent or temporary impediments that are eventually imposed by legislation. Independent of any other legal restriction, Companies are also prohibited of contracting a Public Agent, directly or indirectly, for the purpose of obtaining or withholding business or gain improper advantage with public administration.

#### **Section 4 – Congresses, Symposia, Seminars and Other Events**

##### **The sponsorship of events undertaken by medical associations or other entities**

4.1. Companies can sponsor symposia, congresses and other events of scientific or educational nature aimed at providing ongoing development of Healthcare Professionals or Related Healthcare Professionals.

4.1.1. The acquisition of quotas to sponsor congresses, symposia, seminars and other events shall be set forth in writing with the company or organizing entity and cannot be subjected to any kind of interference in the definition of the schedule, objectives, selection of keynote speakers or any other aspects related to the event.

##### **The engagement of Healthcare Professional or Related Healthcare Professional as keynote speaker in seminars and other events**

4.2. Healthcare Professionals or Related Healthcare Professionals engaged as keynote speakers in symposia, congresses, meetings, conferences or any other events shall enjoy unrestricted independence to formulate their opinions and analyses. Companies must make every effort to inform the audience present at the event about eventual conflicts of interests on the part of the engaged keynote speaker, before he begins his conference.

##### **The participation of Healthcare Professional and Related Healthcare Professional in a scientific event at the invitation of a Company**

4.3. Companies can sponsor Healthcare Professionals or Related Healthcare Professionals to attend symposia, congresses and other events of technical-scientific nature aimed at ongoing professional development, through the payment (or reimbursement) of transportation, meals, accommodation and enrollment fees charged by organizing entity.

4.4 The following factors indicate that the attendance of Healthcare Professional or Related Healthcare Professional invited by Companies complied with the ethical principles outlined in this Code:

- a) The chosen venue for the event offers an adequate setting for the presentation of proposed scientific and educational themes, counting with conference rooms and support materials for presentations, workshops and professional meetings. Venues with a touristic appeal, not compatible with the technical-scientific nature of the event, must be avoided.
- b) The payment of transportation, meals and accommodation expenses is limited to those inherent to the event itself and to the invited professional. The payment or reimbursement of any expenses relating to relatives, companions or guests of Healthcare Professional and Related Healthcare Professional is expressly prohibited.
- c) Any and all forms of entertainment provided to Healthcare Professional and Related Healthcare Professional shall be modest and secondary in nature to the scientific event itself.
- d) Any sponsorship to Healthcare Professionals and the Related Healthcare Professionals to participate of events, whether national or international, cannot be conditioned to prescription, sales or promotion of any kind of medicine or Company, and
- e) Invited Healthcare Professionals and Related Healthcare Professionals cannot receive any kind of remuneration, directly or indirect, for time spent in attending the event.

#### **Company as organizer or promoter of its own event**

4.5. Companies can also realize their own events in order to promote new medicines or scientific knowledge to Healthcare Professional or the Related Healthcare Professional.

4.5.1. Events organized or promoted by Companies must take place in the country where they are located, unless the promotion in a foreign country is justified by security or logistic issues, as for instance, in international events with participants of different countries.

4.5.2. Scientific events promoted by Companies are subject to the same standards of legitimacy established in item 4.4 above.

4.6. It is forbidden to offer first class tickets to Healthcare Professionals and Related Healthcare Professionals to attend symposia, congresses, seminars or any other sort of professional meetings. This prohibition applies, indistinctly, to events organized by the Company, by medical or patient associations, academia or any other public or private entity.

#### **Section 5 – Promotional Materials**

5.1. Promotional Materials produced by Companies must comply with the following principles:

- a) Respect to the legislation in force and is in conformity with information submitted to the Sanitary Agency (ANVISA) at the time the material was produced.
- b) Keep coherence and consistency between visual and artistic planning and the text.

- c) Contain honest, impartial and balanced data.
- d) Graphs and illustrations must give proper support to the information it refers to, and
- e) Scientific and medical information must be clear, reliable and up-to-date, avoiding the use of artifices that can lead to wrong or ambiguous interpretations.

5.2. All and any scientific and medical quotations, paraphrases and information included in printed material shall be based on reliable sources, as officially well-known literature. Any data originated from scientific publications shall have complete bibliographic reference, with at least the following information: author, name of the article, magazine, year of publication and number of issue and pages.

5.3. All references used shall be immediately made available to sanitary authorities and to those who request them.

5.4. The quotations, tables or illustrations extracted from scientific publications and used in any advertising, publicity or promotion shall not change or distort the sense and meaning intended by their authors. Third party rights, especially those connected with copyright, must be rigorously observed.

5.5. Should there be a visual adaptation to graphs from scientific publications, they should be clearly mentioned (adapted from) and referable and they should not change the original meaning proposed by the author.

5.6. Data of "in vitro" studies and in animals shall be identified as such and their results cannot be extrapolated to clinic practices.

5.7. The use of images containing children, pregnant women, people practicing sports and naked bodies shall be in line with and coherent to the characteristics of the promoted medicine.

5.8. All Promotional Material, including advertisements, must inform the year and month it was produced.

5.9. Internet, e-mail and other electronic media shall comply with the applicable principles of Promotional Material in general, set forth in this Section, in addition to complying with legislation directives and of this Code of Conduct with respect to the product advertised (with or without the requirement of a medical prescription).

## **Section 6 – Comparative Advertisement**

6.1. Comparative Advertisement shall respect the following principles and limits:

- a) The use of third party trade marks, without their consent, is prohibited;
- a) Should not characterize dishonest competition or denigrate the image of other companies' trademarks and medicines;
- c) Should not cause confusion between competitor's medicines.
- d) Comparison should be objective and with technical fundamentals, and
- e) Comparisons and allegations must be subject to substantiation and should be supported by evidences.

6.2. The comparison of adverse reactions data and the allegation of possible therapeutically superiority of a product over the others are only possible when well-founded and properly supported by well-known indexed publications, with source information to support the allegation.

6.3. Superiority allegation about efficiency is only permitted when the difference is statistically expressive. Clinical relevance shall also be taken into account.

6.4. References that prove what has been alleged in comparisons shall be immediately made available to sanitary authorities, to competitor's company and to whoever else requests them.

## **Section 7 – Sales Outlet Activities**

7.1. In order to preserve the consumer's purchasing intention as well as respect prescription (in the event of medicines subject to medical prescription), Companies are prohibited to give or offer, directly or indirectly, advantages, of any kind (including bonus shares) and under whatever pretext, to Healthcare Professionals or to Related Healthcare Professionals.

7.2. Advertising and publicizing medicines subject to prescription to drugstore's non-pharmaceutical owners, over-the-counter attendants or other unqualified persons to dispense medicines is prohibited.

## **Section 8 – New Medicine Communication and Off-label Indications**

8.1. The promotion, publicity, advertisement or sale of pharmaceutical products, without indication of usage, including new therapeutic indications or use, without prior approval by ANVISA is prohibited.

8.2. Information disclosure about indications or about off-label products can only be made when connected with medical and scientific information in congresses, symposia or other scientific events, provided the audience is duly informed that it is an "off-label" product.

8.3. Clinical studies related to products or indications not yet registered with ANVISA can be exclusively disclosed to Healthcare Professionals when requested.

8.4. In international events where a significant number of keynote speakers or audiences from different countries are invited, communication about Off-label medicines and indications can be made in accordance with the conditions already approved in the country or origin or other countries. In this case it is compulsory to include notices and information that informs the Healthcare Professional that the medicine or condition is not yet approved in the country where the event takes place. Healthcare professionals must also be informed about the country, or countries, where the product or indication is already registered and approved for marketing.

8.5. The provisions of this section 8 will not be applied in order to prevent the dissemination of relevant information to the scientific community about technological advances, access to clinical research results and new discoveries concerning patient treatments. The dissemination of information about unregistered product will also be permitted, whenever such disclosure is necessary to meet legal or judicial inquiries.

## **CHAPTER 2 – Rules Related to Medicines Subject to Medical Prescription**

### **Section 9 – Free Samples**

9.1. Distribution of medical free samples shall be exclusively made to Healthcare Professionals and in the needed amount to allow Healthcare Professionals and patients familiarize themselves with the product.

9.2. Offering free samples to Healthcare Professionals as an inducement to prescribe, recommend or administer products is prohibited.

### **Section 10 – Visit to Healthcare Professional**

10.1. The Company's representative activities shall comply with the highest ethical and professional standards, and shall have as main objectives:

- a) Inform Healthcare Professionals about the advantages and risks of their products;
- b) Provide all the necessary scientific information related to their products, supported by relevant studies;
- c) Obtain information from Healthcare Professionals about their product acceptance and possible registered adverse effects.

10.2. Companies' representatives must provide Healthcare Professionals complete and accurate information about the medicines they are promoting, always limiting themselves to information and characteristics registered with ANVISA.

10.3. Offering benefits of any kind to Healthcare Professionals as an inducement to prescribe, recommend, purchase or administer any product is prohibited.

10.4. The Company's representative can sponsor modest and occasional meals for Healthcare Professionals provided the event occurs in an appropriated venue and with the purpose of discussing or exchanging scientific and educational information. The attendance of the Company's representative to the event is compulsory.

10.5. It is forbidden to pay meals or any other expenses to any Healthcare Professionals' companion.

### **Section 11 – Giveaways and Gifts+**

11.1. Companies are allowed to offer giveaways and gifts to Healthcare Professionals provided the following conditions are respected:

#### **Giveaways:**

- i) Restricted to objects with renowned promotional appeal and always identified with the company's trade mark or product's name;
- ii) Restricted to items related to medical practices or to the doctor's office routines; and
- iii) Restricted to objects with maximum individual value not superior to 1/3 of national minimum wage in force on the date of acquisition;

#### **Gifts:**

- i) Offered only on occasional basis, such as professional or national celebration dates, including the Healthcare Professional birthday, provided it does not exceed the limit of 3 occasions per year; and
- ii) Value limited according to the kind of gift, as follow:
  - ii.a) items related to medical practices, such as: anatomical models, books, magazines (subscriptions not included) and other scientific publications regardless the format or media – two (2) national minimum wage in force on the date of acquisition; and
  - ii.b) items unrelated to medical practices – one-fifth (1/5) of national minimum wage in force on the date of acquisition.

11.2. Under no circumstances can cash, or equivalent, be offered, directly or indirectly, to Healthcare Professional

## **Section 12 – Donations and Contributions to Institutions, Bodies, Associations and Companies related to healthcare area**

12.1. Donations and other forms of contributions (“Contributions”) to Institutions, Bodies, Associations and Companies related to Healthcare Areas must comply with legitimate interest and always revert to the community or society being supported. Donations and contributions must always be supported by a written document indicating, at least, a clear specification of value, date, purpose and other eventual charges.

12.2. Contributions to Institutions, Bodies, Associations and Companies of the Healthcare sector must be transparent and solely reserved to entities formally established, and not be given to individuals.

12.3. Contributions must not be used as an inducement to withhold or obtain business, with the objective of obtaining improper advantage, or be connected to inducement to recommend or purchase Companies’ products. Institutional promotion shall be considered as the only inducement allowed for Contributions done by Companies.

12.4. Companies must make sure that recipients of Contributions have the necessary sustainability mechanisms to guarantee its subsistence, independent of Contributions.

## **CHAPTER 3 – Rules related to over-the-counter drugs**

### **Section 13 – Over-the-counter drugs (OTC)**

13.1. Without prejudice to the applicable legal provisions, advertisement or promotion of OTC drugs shall observe the following:

- a) the benefit to and safeguard of the consumer must always underline any advertising initiatives;
- b) respect for the consumer and Healthcare Professionals must be the main basis of the promotional actions;
- c) they must favor orientation of consumer and Healthcare Professionals, and;
- d) promotional pieces must underline that promotional products are medicines in order to avoid any confusion with other products of free consumption.

13.2. Use of images of people unconnected with the medicine or pharmacy world in the promotion or advertisement of over-the-counter products will be permitted, provided that such images are used with equilibrium and discernment, and without inducing consumer to a false association related to muscular gain, esthetical improvement, increase of intellectual capacity, except when these benefits are proven.

13.3. The promotion or advertisement of OTC medicines:

- a) Must not lead the consumer to a confusion regarding content, pack size, appearance, usage, relief or product actions;
- b) In the event of any references to studies, whether scientific or consumption, must be always based on researches done and interpreted correctly, and the results or conclusions presented to the consumer must be substantiated;
- c) Must not insinuate cure or prevention from any disease which requires treatment under the supervision of a Healthcare Professional;
- d) Must not induce the consumer to an unnecessary usage of medicines;
- e) Must not induce consumption by children and teenagers;
- f) Must not induce fear or apprehension, on the part of the consumer, who can be suffering or might suffer from any severe disease;
- g) Must not promise any cash refund or other benefit, of any kind, for the purchase of a medicine, due to a possible consumer's dissatisfaction;
- h) Must not contain any statement or presentation, of any nature, that might be considered obscene, repulsive, rude or of discriminatory nature regarding race, sex, creed, social or intellectual condition and, moreover, inspire violence or disseminate superstition, and;
- i) Must not use items that contain infantile appeal such as, but not limited to, toys and dolls.

#### **Section 14 – Direct Contact with Consumer**

14.1. In the relationship with the Consumer, whether by call centers or any other interaction form, Companies shall observe the following:

- a) Recommending substitute or similar products to replace discontinued or non-commercialized products is prohibited;
- b) Providing exclusive services of Healthcare Professionals is prohibited;
- c) Justifying, denying, or confirming the conduct or treatment of a Healthcare Professional is prohibited, always recommending the patient's return visit to the Healthcare Professional, and;
- d) Dissemination of any medical information that is not mentioned in the medicine's brief is prohibited.

14.2. General information about diseases prevention, healthy habits and about health in general, which are not of a promotional nature, can be disclosed to the public in general through consumer's call center or any interaction form.

14.3. Contact with the consumer, when undertaken by a Healthcare Professional or Related Healthcare Professional, will abide by the rules applied of the corresponding professional category to which he is legally associated with.

## **CHAPTER 4 – The Procedures for Dealing with Complaints**

### **Section 15 – Application and Effectiveness of the Code of Conduct Rules**

15.1. Interfarma encourages Companies and any other people or institutions interested in submitting well founded claims against actions, which can be characterized as violation of conduct rules set forth in this Code.

15.2. Any claim submitted by any Company, person or institution to Interfarma will be analyzed in terms of its consistency in order to evaluate the possible opening of an investigation procedure. Once a claim is admitted and the investigation process is initiated, it cannot be cancelled. The Ethics Commission will process the claim in order to determine the applicable penalties.

15.3. The Ethics Commission will process all claims that refer to facts occurred up to 1 (one) year before the submission to Interfarma. The claims related to facts occurred before this deadline will be dismissed, without appeal

### **Section 16 – Ethics Commission**

16.1. The Ethics Commission will execute its duty of preserving the principles and provisions set forth in this Code with total independency.

16.2. The application of penalties set forth in this Section shall comply with the highest criteria of justice and impartiality. In its application, the following shall be taken into account:

- a) The severity of the infraction;
- b) The advantage obtained or expected by the infractor;
- c) The consummation or not of the infraction;
- d) The degree of loss, or risk of loss to Companies, consumers or third parties;
- e) The negative effects on the pharmaceutical market;
- f) Attenuating and aggravating circumstances, as defined by 17.5 below; and;
- g) The financial capacity of the infracting Company based on its gross turnover in its last fiscal year, without taxes.

16.3. The procedures and rules that govern the Ethics Committee will be defined by its own charter, which shall constitute an integral part of this Code.

### **Section 17 – Penalties**

17.1. The penalties defined in this Section 17 are not progressive. The Ethics Commission will define the applicability of penalties taking into consideration the circumstances related to the case under exam.

17.2. Without prejudice to the immediate cessation of the violation, the Company that violates the rule of this Code of Conduct, shall be subject to the following:

17.2.1 Suspension of associated Company of his membership rights at INTERFARMA for up to one hundred and eighty (180) days, without suspension of membership contributions;

17.2.2 Exclusion of associated Company from membership of INTERFARMA;

17.2.3. Circulation of admonition among Companies;

17.2.4. Payment of the following fines:

- a) From two thousand and two hundred Reais (R\$ 2,200.00) to eighty-two thousand and five hundred Reais (R\$ 82,500.00), for minor infractions consisting of one attenuating violation;
- b) From eighty-two thousand and five hundred Reais (R\$82,500.00) to twenty-two hundred thousand Reais (R\$ 220,000.00), for major infractions consisting of one aggravating violation, and
- c) From twenty-two hundred thousand Reais (R\$ 220,000.00) to one million sixty-five hundred thousand Reais (R\$ 1,650,000.00), for severe infractions consisting of two or more aggravating violations.

17.3. Only Interfarma's associate members, subject to this Code of Conduct, will be subject to the penalties referred to in items 17.2.1 and 17.2.2 above.

17.4. The fine paid by Company will revert directly as the infractor's donation to charities indicated by INTERFARMA. Donations, in kind or converted into assets of equivalent value, shall be of a punitive nature and cannot be used by the infractor Company in adjusting its balance sheet.

17.5. In defining the gravity of the infraction and settlement of fine to be imposed, the following shall be considered:

17.5.1. Attenuating circumstances:

- a) The infractor's good faith;
- b) The infractor's action was not essential to the consecution of the event;
- c) The infractor, spontaneously and immediately, seeks to mitigate or remedy consequences of imputed violation, and
- d) the infractor is a first-timer.

17.5.2. Aggravating circumstances:

- a) The infractor is a relapsed offender;
- b) The infraction is damaging to public health;
- c) If, aware that it is in violation of this Code, the infractor does not take measures to avoid such violation, and

d) The infractor acted deceitfully, even though eventually, fraudulently or in bad faith.

17.6. Should there be attenuating and aggravating concurrence, the application of penalty will take into account the preponderant factor.

17.7. INTERFARMA will, periodically, circulate in its website, a report with compiled information about the activities of the Ethic Commission concerning its findings regarding violations of this Code of Conduct.

## **ETHICS BOARD REGULATION**

### **PRELIMINARY PROVISIONS**

Any issues regarding violation of the Code shall be examined by the Ethics Board.

Settlement of conflicts by the Ethics Board shall be solely and exclusively limited to the penalties provided for in the Code.

Ethics Board's meetings will be held at INTERFARMA's head offices or at another place previously indicated by INTERFARMA, subject to the schedule of meetings defined by the appointed Board members.

All the documents, petitions and written notices shall be submitted in a number of copies equal to the number of Board members indicated to settle the conflict, with an additional counterpart to INTERFARMA and another to the accused Company.

The notices shall be sent to the address stated on INTERFARMA's records, which must be updated permanently, and may be done by any means evidencing their sending, among others, by e-mail, certified letter, fax or cable.

The terms fixed in this Regulation will start to run as of the first business day following the day of receipt of the notice and will include their due date. The term will be extended up to the first following business day if the due date falls on a holiday, whether at the place where INTERFARMA's head offices are located or of any Company (ies) involved with the accusation.

### **BEGINNING OF the examination PROCEDURE**

The one willing to present an accusation shall notify such intention to INTERFARMA (the "Notice"), which in turn will verify whether the elements presented are sufficiently formally and materially consistent in order to proceed with the examination.

The following requirements shall be met so that the accusation is considered formally consistent:

- (I) identification of the accuser and the accused Company; and
- (II) brief report on the alleged violation or violations of the Code with the pertinent evidentiary documents.

The material consistency of the accusation will be a preliminary examination by INTERFARMA's Chief Executive Officer of the apparent truth of the facts and the further ascertaining that the issue effectively refers to the Ethics Code.

If the accusation is deemed formally and materially consistent, INTERFARMA will proceed to the investigation by sending Notice to the notified Company to pronounce itself within a fifteen (15) day-term on the conduct object of accusation.

If the accusation is deemed inconsistent, whether formally or materially, INTERFARMA shall determine that it be dismissed by means of a grounded decision, and the procedure will be automatically closed without any chances whatsoever. The accusation dismissed at the order of INTERFARMA's Chief Executive Officer may be presented again by any interested party, as long as the formal or material defects that resulted in the dismissal are remediated.

Once the accusation is admitted, INTERFARMA shall not fail to proceed with the investigation procedure for the refusal or default of any interested party.

## **ETHICS BOARD**

Each Company shall appoint a regular representative and his respective substitute to exercise a two (2) year term of office as Board member, reelection being permitted.

The Board members appointed by the Companies will be part of the group of qualified Board members to compose the Ethics Board, whenever summoned by INTERFARMA.

The Ethics Board shall be established on an "*ad hoc*" basis, always meeting for the specific purpose of deliberating on the case(s) included in the day's agenda. After the resolutions included in the agenda are dealt with, Board members shall be exempted from their duties in the Ethics Board, and may be summoned again in the future if new accusations of violation of the Ethics Code arise.

In order to install the Ethics Board on an "*ad hoc*" basis, INTERFARMA shall draw lots to choose Board members in a sufficient number to meet the quorum required to compose the First Instance Chamber or the Superior Chamber, according to the corresponding jurisdiction level. The First Instance Chamber shall be composed by up to five (5) Board members, whereas the Superior Chamber shall have up to nine (9) members.

Without prejudice to the foregoing, the Ethics Board may resolve without the full composition of its judging bodies as long as the minimum deliberative quorum is met, i.e., three (3) Board members for the first instance and five (5) members for the superior instance (appeals).

If a summoned Board member is hindered from participating in the judgment session, and his substitute cannot also step in for him, the Board member shall inform INTERFARMA of his impediment within a maximum term of forty-eight (48) hours so that a substitute is chosen by lot. In case the minimum deliberative quorum set forth in item 3.5 above is ensured, INTERFARMA may, at its discretion, fail to choose by lot a substitute Board member.

If it is impossible to meet the minimum deliberative quorum, the session shall be adjourned and rescheduled to be held within seven (7) days at most, pursuant to allotment of new Board members that will substitute for Board members impeded to exercise their duties at the Ethics Board.

Board members participating in the decision rendered in the first instance shall be hindered from participating in the session convened to decide the same case in the superior instance.

Ethics Board members shall execute an Autonomy, Commitment of Exemption and Secrecy Deed, and shall have the duly signed document delivered at INTERFARMA up to the date set for the judgment session.

INTERFARMA's Chief Executive Officer may determine the permanent substitution of the Board member not complying with the terms and rules of this Regulation, or who, at his discretion, is not able to exercise the duties for which he had been appointed.

Decisions made by INTERFARMA's Chief Executive Officer regarding the appointment, confirmation and substitution of the Board member will be definitive.

### **PLEADING OF BOARD MEMBER'S IMPEDIMENT**

The one willing to plead the occasional impediment of a Board member for lack of autonomy or any other reason whatsoever, shall do so before INTERFARMA within two (2) business days as of the moment he becomes aware of the facts or circumstances that led him to deduce such intention,

The impediment pleading shall be addressed to the Ethics Board members designated to analyze such specific issue pursuant to a justified request and filing of pertinent evidences. No appeal may be filed against the decision of the Ethics Board determining the substitution or maintenance of the Board member whose impediment had been raised.

The Board member will be subject to definitive substitution if (i) he becomes hindered to exercise his duties; (ii) he leaves the Company that had appointed him for that attribution; or (iii) he is related, directly or indirectly, to a company competing with any party involved in the dispute.

Without prejudice to the foregoing, the person called to be part of the Ethics Board shall be encouraged at all times to disclose spontaneously any fact indicating or that might indicate justified doubt as to his impartiality and independence.

### **EVIDENCES**

It will be up to the one making the allegation the burden of gathering evidences necessary to sustain one's arguments. The Ethics Board, at its discretion, may also request the parties involved in the issue to submit the additional evidences it deems necessary or appropriate.

If the Ethics Board requests or allows new evidences to be attached to the original accusation, the other party will be notified, within at most a five (5) day-term to pronounce itself on the new documents submitted.

If a party duly summoned to submit evidence or take any other action fails to do so within the term set forth by the Ethics Board, without submitting justified reason to that effect, the Board may render the decision based on the evidences available in the records.

The Ethics Board will be allowed to consult technicians with expertise in specific matters related to the demand, or to request the submitting of expertise evidence, whenever deemed convenient, to better pronounce itself on the matter. If expertise evidence is determined, the parties involved will have a common term of five (5) days to submit the queries and appoint assistant appraisers.

The Ethics Board will specifically consider the delivery of confidential material according to its convenience and opportunity.

## **JUDGMENT SESSION**

The judgment session will be preferably held at INTERFARMA's head offices, except if INTERFARMA, pursuant to the consent of the parties involved, decides otherwise. The change in the place set for the judgment session shall be priorly notified to the interested parties.

The judgment session will be held on the date set pursuant to the installation of the Ethics Board, with a First Instance Chamber or Superior Chamber, as the case may be, subject to the minimum quorum necessary for the resolution.

The Ethics Board will appoint the President of the Session, who will be empowered to conduct the procedures according to the provisions of this Regulation. The President of the Session will also give the casting vote whenever the Board members in attendance do not render a majority decision on the issue under analysis.

After the session begins, the representatives of the involved parties will be requested to call the witnesses they deem appropriate, in a number not exceeding two (2). The witnesses will be heard for no longer than fifteen (15) minutes each, answering the questions the parties and the Ethics Board make. The President of the Session will act with the necessary balance to observe the time intended for hearing each witness and the preference in the posing of the questions.

After hearing the witnesses, the representatives of the involved parties will be called to present their oral arguments before the Board, for at most ten (10) minutes each. The first one to present will be the accuser, and subsequently, the accused Company.

Except for the testimonial evidence, any other evidences may only be submitted during the judgment session under exceptional circumstances, at the discretion of the acting Ethics Board, subject to the existence of justifiable circumstances. If new evidences are accepted during the judgment session, the one against whom the evidence is submitted may request that the session be adjourned for review and pronouncement within a five (5)-day term. The session that comes to be adjourned must resume as of the point it was dismissed, and the President of the Session must set a new date within a period not exceeding ten (10) days.

The personal deposition and hearing of witnesses may be held by videoconference, or by any other means using data, voice and image communication technology.

The absence of any interested party will not hinder the Ethics Board from deciding over the matter under judgment.

After the completion of the evidentiary phase, the Ethics Board will decide the issue by simple majority, always based on reports, evidences and documents stated on the records. If there is no majority agreement, the vote of the President of the Session shall prevail.

The Board member diverging from the majority may, if he so wishes, declare his vote in separate.

The President of the acting Board will forward the decision made in that judgment session to INTERFARMA, which shall in turn notify the decision to those interested on the business day following the one on which it had received the same, pursuant to the sending of a copy, by mail or any other means of communication, against acknowledgment of receipt, or further, delivering it directly to the parties against acknowledgement of receipt.

### **DECISION MADE BY THE ETHICS BOARD**

The decision rendered by the Ethics Board will necessarily have:

- (I) the respective report, containing the names of the accuser, the accused and a brief of the controversy;
- (II) the grounds for the decision, whereby factual and legal matters shall be analyzed;
- (III) the provision whereby Board members are to settle the issues submitted to them;
- (IV) the term for the decision's fulfillment,, and as the case may be, the conditions for the accused Company to prove having complied with the penalty imposed on it;
- (V) signature of Board members, representatives of the involved parties and two witnesses; and
- (VI) date and place where the same was rendered.

In the event that any of the Board members or representatives of the parties cannot or does not want to subscribe to the decision made by the Ethics Board, it will be up to the President of the Session to certify such fact.

Costs and expenses incurred in the conduct examination process will be borne by the party that shall cause it, it being understood as the accuser if the accusation is granted no relief, or the accused, if the accusation is granted relief.

Within a five (5)-day term as of the receipt of the notification or the personal acknowledgment of the decision rendered by the Ethics Board, the interested party, pursuant to notice to the other party, may request that:

- (I) the Ethics Board rectifies any material error that may be found in the decision;
- (II) the Ethics Board sheds light on any obscurity or contradiction of the decision, or pronounces itself on an omitted issue about which it should have pronounced itself.

If the hypothesis provided for in item 7.4 above materializes, the Ethics Board may hear the interested party on the arguments submitted pursuant to a pronouncement within, at most, five (5) days. After the other party is heard – or if the Ethics Board does not deem it pertinent, after receiving the request, the Board shall decide on the same within a ten (10)-day term, making an addendum to the decision if the request is granted relief.

## **THE PROCEDURE IN THE SUPERIOR INSTANCE**

An appeal may be filed against the non-unanimous decision rendered by the Ethics Board First Instance Chamber. The appeal must be filed with the Ethics Board, care of the President of INTERFARMA, and INTERFARMA shall be in charge of carrying out the measures necessary for installing a Superior Chamber empowered to examine the issue.

The term to file an appeal will be ten (10) days as of the date of acknowledgment of the decision made by the First Instance Chamber, or of the decision on the request for review due to error, obscurity or contradiction, if so requested.

The terms and procedures for installing the Superior Chamber will be identical to the ones established for installing the First Instance Chamber, especially with regard to the conditions for the functioning of the Superior Chamber, allegation of impediment of a Board member and procedures for the judgment session.

## **EFFICACY OF THE DECISION MADE BY THE ETHICS BOARD**

The decision rendered by the Ethics Board results in obligations to the parties and their successors, and will be converted, whenever applicable, into written evidence , with the purpose of serving as grounds for a future monitory action or other measures legally admitted.

## **COSTS**

The interested parties may be called to pay the values set by INTERFARMA as procedure development, prior to the conduct examination procedure.

## **CONFIDENTIALITY**

Unless otherwise provided for or if required by the applicable law, Board members shall maintain confidentiality on the matters related to arbitration. The confidentiality commitment will be also excluded in relation to the public domain information or information that somehow is disclosed before being transmitted to the Board members.

INTERFARMA may disclose excerpts of the Ethics Board decision in its website or other means that it may deem convenient.

## **FINAL PROVISIONS**

INTERFARMA will not be liable for any fact, act or omission, of any nature whatsoever, related to the acts taken by the Ethics Board, unless in case of evidenced deceit or bad faith with respect to the pertinent acts.