CODE OF GOOD PRACTICES

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1 GENERAL PRINCIPLES

1.1 Message from Fedefarma to the Industry and Trade Members

A dynamic and growing trend currently exists in the global context to adopt self-control measures with the aim of achieving greater transparency in all transactions and a more effective accountability, in this way responding to the social demand for companies to promote ethic conduct and practice social responsibility.

The International Federation of Pharmaceutical Manufacturers & Associations –IFPMA— has joined the WHO and the World Medical Association in its efforts to promote actions regulating their interaction with health-care companies, including pharmaceutical companies, by updating their Code of Good Practice for the Promotion of Medicines, a task that was carried out throughout 2006 and became effective as of January 2007. This code has been newly updated in 2012.

The Central American Federation of Pharmaceutical Laboratories (FEDEFARMA for its initials in Spanish), the IFPMA regional chapter clustering fourteen multinational pharmaceutical research companies, echoes this initiative as of the end of 2006 and appoints a specific committee to prepare a Code of Good Practice for the Promotion of Medicines that is fully in tune with the IFPMA Code and includes the peculiarities of our region. Our Ethics Committee again reviewed this code in 2011, on its own initiative, and halfway through 2012 so as to incorporate the modifications made by IFPMA to its code at the beginning of that same year.

FEDEFARMA hereby presents its Code of Good Practices to all those interested sectors, to be bindingly observed and applied by all of its members and through which a self-regulation instrument is set forth in a framework of action that is committed to universal principles of ethics and social responsibility.

1.2 The Objective of this Code of Good Practices

Fedefarma and its member companies are committed to a high level of professionalism in their marketing and sales tasks. This commitment constitutes the basis for the high ethics standards required in the marketing and sale of pharmaceutical products. Both sectors shall comply with all the applicable international and national regulations, as well as the Codes of Good Practices.

This Code, in accordance with its implementation by the Fedefarma member companies, provides the corresponding work standards. All employees working in each associated company and third parties acting in representation of each of the associated companies (that is to say, where Fedefarma or each associated company possesses a title, license or any other right to use and dispose of trademarks and intellectual property rights) are compelled to comply with this Code.

This document has been prepared in accordance with the codes and policies applied to activities of Fedefarma member companies in those territories where Fedefarma associates carry out their business activities, and are subject to local laws and regulations, namely:

- Fedefarma policies;
- The Code of Pharmaceutical Marketing Practices of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA 2012).
- **General Health Law and Health Codes and their respective regulations, effective in each country.**

This document has been prepared to be applied to Fedefarma and its associated companies in their relations with health care professionals and shall likewise be applicable to the activities and communications on the sale of prescription drugs.

Exclusions: This Code **does not intend** to regulate the following activities:

- The promotion of pharmaceutical products addressed to the general public, in other words, Direct-to-Consumer Advertising.
- The promotion of self-medicated products sold without a prescription (Over the Counter— OTC— drugs)
- Prices and other marketing conditions for dispensation of pharmaceutical products
- Contracting a health care professional to provide its legitimate consultancy services and other legitimate services to the member company.
- Performing clinical trials
- **The provision of non-promotional information by the member companies**

In the event of a conflict between this code and the local regulations, the trade members shall apply that which is the strictest between the two.

1.3 Responsibility

Fedefarma or the associated companies shall be responsible for the statements or undertakings and other activities carried out by their employees during the course of their employment. Therefore, it is essential that all Fedefarma personnel members and those of the associated companies be informed of, fulfill and be faithful to all aspects of this Code

1.3.1 *Ethics Committee*

An Ethics Committee has been created within Fedefarma to ensure the implementation and execution of this Code.

A list of members, activities and responsibilities is included in Fedefarma's charter.

1.4 Use of this Code

This Code provides the minimum ethical standards on which the activities performed by those Fedefarma member companies should be based, in their relations with healthcare professionals, with regard to the marketing of pharmaceutical products and education regarding the use of such products. It has been created so as to comply with the effective legislature, regulations and Codes of the industry. It is essential that the spirit and content of this Code be respected upon organizing activities involving pharmaceutical products.

This document is designed in such manner that the individual sections correspond to specific activities carried out or organized by Fedefarma member companies. Upon organizing a specific activity, it is advisable for employees to refer to the relevant unit in this document, as well as to review those sections directly or indirectly related with the nature of such activity and participants, and to follow such references to other sections when so required and even when not expressly mentioned.

There are three key elements for each section of this document:

1. The beginning of the section: The definition and scope

2. The general principles y specific requirements.

3. Where suitable, the approval and documentation requirements are summarized at the end of each section.

The general approval is structured in accordance with the following principles:

- Material containing medical claims or relating to products approved by the Designated Signer

- Medical or scientific initiatives are approved by the Medical Department and the Designated Signer (as domestically defined).

In those instances in which the precise scope of a specific section of the Code of Good Practice is unclear, users must initially seek guidance from the Official of Good Practices, Ethics and/or Compliance of the Member Company or its equivalent. Should the concern persist, the Ethics Committee shall be consulted

2 Promoting Products to Healthcare Professionals (HCPs)

2.1 Key Promotion Principles

2.1.1 Definitions

"Promotion" means any activity carried out, organized or sponsored, that addresses healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of pharmaceutical products by any means, including the Internet. The terms "Promotional Activity" and "Promoting" have the same meaning as "Promotion"

"Healthcare Personnel" refers to any person or group of people providing some type of healthcare service. In those countries covered by FEDEFARMA, these persons are professional physicians, dentists, pharmacists, nurses, nutritionists, therapists or any other similar person, that may in some way participate in the prescription, recommendation, purchase, supply or administration process of a pharmaceutical product or therapeutic activity during the course of their activities. For the effects of this Code, the following categories shall be distinguished:

a. **"Healthcare Professional Authorized to Prescribe"** (**HPP**) any person that, through formal education and training, is certified and legally authorized to prescribe medications and medical devices. In those countries covered by FEDEFARMA, these professionals are physicians and dental surgeons.

b. **"Healthcare Professionals NOT authorized to prescribe" (HPNP)** any person that, through formal education and training, is certified and legally authorized to administer prescribed medications, to carry out or assist in prescribed treatments or to dispense medications. Ion the countries covered by FEDEFARMA, these are Nursing, Pharmacy, Nutrition and Supportive (Physical, Respiratory, etc.) Therapy Professionals.

c. **Medical Support Staff (MS S)** any person that, through education or training, is qualified to dispense or deliver medications or to collaborate in health activities, under the supervision of a reputable professional. In those countries covered by FEDEFARMA, these persons are pharmacy assistants or attendants, nursing assistants or technicians in various diagnostic and therapy activities.

"**Pharmaceutical Products**" means all pharmaceutical or biological products (regardless of the patent status or that have or lack a trademark) that are destined to be used with the prescription of a health-care professional or under his/her supervision, which purpose is that of its use in diagnosing, treating or preventing an illness in humans, or affecting the structure or any function of the human body

"**Regulations**" are laws, rules, legal regulations, health standards, handbooks and other guidelines issued by State bodies and their agencies

2.1.2 Key Principles

1. Fedefarma member companies shall comply with the requirements of the countries' local regulations, applicable Industry Codes and high ethical standards regarding all Promotional Activities / Materials.

2. The use of a product must not be promoted until the health certificate (market approval) has been granted.

3. The product shall not be promoted before a Health-Care Professional if such has clearly stated that he/she does not wish to receive such promotion.

4. Disguised promotions shall not be performed. All communications must clearly state the name of the responsible member company

5. The promotion shall not be disguised through the use of clinical evaluations, post-marketing surveillance, experience programs and non-interventional studies (NIS). Such evaluation programs and studies are only performed when a primary scientific and educational purpose exists.

6. All promotional communications, whether written, electronic or oral, must be clear, specific, balanced, fair, objective and sufficiently complete to allow the receiver to form his/her own opinion regarding the therapeutic value and properties of the pharmaceutical product at hand.

7. All promotional communications must be based on an updated assessment of all the relevant scientific evidence, and such must be clearly reflected. The promotion must encourage the appropriate use of the Pharmaceutical Products. It must in no way be misrepresentative either by distortion, exaggeration, excessive emphasis or any other manner. All efforts must be made to avoid ambiguities. No affirmations, whether absolutes or superlatives that may give rise to unfair completion shall be used, unless confident and trustworthy proof demonstrating such exists.

8. The promotion must be backed by the prescribing information approved by the respective Health Departments or by scientific evidence supporting the statements contained in the product information. Such evidence must be available to healthcare professionals in the event that it is requested and according to such professional's level of responsibility, according to what is set out in this Code. Member companies shall objectively manage the requests for information submitted in good faith and shall provide data that is appropriate for the reference source.

9. The acknowledged sources to support the medical/scientific statements must consist in scientific information that has been published or made available to the public, such as:

    - Journal publications reviewed by other professionals (or articles which publication is accepted in a journal reviewed by other professionals)
    - Official conference documents;
    - Published presentations/posters of scientific/medical meetings;

- Publications on websites (for example, clinical result records);
- 'Data on File' which disclosure has been approved

10. The quotes from medical and scientific literature and personal communications must be faithfully reproduced, unmistakably identifying the sources, without changing or distorting the intended meaning of the author, within the context of its source.

11. With regard to the comparative publicity, the promotion must be supported by scientific studies and on the qualities of the product and not on the weaknesses of the competitors. The comparison shall be acceptable as long as it is objective, true, and does not contain affirmations unjustly affecting the good name of third parties.

2.2 Promotional Materials

2.2.1 Definition and Scope

Promotional material, for the purposes of this document, shall refer to any promotional item or communication mentioning the name of a product or containing information about the product or medical information intended to be used or distributed to health-care professionals, and which objective is to increase the scientific knowledge about a product and ensure the adequate prescription of the promotional products. Providing non-promotional information shall not be considered as a promotion.

The principles specified herein also apply to public promotions of prescription drugs, wherever they are legally accepted. When an adaptation is required for the public promotion of medications that are freely sold, relevant laws, regulations and local codes must be applied.

Promotional material includes, but is not limited to:

- Visual aids
- Hand outs
- Invitations to meetings
- Brochures/Pamphlets provided at meetings
- Magazine ads (including "reminder" ads)
- Promotional websites, emails and other promotional use through electronic media
- Promotional aids (trademark reminders) (See Section 2.5)
- Other articles making statements about pharmaceutical products

When reference to the product is made by an external lecturer in his/her presentation, whether or not promotional, the regulations set out in Section 4.1.3 of this Code shall apply.

The reproduction of medical and scientific articles not prepared by pharmaceutical companies is not considered as promotional material. However, if such are accompanied by any promotional article or communication mentioning the name of a product or containing information about such product, they will be considered as promotional material.

2.2.2 General Principles

1. All promotional materials must comply with the Promotion Principles detailed in Section

2. All promotional materials must be approved by the Signer Designated by the member company, as per their internal approval processes.

3. Quotations, tables, charts, or other reports taken from scientific publications or statements made by third parties must always be precisely and faithfully reproduced, unmistakably identifying the sources without changing or distorting the intended meaning of the author, within the context of its source.

4. Staff in charge of product promotion is responsible of ensuring that promotional materials that are valid and approved by the corresponding internal agencies, including the Medical Department, are always used.

5. Promotional material may not be used without the approval of the Designated Signer. In no event may an employee:

- Use home-made materials or modify approved materials (including cutting or pasting approved materials);
- Use or distribute unapproved magazine articles or reference texts;
- Use or provide approved material to health-care professionals that is outside the scope of their expected use and specific audience. (Country, Medical Specialty, etc.)
- Write notes, letters or other communications containing medical/scientific information to health-care professionals without the approval of the Designated Signer.

6. The same requirements for electronic promotional materials must apply to printed material. The following must be specifically observed with regard to product-related websites:

- The identity of the pharmaceutical company and specified audience must be easily identifiable;
- The content must be appropriate for the expected audience;
- The presentation (content, links, etc.) must be appropriate and clear for the expected audience; and
- The specific information for a country must comply with local laws and regulations.

7. For the effects of promotional material, the term “new” may be used to identify a product, a new presentation or a new indication that has been marketed for less than twelve months in the local market.

2.2.3 Required Information for Printed Material

The following requirements apply and are subject to the national law, regulations or codes describing the mandatory information requirements:

1. All printed promotional materials (including electronic and audiovisual materials) except for "Reminder" ads (material in which no medical assertion is provided regarding the indication or product) and article reprints, must be legible and include:

- The product name (normally the trademark);
- Active ingredients, using the approved names, when such exist
- Name, address and phone number of the company responsible for the product and/or place of contact;
- Date on which the promotional material was created;
- Abbreviated prescribing information
- Internal identification code of the material

2. The abbreviated prescribing information must be approved by the Designated Signer, as per the guidelines set out by the regulatory authorities of each country. In any event, the abbreviated prescribing information must include:
   - Approved indications or recommended use;
   - Dosage and form of use;
   - Brief statement regarding contraindications, precautions and side effects.

3. Abbreviated prescribing information is not required on "reminder" ads and promotional aids only containing the product name.

   - A "reminder" ad is defined as a short ad only containing the name of the product and a simple statement about the instructions to designate the therapeutic category of the product.

4. Where reference is made to a specific study or publication, a clear reference enabling the reader to refer to the source must be provided:
   - Copyrights and Publisher rights must be respected and the necessary licenses must be obtained, when applicable.

5. Material in active use must be reviewed periodically or when significant changes take place (for example, upon adding a warning or side effect to the prescribing information), and in this way ensure its compliance with the relevant local regulations.

6. Adequate procedures to ensure the complete fulfillment of the information required in the promotional material and to ensure that the applicable legislation is complied with, must be set up and maintained to review and oversee all promotional material.

7. Every promotional assertion must contain the appropriate scientific support in the reference section of the material.

2.3 Promotional Visits

2.3.1 Definition and Scope

Promotional visits refer to any oral communication with a health-care professional to promote a pharmaceutical product of the Fedefarma member companies.

- The support material for these product visits is covered in Section 2.2

2.3.2 General Principles

- All product statements must conform to Section 2.1

2.3.2 Handling Questions on Unauthorized Indications for Medications

No products or uses that are not authorized by local regulatory authorities shall be promoted.

The staff in charge of promotions must not initiate discussions on unauthorized products or uses. When unexpected requests for information are made by a health-care professional regarding unauthorized products/uses, the sales representative must refer such professional to the local Medical Department.

The Medical Department can provide relevant information/material to the healthcare professional authorized to prescribe, as long as its unauthorized nature is clarified. The material must be clearly addressed to the healthcare professional (that is to say, mentioning his/her name), and must clearly indicate that its use is not certified and that the company does not recommend any other use than the approved indications.

All information on unapproved use, whether oral, electronic or written, must:

- Not be promotional with regard to its language or intent
- Be directly relevant to the inquiry and not cover other subjects
- Use clear, scientific and objective language.
- Be factual and objective, and reflect all the available published evidence, except for privileged or confidential information.
- Use the generic name of the product
- Only answer the question and not provide any other unrelated product information
- Clearly indicate the unauthorized use and that the company does not recommend its use other than according to the approved instructions

2.4 Samples

In accordance with local laws and regulations, free samples may be provided to the healthcare professional authorized to prescribe for he/her to become familiarized with the pharmaceutical products and allow such professional to gain experience with the product, or upon the request of such, as long as the sample handling and distribution is in agreement with local laws. This section does not apply to seedings and/or preliminary experiences regarding the original presentations of a product

Adequate control and follow-up systems must be set up for the samples delivered to healthcare professionals authorized to prescribe, including the surveillance of such when controlled by sales representatives.

Medical samples are destined for healthcare professionals authorized to prescribe and must not be used for sale, to grant bonuses, discounts or any type of commercial transaction. These samples must be marked as samples, both on the primary and the secondary packaging so that they are not resold or inappropriately used.

2.5 Gifts for Healthcare Professionals

2.5.1 Definition and Scope

Gifts shall be defined as one of the following:

- Promotional aids (trademark reminder items): Items intended to promote the product
- Useful medical items: Items that offer a significant benefit for the rendering of medical service or patient care. These usually do not contain the product trademark or have a significant commercial value but can include recognition of the company.

No type of gifts or benefits should be offered to healthcare professionals to induce them to prescribe, provide, administer, recommend or purchase any product, or obtain access to such.

No monetary disbursements or financial benefits of any kind must be made.

Written promotional material such as pamphlets, flyers, self-adhesive and others shall not be considered as gifts

2.5.2 General Principles

1. As per local laws and regulations, as well as the regulations of the IFPMA Code, financial benefits or benefits of other kind must not be offered or provided (including subventions, grants, subsidies, support, consulting agreements or items related with the medical practice, exceeding the limits and criteria set out in Article 25.1) to a health-care professional in exchange for his/her prescribing, recommending, purchasing, providing or administering products or his/her commitment to continue doing so. Nothing may be

offered or provided in such manner or condition that it inappropriately influences the prescription practices of the healthcare professional authorized to prescribe.

2. No gift must be offered or provided to the healthcare professional, in cash or in cash equivalents (gift certificates, vouchers, lottery tickets, etc.)

3. Promotional gifts must be directed towards supporting the medical practice or the work of healthcare professionals.

2.5.3 Useful Medical Items:

Useful medical items may be delivered to the health-care professional if they offer a clear benefit for the patient or patient care support. Examples of such items include:

- Equipment to demonstrate the use of medical devices;
- Medical textbooks
- Subscriptions to medical journals available through medical institutions or associations.
- Electronic storage devices, which must not be of a significant value and be capable of adapting to the content.

Useful medical items must be of a modest value and may be occasionally provided to the Healthcare Professional with educational or “trademark reminder” purposes. A process must be established to ensure that a healthcare professional does not individually receive items of this kind on a regular basis.

3 Scientific Communications and Information Regarding Unauthorized Products and Uses

No product for use in a specific country must be promoted until the market approval requirement for such use has been obtained in that nation. Any inquiry regarding the unauthorized use (off label) must be made before the Medical Department of the member company to be attended to by such department and must be accompanied by the corresponding documentation and medical support.

This precaution does not intend to prevent the right of the scientific community and the public to be fully informed of the medical and scientific progress. It also does not intend to restrict a full and adequate exchange of scientific information with regard to a pharmaceutical product, including the appropriate dissemination of research findings in scientific media, other media and scientific conferences. It also must not restrict the disclosure of information to shareholders and others with regard to any pharmaceutical product, as may be required or desirable under local laws, rules or regulations. In any event, the clear and legible indication regarding the unauthorized use of the product in the country or locality must be included.

Scientific information may be shared in a non-promotional manner, seeking to:

- Generate greater scientific knowledge;
- Support the medical community in obtaining information about the scientific/medical progress;

- Share information on current medical practices.

Non-promotional scientific information may be shared by qualified and duly authorized personnel members, considering that it will be addressed to a scientific/educational stakeholder audience (scientific community, healthcare professionals, regulatory agencies), and without a promotional interest. These situations are the following:

- As part of an approved pre-launching communication; for example, a diagnostic or epidemiologic subject.
- In answer to specific questions by healthcare professionals
- As part of a scientific meeting
- As part of normal conversations and communications provided by the Medical Department, with regard to clinical research activities

A communication or activity may be considered as an off-label promotion:

- If the material reaches unsupported conclusions regarding therapeutic implications;
- If the material does not use clear, scientific and objective language or uses language of a promotional nature, instead.
- If the material is not factual and objective, and reflects available published and unpublished evidence
- If the material uses the trademark instead of the generic name of the product;

With regard to managing questions on off-label use, which is stated in Section 2.3.3 shall apply

4 Meetings

Meetings for health-care professionals may be designated as company meetings (4.1), sponsored meetings (4.2) or sponsorship for the participation of health-care professionals in external meetings (4.3)

4.1 Company Meetings

4.1.1 Definition and Scope

A member company meeting is defined as a meeting among various (more than five) healthcare professionals and one or more company employees that is organized and managed by the company.

A meeting is not considered a member company meeting if such is only financing the meeting and such financing is received by a medical society, healthcare institution or other organization grouping healthcare professionals or those with a scientific interest. Additionally, the agenda of the meeting is not defined nor managed by the company.

This section applies to all external meetings, whether locally or internationally organized, such as:

- Private meetings;
- Congresses and symposiums;
- National and regional meetings;
- Meetings with an external lecturer;
- Meetings conducted by sales representatives (for example, round table meetings);
- Continual medical education activities;
- Clinical study meetings;
- Advisory Board meetings.
- Medical congresses, hospitality workshops, company meetings and others.

4.1.2 General Principles

1. Those meetings that are organized must have a scientific or educational objective and relevance regarding the appropriate practice and use of medications. Meetings, with healthcare professionals authorized to prescribe, of a purely social nature, should not be organized, sponsored or co-sponsored.

2. Participants should not be paid for their attendance or time invested in meetings, unless providing a service in that meeting, in which event that set out in Section 5 of this Code shall apply.

3. Fedefarma member companies are responsible for ensuring the compliance of all relevant regulations, codes and guidelines upon organizing activities and meetings with healthcare professionals authorized to prescribe, and in the event that the organization is delegated

or its indirect participation in such, it will continue to be responsible and must inform the organizers and ensure that these regulations are respected and complied with.

4. For international meetings, the national codes of participants as well as the code of the country in which the meeting is held and the national code of the country from which the meeting is being organized must be respected. In such cases, the most specific regulations shall be applied to their fullest extent

4.1.3 Content of the Meeting

All submitted materials must be relevant and internally approved by the member and must state the member company sponsoring the meeting.

Presentations with External Lecturers

External lecturers must be appropriately informed so that they do not find themselves violating local codes, regulations and the requirements specified in this Code.

Promotional meetings must not include the presentation of information on unauthorized products or uses.

Non-promotional meetings may include scientific/educational information provided by external lecturers that, subject to local codes and regulations, may include references to unauthorized products/indications. Should such reference be made, the lecturer shall be asked to clearly state that the information involves an unauthorized product/indication. The discussion must be strictly limited to a legitimate exchange of medical and scientific information. Meetings designed to promote off-label use are not permitted.

International Meetings

The promotional material distributed to the participants may refer to products that are not registered in the country of some participants, as long as it is truly an International Scientific Meeting, and that the fact that registration conditions vary from one country to another is stated in the form of an explanation specifying that registration conditions differ from one country to another. Additionally, the rules set out in any relevant Industry Code, laws and local regulations must be complied with.

4.1.4 Attendants

Attendance to all meetings must be limited to healthcare professionals authorized to prescribe and others justified by their professional field, based on the content of the meeting. They must not attend accompanied by spouses, family members and partners. In special circumstances and upon evaluating the case, which shall be considered exceptional, the attendance of caretakers for attendants showing physical difficulties or limitations must be justified.

Invitations shall be issued to Healthcare Professionals. The invitation shall not include spouses, family members or escorts to the events; third party expenses, in case the physician is accompanied to the venue, shall also not be covered.

Expensive, inappropriate or apparently extravagant venues shall not be used for meetings.

Meeting venues must be appropriate and adequate for the main objective of the meeting venues known for their entertainment installations must be avoided.

Additionally:

- The venues must not be recreational, unless no other meeting venue is available due to the capacity, facilities, etc.
- Meeting venues must be logistically appropriate in order to ensure easy access and facilitate the trip for all participants.
- The meeting venues must be chosen to comply with the applicable local codes

Meetings in which the majority of participants are from only country must not be held outside the country, except if the relevant source and experience constituting the main object or matter of the meeting is located outside this territory; for example, a visit to a specific clinic, manufacturing facilities, laboratory, expert accessibility).

4.1.5 Hospitality, Lodging and Travel

Hospitality must be limited to snacks and meals inherent to the main purpose of the activity. Hospitality must be moderate and reasonable, according to local standards. Lodging and meals must not be provided in expensive and luxurious venues. Hospitality may be provided and reimbursed only to participants of the meeting, and must always be secondary to the main objective of the meeting. Hospitality must comply with local codes and regulations.

Subject to the strict compliance with industry codes, participants in the meeting may be reimbursed for travel, lodging and registration, when applicable, within reasonable limits.

Individual entertainment and other social activities or hobbies must not be provided or paid for. Modest entertainment that is secondary with regard to snacks and meals (for example background music) is permitted in the activities.

Lodging may only be offered in cases where the attendants have traveled a reasonable distance, and where the duration of the meeting is enough to justify one or more overnight stays.

The following should not be provided or reimbursed:

- First-class air travel;
- Business class travel for short flights, for example, those that are less than the hours specified by the company, or according to local laws or regulations.
- Luxury hotels (no more than the local equivalent of a 4 star hotel except when one must resort to a higher class hotel due to the magnitude of the event).

- Highly expensive meals or refreshments (of no more than a medium quality local restaurant). Expensive/luxurious liquor or wine should not be offered.

If the delegates wish to stay for more time than that necessary to attend a meeting, they will be required to pay for all additional costs. Invitations do not need to be provided nor entertainment programs arranged, for escorts, who must not attend any activity, including, but not limited to, scientific meetings and business dinners.

4.1.6 Control, Follow-Up and Documentation

Fedefarma member companies shall be responsible for implementing adequate approval, control and follow-up systems for meetings and activities with healthcare professionals authorized to prescribe. These processes must be aligned with and contemplate the local regulations pertaining to the healthcare professional. Relevant authorization levels must be included as well as descriptive elements that suffice with regard to understanding the magnitude of the activity, conditions in which it is being developed, and its compatibility with this Code.

Information regarding all meetings (for example, the agenda, presentation, etc.) must be documented.

The documentation must at least include the following:
•List of attendants
•Related-service agreements
•Internal approvals
•Approval of external regulations, if required by local laws or codes

4.2 Sponsored Meetings

4.2.1 Definition and Scope

This section applies to all meetings totally or partially financed, but not controlled, by a member company. The member company does not control the agenda, nor is it in charge of choosing the location, inviting the lecturers, or selecting the participants. Typical examples include scientific meetings/congresses held by a medical society or a medical provider.

In those cases in which the member company controls or significantly partakes in preparing the agenda, choosing the location or inviting the lecturers, that contained in Section 4.1 must apply.

4.2.2 General Principles

1. The sponsored meeting must have a scientific or educational objective and be relevant for the practice or use of medicines.

2. Sponsorship must only be provided to legally established institutions, groups or entities that work in a health or scientific/educational work-related environment

3. Only those meetings acceptable with regard to the venue, hospitality, lodging and other arrangements, such as those specified in Section 4.1., must be sponsored.

4. Employees may actively procure sponsorship opportunities as well as respond to sponsorship requests; however approval must be obtained before any formal agreement is reached.

5. A contractual agreement must exist for every sponsorship undertaking, which includes the sponsorship amount and the contractual obligation. The agreement needs to define the use of the funds provided. The inclusion of all the necessary elements to make sure that the actions of the organizers do not put the company at risk of violating the applicable codes or regulations must be ensured.

6. Sponsorship to attend a sponsored meeting may be provided to delegates (see 4.3)

4.2.3 Sponsorship Scope

Sponsorship for meetings may be both monetary and non-monetary, but must only cover relevant items that are relevant to or support the meeting.

Sponsorship must be associated to a relevant scientific activity, related with medical associations, health-care institutions, scientific centers and entities renowned for their scientific, educational and health-related work.

The level of financing must represent a fair market value regarding the cost of the meeting.

4.2.4 Control, Follow-Up and Documentation

Fedefarma member companies are responsible for implementing adequate approval, control and follow-up systems for meetings and activities with health-care professionals. These processes must be aligned with the provisions of this Code and contemplate the local

regulations pertaining to the health-care professional. Relevant authorization levels must be included as well as descriptive elements that suffice with respect to understanding the magnitude of the activity, conditions in which it is being developed, and its compatibility with this Code.

At least the following details must be documented:

- Receiver
- Amount of money or type of material provided;
- Use of the funds.
- Agenda for the Event (identifying the scientific and entertainment content)

4.3 Sponsorship for the Participation of Healthcare Professionals Authorized to Prescribe in External Meetings.

Sponsorship may be granted for individuals to attend independent meetings that are externally organized, as long as:

- The nature of the meeting is clearly medical or scientific.
- The meeting is well-recognized and accredited by the medical/scientific community.
- The content of the meeting is relevant to the daily practice of the health-care professional.
- Sponsorship for delegates to attend meetings complies with the industry codes, standards and local laws

Only attendance to meetings that are acceptable with regard to the venue, hospitality, lodging and other arrangements, as defined in Section 4.1, may be sponsored.

Sponsorship for healthcare professionals authorized to prescribe to participate in meetings may be provided as payment or reimbursement to cover the following:

- Registration fee;
- Travel expenses, as per the requirements of Section 4.1, in complying with the industry codes and any internal limitation
- Lodging, in accordance with the requirements of Section 4.1, in complying with the industry codes and any internal limitation.
- Meals, in accordance with the requirements of Section 4.1, in complying with the industry codes and any internal limitation.

Payment or reimbursement of travel expenses, lodging and other expense for individuals accompanying the guest, are is not permitted.

Whenever possible, participation and registration fees must be directly paid to the organizer and not to the individual receiving the sponsorship.

The sponsorship of healthcare professionals in external meetings must not lead to or motivate the prescription, provision, sale or administration of a pharmaceutical product.

Proof of payment of all reimbursed expenses must be received.

4.4 Supporting CME (Continuing Medical Education)

Continuing Medical Education (CME) contributes towards ensuring that healthcare Professionals obtain more modern and precise information and comprehension of therapeutic areas and related interventions that are essential to improve care provided to patients and the healthcare system in general. The main objective of an educational meeting must be that of improving the medical knowledge and, therefore, obtaining the financial support of the companies is appropriate.

When companies provide the content for the CME activities and programs, such material must be honest, balanced and objective and be designed to enable the inclusion of different well-known theories and opinions. The content must consist of medical, scientific or other type of information contributing to improve patient care. Companies must proceed in accordance with that stipulated in Section 4.1 of this Code, when applicable.

5 Participation of Healthcare Professionals Authorized to Prescribe and Outsourcing Organizations

5.1 Key Service Contract Principles

5.1.1 Scope

This section applies to all activities in which payments are made to health- care professionals in exchange for services delivered to the company including, but not limited to:

- Offering and presiding over conferences;
- Performing medical/scientific studies;
- Providing entertainment services;
- Providing consulting services;
- Participating in Consulting Committee meetings
- Preparing educational material

The following activities are outside the scope of this section:

- Sponsorship of meetings (see Section 4.2)
- Sponsoring individuals to attend meetings (see Section 4.3)
- Donations (See Section 7.1);
- Reimbursement of expenses for health-care professionals (see Section 4.3).

5.1.2 General Principles

1. The company must not hire/pay a health-care professional authorized to prescribe to have access or be entitled to promote a product.

2. Health-care professionals must not be selected to provide contracted services as an incentive to prescribe, provide, sell or administer a pharmaceutical product.

3. Meetings with contractors must be acceptable with regard to the venue, hospitality, lodging and other arrangements, as defined in Section 4.1.

4. If the laws, regulations and, in general, local legal guidelines so require, authorization must be obtained from the public employer, before being able to contract a health-care professional.

5.1.3 Selecting Contractors

Health-care Professionals authorized to prescribe must be selected based on their ability and qualifications to perform the required service. The selection criteria for a physician may include:

- Experience with the product, therapy and subject matter in question;
- Scientific reputation
- The publication of abstracts or articles directly related with the therapeutic area, illness or subject discussed.
- Objectively proven equivalent experience in the matter being discussed;
- Affiliation with a university/research center related with the subject matter at hand;
- Experience as a lecturer or similar participation in a relevant scientific program.

5.1.4 Compensation

Compensation for participants must be reasonable, pre-established, based on a fair market price for their services, and reflect the time needed to perform the service.
Fair market price means a price based on typical compensation levels for the relevant healthcare professional, and must take into account:

- The required preparation and execution time;
- The experience, reputation and seniority of the health-care professionals (for example, regional, national, international opinion leader)
- Locally acceptable and respected fees

5.1.5 Contracting

A written agreement must be entered into by and between the company and the health-care professional for each service contract. Such must be signed by both parties and, minimally, contain the following:

- A detailed description of the service being provided;
- Delivery date;
- Sum and payment basis details
- Other benefits including lodging, meals and transportation, among others.
- Contracting term and conditions

5.2 Total Payments to Individual Healthcare Professionals Authorized to Prescribe

It is important that the member company is not perceived as having undue influence over health-care professionals, according to the total level of payment received by individual health-care professionals. Therefore, internal controls should be implemented in order to learn of such individual cases.

5.2.1 Transparency

The engagement of a lecturer by the member company must be transparent. In meetings organized by the member company transparency may be achieved by stating in the materials used for the meeting that the event has not been organized by the company. In meetings organized by third parties, an agreement shall be reached with the organizers regarding the inclusion of an adequate statement in the materials of the meeting specifying that the meeting is supported by a member company.

5.2.2 Documentation

The following information must be documented.

- Proof that the contracted services have been performed;
- Compensation and justification levels

6 Market Research Studies

6.1.1 Definition and Scope

For the purpose of this Code, market-research studies shall be defined as any form of data collection (typically of a statistical nature) that includes health-care professionals or patients, to better understand patient and health-care professional preferences with regard to a product, service or practice.

This section includes all forms of market-research studies, whether carried out by third parties on behalf of the company, or where the company reaches direct agreements with healthcare professionals or patients. In any event, the Fedefarma member company must inform the firm that it contracts to perform the market-research study about the principles and regulations contained in this chapter, and shall be accountable for the observance of such

6.1.2 General Principles

1. The objective of every market-research study must be that of obtaining qualitative or quantitative data on the market environment and understand the trends and conditions of illnesses, therapies, preferences and treatment usage methods.

2. Retrospective in nature, the market-research study must not imply an act of prescribing as a requirement for the study.

3. The market-research study must not have a promotional intention or effect and if any doubt should exist, the Designated Signer must be asked to review the project. Only materials relevant to the objectives of the market-research studies must be used as a part of such. Such study must not be used in a concealed form of promotion.

4. The applicable regulations on data privacy must always be complied with upon performing a market-research study. These regulations may depend on the rules of the country/countries, both regarding where data is collected and where such is stored and used. Additionally, the following must apply:

6.1.3 Compensation

When the market-research study is performed through an agency, the participants must be paid directly by the Agency.

Market-research study agencies: such agencies must comply with the national code of practices regarding compensation levels that must be specified in the Agreement reached with the Agency or directly established in the Contract.

Payment and reimbursement to participants for the services they provide must be reasonable, be based on a just market price, and reflect the time required to perform the service

7 *Donations and Sponsorships*

7.1 Donations

7.1.1 Definition and Scope

Donations are monetary or material contributions for charities/non-lucrative organizations for which the company does not require returns.

This section applies to all donations given by the company to external receivers, including medical societies, local community groups, medical investigation charities, educational charity organizations, etc. It does not cover contributions provided to commercial organizations or those provided in exchange for services rendered to the company.

7.1.2 General Principles

Donations must not require any service or other benefit for the company in exchange for the provided contribution. Particularly, donations must not be linked to past or future sales/prescriptions.

1. The potential beneficiaries of the donations must be charities or non-lucrative organizations and must meet the following criteria:

- Must be a private foundation, company or association set up with investigative/charitable objectives (for example, public hospitals, universities);
- Must be legally incorporated and authorized to operate in accordance with the laws of the country where it carried out its activities.

2. The company may actively procure and respond to requests relating to donations.

3. Donations must be monetary and material including medical equipment, diagnostics, etc. that are useful for such use, as per that stipulated in the law applying to the member company providing such.

4. Requests from institutions intending to improve the medical research or create facilities with medical benefits for patients:

- Must be backed by adequate documentation that clearly indicates that it is a donation that fulfills the ground rules.
- Must not be linked to the inclusion of a National Therapeutic Form, nor other relation with a past/future turnover.

7.2 Sponsorships

7.2.1 Definition and Scope

This section applies to every form of sponsorship provided by Fedefarma. Sections 4.2 and 4.3 provide more details concerning the sponsorship of meetings and sponsoring the attendance of health-care professionals.

Sponsorship is defined as the monetary or non-monetary contribution for an activity or initiative in which

- The name Fedefarma Member Company and/or Fedefarma is associated with the activity;
- The contribution is destined to a certain predefined initiative/activity;

Examples of sponsorship activities or initiatives possibly financed by Fedefarma would include:

- Sponsorship of educational programs
- Sponsorship of research activities;
- Sponsorship of Internet pages
- Sponsorship of public information programs

7.2.2 General Principles

1. In addition to sponsoring meetings, Fedefarma member companies and/or Fedefarma may provide financing in the form of sponsorship for initiatives and activities implemented by third parties that have a scientific or educational objective, are relevant to the practice and use of medicine, or benefit patient care.
   - Sponsorship may only be provided for predefined and destined initiatives/activities.
   - Promotional opportunities are not included and, should this be the case, a specific contract or procedure must be individually kept.

2. Sponsorships must be provided to legally established institutions, groups or entities working in the health-care environment, or having an indirect impact on the health-care environment. Sponsorship must not be provided to individual health-care professionals.

3. The contribution level must not be excessive and must be proportional to the cost of the initiative.

4. The member company, as part of the sponsorship agreement, must make sure that the organizers of the sponsored meetings undertake to not carrying out activities that may place the company at risk of noncompliance with the industry codes and relevant regulations

7.2.3 Documentation

The following information must be documented for all sponsorships:

- Receiver
- Amount of money or type of material provided;
- Use of funds

8 Interacting with the Public, Patients and Patient Groups

8.1 General Principles

1. Where permitted by local law and regulations, all direct communications with patients regarding prescription medicines must be precise, fair, non-misleading and in accordance with the guidelines of local regulations and laws. For more details please resort to the specific regulations of each country.

2. Companies may provide non-promotional information on treatments, illnesses and healthcare to the public so as to improve the quality of life, health-related knowledge, and support the safe and effective use of pharmaceutical products.

3. Companies may carry out or assist in leading public/patient awareness programs on illnesses, to satisfy the growing social demand for more information and increase the public's understanding of illness prevention, signs and symptoms of medical conditions, illnesses and available treatments. Such activities must follow the highest standards of precision and must constitute support for the role played by health-care professionals.

4. The company is responsible for the information about products that is released by the public relations agencies. The signature of the designated Signer must be obtained.

8.2 Direct Promotion to the Public

Where the promotion of prescription drugs to the public is permitted, all local laws, regulations and codes shall be strictly applied in accordance with that set out in this Code. Likewise, when the member company promotes over the counter drugs to the public, it must strictly abide by all the applicable laws, regulations and codes, in accordance with this Code.

Educational material addressing patients must contain the following text: “EDUCATIONAL MATERIAL COURTESY OF (name of the member)” and the text “SEE YOUR DOCTOR”. Where prohibited by local laws and regulations, such material may not contain prescription information, logo and/or affirmations regarding and prescription product

8.3 Interacting with Patient Groups

8.3.1 Definition and Scope

"Support" refers to any assistance provided to Patient Groups and, eventually, to relatives that may be engaged in the treatment of the patient at a certain time. This includes, but is not limited to, donations, monetary payments and payments in kind for specific projects or unconditional donations, paying agency accounts (for example, public relations agencies), providing qualified personnel to work on the projects and providing services (for example, web page design). "Support" does not include informal discussions or providing information, whether proactively or in replying to a request.

8.3.2 General Principles

1. Support to the Fedefarma member must only be directed towards improving the wellbeing of the Patient Group and must never be provided as an incentive or award for prescribing, administering, recommending, purchasing, paying for, reimbursing, authorizing, approving or providing any product or service sold or provided by the Fedefarma member, or to obtain any inappropriate advantage for the Fedefarma member.

2. Support should not be provided to promote the products of the Fedefarma member and should never be pre-conditions to Patient Groups making positive statements regarding the products of the Fedefarma member. Exclusive agreements preventing or inhibiting one of the parties to work with others is not permitted.

3. The relationship must be based on transparency and trust and explicitness of detail must be provided regarding the agreements and expectations of the parties. Patient Groups should be urged to be transparent regarding the support they have received. This includes statements on web pages and specific productions.

4. All support to Patient Groups must:
    - Be covered by a written agreement or consent
    - Be formally approved by the Designator Signer, in writing.

5. The severability of the Patient Group must not be jeopardized. The Fedefarma member must not try to influence the content of the Patient Group material sponsored by the Fedefarma member.
6. The support agreements must not harm the reputation of the Fedefarma member or that of the Patient Group.

7. The support agreements must always comply with the local legislation, regulations and conduct codes.

8. Non-promotional information on health, illnesses and medications, in which the Fedefarma member has a responsibility or participates in the publishing, may be provided to the

Patient Groups and such information must be formally reviewed and approved by the Designated Signer.

9. Support must not be provided for events that are purely social. Support may be provided in the form of snacks provided at a scientific or educational event (such as a conference), as well as donations for patient support activities (such as patient care or creating special days for the disabled).

10. Any Meeting with Patient Groups must be governed by the principles set out in Section 4 of this Code.

11. The Fedefarma Member shall not use the logo or material owned by the Patient Group without obtaining the prior written consent of the organization.

12. The Patient Group must be legally established according to the laws of its country.

8.3.3 Key Activities

The Fedefarma member must keep an annual list of Patient Groups with local support and dollar amounts. This must include a brief description of the type of support.

8.4 Patient Programs

8.4.1 Definition and Scope

A Patient Support Program refers to an action or set of actions designed to improve or facilitate the observance of pharmacological therapy or therapy persistence of patients with chronic illnesses requiring extended or lifelong treatment with some of the products of the Fedefarma member. Actions promoting medications and discounts granted to the patient by the Fedefarma member or third parties are excluded from this definition.

8.4.2 Program Manager

1. A contract must exist between the Fedefarma member and the entity in charge of managing the Patient Program

2. Such contract must clearly specify the activities that shall be carried out by the Manager and include those practices or activities that are prohibited.

3. The contract must include a clause granting the Fedefarma member the right to audit and review the operations of the Manager relating to the Program.

4. No company may request to be the exclusive provider of funds of the patient organization or any of its programs.

8.4.3 Patient Information

1. Neither the Fedefarma member nor any of its business or sales employees may in any way (directly or indirectly) expressly request the personal data (name and surnames, phone number, address, prescribed medication, etc.) of a patient registered in the Program for purposes other than medical, educational or statistic uses or unless the patient expressly decides to share such information.

2. All information managed by the Fedefarma member regarding patients registered in the program must be statistical and anonymous, so as not to enable the patient to be identified. Only the Medical Department of the member may set the rules to access and analyze this information.

3. No direct or indirect contact should exist between the Fedefarma member and the patients for business or promotional purposes, so as to minimize the risk of direct promotions to patients and that of violating the privacy of the patient's information. Educational and/or follow up support programs on the patient's therapy are excluded.

4. All material produced by patients must comply with the rules and regulations of the corresponding country.

5. All material produced by patients must be educational and must not be of a promotional nature. It must not refer to the uses or characteristics of a product, except for those requiring specific instructions for use.

6. For the effects of transparency, all material for patients must contain the name of the Fedefarma member.

7. All support provided to the Patient must be covered by the patient's informed consent.

8. No medication lacking the respective prescription from the attending physician must be provided.

8.5 Educational Activity

In the framework of the programs educational displays and workshops may be provided for Patients and Patient Groups. The content of the educational activities is instructive with regard to the pathology of patients in general, to their possible treatment (including diet and lifestyle actions and pharmacological therapies), as well as the importance of continuing with the chronic pharmacological treatment.

9 Promotional Visits to Healthcare Professionals NOT Authorized to Prescribe or to Medical Support Personnel

9.1 Key Promotion Principles

9.1.1 Definitions and Key Principles

Communication with or visits to Healthcare Professionals NOT authorized to prescribe or Medical Support Personnel, especially pharmacy assistants and/or attendants must not be performed with the aim of motivating the prescription or recommending products that require medical prescription. Payment of “Push Money”, payment of vignettes and/or programs which objective is to provide a financial incentive in money or in kind (prizes) so as to motivate the prescription and/or recommendation of products at the pharmacy is strictly prohibited.

For that provided in this section, that set out in sections 2.1.1 and 2.1.2 of this Code shall apply.

9.2 Promotional Materials

With regards to this section, that which is set out in sections 2.2.1, 2.2.2 and 2.2.3 of this Code shall apply.

9.3 Promotional Visits

With regards to this section, that which is set out in sections 2.1 and 2.2 of this Code shall apply.

9.4 Samples and Gifts

In accordance with local laws and regulations and to the spirit of this Code, neither medical samples nor gifts of a significant value may be provided to Healthcare Professionals NOT authorized to prescribe or to Medical Support Personnel. Also prohibited are any type of incentive or bonus granting a competitive advantage and/or creating an unfair promotion or competition. Samples must be marked as such so that they cannot be resold or inappropriately used.

10 Subsequent Obligations

Fedefarma and the member companies undertake to prepare a calendar, to be attached to this Code, which, among others, shall contemplate the following activities:

- The publication and disclosure of the Code;

- The implementation of the Fedefarma Code and adaptation of the internal policies of each Fedefarma member company, when required in order for this Fedefarma Code to be in force and effectively applied.

- Preparing an Annex containing the continuous collection and updating of the local laws, rules and regulations applicable to the subject matter that have been issued and are mandatory in each country where Fedefarma member companies are developing marketing businesses.

- The effective and coordinated implementation of the obligations deriving from the Code by each Fedefarma member company.

- To annually issue a statement regarding compliance and commitment to the Fedefarma Code by each member company.

11 Clinical Research and Transparency

11.1 Objective Other than that of Promotion

Research on human beings must have a legitimate scientific objective. This research, including clinical trials and observational studies, must not consist in a disguised promotion.

11.2 Transparency

Companies have a commitment to the transparency of the sponsored clinical trials. Admittedly, important health benefits exist with regard to making the information on clinical trials more available to the public, for health professionals, patients and others. Such disclosure, however, must protect the privacy of the individual, intellectual property and contractual rights, as well as observe the laws and national practices that are in effect regarding patents. Companies disclose information on clinical trials as set out in the joint Stance regarding the revelation of clinical trial information through records and clinical trial databases (2009) and the joint stance regarding the publication of clinical trial results in scientific publications (2010) published by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Japanese Pharmaceutical Manufacturers

Association (JPMA) and the US Pharmaceutical Research Manufacturers Association (PhRMA).

12 Company Procedures and Responsibilities

12.1 Procedures

Companies must establish and maintain adequate procedures to ensure the fulfillment of the relevant codes and the applicable laws as well as to review and watch over all its activities and materials, in this sense.

12.2 Training

Companies must also make sure that the relevant employees are adequately trained to be able to fulfill their duties.

12.3 Responsibilities Regarding the Approval of Promotional Communications

An employee with sufficient knowledge and appropriate skills shall be designated as the person in charge of approving all promotional communications. Alternatively, one or more employees of the hierarchical ladder may be placed in charge, as long as they receive scientific guidance regarding such communications by qualified and adequate scientific staff members.

Annex A.

Glossary of Used Terms

“Donations”: Monetary or material contributions or personal support to charities/non-lucrative organizations for which Fedefarma or its members do not receive any service or benefit in return**.**

“Fedefarma Meeting”: A meeting, regardless of where it is held, with some Health-Care Professionals and in which one or more employees of Fedefarma or any of its member companies participate and that is organized by Fedefarma or any of its member companies. A meeting is not considered a meeting of Fedefarma or its member company if Fedefarma or its member company is financing the meeting but does not control the agenda, invitations, location, etc.

“Gifts”: items, monetary and financial benefits of any type, including, but not limited to, Promotional Aids and Medical Use Items. Promotional materials such as pamphlets, fliers, self-adhesive materials are not considered gifts.

“**Healthcare Personnel**”: any person providing any type of healthcare. In countries covered by FEDEFARMA, these are medical, dental, pharmaceutical, nursing, nutritional, therapeutic and any other similar type of professional that during the course of his/her activities may in some way participate in the processes of prescription, referral, purchase, provision or administration of a pharmaceutical product or a therapeutic activity. For the effects of this Code, the following categories are provided:

a. “**Healthcare Professional Authorized to Prescribe**” (PP): any person that through formal education and training is certified and legally authorized to prescribe medications and medical devices. In the countries covered by FEDEFARMA, these are professional physicians and dental surgeons.

b. “**Healthcare Professional NOT Authorized to Prescribe**” (PNP) any person that through formal education and training is certified and legally authorized to administer prescription drugs, to carry out or assist in prescribed treatment or to dispense medications. In countries covered by FEDEFARMA, these are the nursing, pharmacy, nutrition and support (physical, respiratory, etc.) therapy professionals.

c. “**Medical Support Personnel”** (PS) any person that through education or training is trained to dispense or deliver medications and to collaborate in health actions under the supervision of a well-known professional. In the countries covered by FEDEFARMA, these are pharmacy assistants and/or attendants, nursing assistants or technicians for different diagnostic or therapeutic activities.

“Hospitality”: Includes lodging, snacks, meals and other subsistence services.

“**Industry Codes**”: any Code of industry practices applying to marketing, sales and promotional practices of the Fedefarma member companies at the international, regional or national level.

“Informed Consent”: Refers to the document in which the guidelines and requirements of a support program as well as the exclusions are explained to the patient or patient group and that must be signed by the patient or patient group before any program action is executed. This consent must imply the acceptance, for an undefined period of time, of the program guidelines, or the automatic renewal of such if the patient does not express his/her desire to revoke his/her consent, or the acceptance of such for a specific term stated in the consent, or the alternative best adapting to the local laws.

“**Market-Research Studies**”: Study which objective is that of gathering and analyzing information to better understand the preference of the researcher or the patient with regard to a product, service or practice. A market-research study is usually conducted through group meetings, interviews or database analysis. Retrospective by nature, these studies must not directly evaluate behaviors at the specific time of the prescription.

“**Meeting Place**”: Geographic and physical location (for example, hotel, conference facilities) used for a venue.

“**Non-Medicinal Products**” means all products of a non-medicinal nature that can be marketed by the member companies. Included are cosmetics, foods, nutraceuticals, veterinary and agricultural products, medical devices, laboratory reagents, orthosis and prosthesis.

“**Over the Counter (OTC) Drugs**”: Those medications freely distributed and authorized as such by the competent authority in order to market them without requiring a medical prescription.

“**Patient**”: Every person requesting healthcare and/or pharmaceutical services; requiring and obtaining such healthcare services; whether or not they required to be hospitalized.

“**Pharmaceutical Product**” or “**Product**” means all pharmaceutical or biological products (regardless of the patent status and/or existence or non-existence of a trademark) intended to be used in diagnosing, treating, or preventing illnesses in humans or to affect the structure or any function of the human body.

“**Pharmacy Assistant and/or Attendant**”: a Medical Support Personnel member, employed by a pharmacy that works under the orders of a pharmacist responsible for such pharmacy and that dispatches, sells or delivers medications to the public.

“**Prescription Drugs**”: Those medications that must be prescribed to the patient only and exclusively by a physician, and who have been expressly authorized as such by the competent authority.

“**Promotion**” means any activity carried out, organized or sponsored by Fedefarma, addressed to health-care professionals to promote the prescription, recommendation, supply, administration, sale or consumption of its pharmaceutical product by any means, including the Internet.

"**Promotional Aids**": Reminder items intended to promote a product of a Fedefarma member company (for examples, gifts containing trademarks, such as pencils, mugs, etc.)

"**Promotional Materials**": Any promotional item or communication mentioning the name of a product or containing medical or product information, intended to be used by health-care professionals or disseminated by them in a promotional manner.

"**Promotional Visits**": Any oral communication (for example, discussions, details) with a Health-Care Professional, intended to promote the product of a Fedefarma member company.

"**Public**": Individual or group of people receiving information on medications, illnesses, preventing illnesses, symptoms and signs of medical conditions.

"**Regulations**": laws, rules, legal regulations, health-care standards, handbooks and other guidelines issued by State bodies and their agencies.

"**Regulatory Authorities**": regional or local authorities in charge of controlling the operations of Fedefarma member companies and others of the Pharmaceutical industry

"Scientific Information": Any information of a scientific nature that, due to its content or expected use, is not considered as promotional information.

"Sponsored Meetings" means all meetings in which Fedefarma or a member company provides sponsorship and/or in which Fedefarma or a member company may receive a promotional opportunity (for example a Promotional Kiosk). However, Fedefarma or its member company does not handle a sponsored meeting, does not control the agenda and does not choose the venue, nor invites the lecturers or selects the participants**.**

"Sponsorship" means providing monetary or non-monetary support for an activity or initiative in which

- The name of Fedefarma or any of its members is associated with the activity;
- The contribution is destined to a certain predefined initiative/activity;
- Fedefarma or any of its members may have opportunities to elevate its reputation;
- The activity or initiative has a scientific or educational purpose, is relevant for the practice or use of medicine, or is a benefit for patient care**.**

"Useful Medical Items": Items providing a benefit for the rendering of medical services or patient care. They usually lack a trademark but may include a company acknowledgment.