CODE OF GOOD PRACTICES

Fedefarma

August, 2020
Replaces March 2019 Version

Fedefarma

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1. General Principles

1.1 Message from Fedefarma to the Industry and Member Companies

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 World Health Organization (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 was updated in 2012.

The Central American Federation of Pharmaceutical Laboratories [Known in Spanish as Federación Centroamericana de Laboratorios Farmacéuticos, and hereinafter FEDEFARMA for its acronym in Spanish], the IFPMA regional chapter clustering eighteen 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. New adjustments were made throughout 2019 pursuant guidelines received by this entity.

In March 2020, following the WHO's declaration of a global pandemic caused by SARS-CoV-2 virus (COVID-19), the countries of our region - Central America and the Dominican Republic - adapted its professional activities to this new reality, in such a manner which allowed them to reinstate economic activities, respecting biosecurity standards required to safeguard agents in this activity and thus prevent the spread of COVID-19. Fedefarma, aware of this situation, made the necessary adjustments to the Code of Good Practices in response to this new reality, unifying and incorporating the pharmaceutical industry's approach to innovation and development, and issuing a new update in August 2020.

Fedefarma hereby presents its Code of Good Practice for the Promotion of Medicines to all those interested sectors, to be bindingly observed and applied by all of its members and tor any person acting in their name and on their behalf, 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 Purpose of the Fedefarma 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 and any person acting in their name and on their behalf, 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 standards with which our industry has agreed to work with.

All employees working within each company involved, and third parties acting on behalf of each such company (this is where Fedefarma or each company has title, license and/or any other right to use and dispose of trademarks and intellectual property rights) are required to comply with this Code.

This document has been prepared in accordance with the codes and policies that apply to the activities of Fedefarma member companies in the territories where they carry out their business activities, and is subject to local laws and regulations, namely:

- Fedefarma Policies.
- Code of Pharmaceutical Marketing Practices of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA 2019).
- General Health Law or Health Code and their respective regulations in force for each country.

This document has been prepared to be applied to Fedefarma and its associated companies in their relations with Healthcare Professionals and shall likewise be applicable to activities and communications on prescription drugs.
This code is not intended to regulate the following activities:

- Advertisement of pharmaceutical products to the general public, i.e. direct consumer advertising.
- Promotion of non-medicinal products.
- Prices or other commercial conditions for the dispensing of pharmaceutical products.
- The provision of non-promotional information by member companies.

In the event of a conflict between this Code and local regulations, member companies shall apply the strictest measure between the two.

1.3 Responsibility

Fedefarma or member companies will be responsible for the statements, undertakings and other activities carried out by their employees within the course of their employment.

It is therefore of the essence that all Fedefarma personnel members and those of the parties concerned understand, comply and respect this Code in its entirety.

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 bylaws.

1.4 1.4 Use of the Fedefarma Code

This Code provides the minimum ethical standards a Fedefarma member should adhere to when such member carries out company activities with Health Care Providers, patients and groups of patients, namely the marketing of pharmaceutical products and education regarding the use of such products. It is designed to comply with current legislation as well as the industry's Codes and regulations. It is of the essence that the spirit and content of this Code be respected when organizing activities involving pharmaceutical products.

This document is designed so that the individual sections correspond to specific activities carried out or organized by Fedefarma member companies.

When a particular activity is organized, we recommend that employees refer to the relevant section of this document and also review those sections that relate directly or indirectly to the nature of the 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:

- Beginning of Section: definition and scope.
- General principles and specific requirements.
- Where applicable, approval documentation and requirements are summarized at the end of each section.

Overall, approval is structured pursuant to the following principles:

- Materials with medical or pharmaceutical claims are approved by the Authorized Signatory.
- Medical or scientific initiatives are approved by the Medical Department and the Authorized Signatory (as locally defined).

Where the precise interpretation or scope of a particular section of the Code of Good Practices is unclear, its users should initially seek guidance from the member's Good Practices, Ethics and/or Compliance Officer, or from an individual holding a similar title. If the concern remains, the Fedefarma Ethics Committee should be consulted.

1.4.1 Definitions

"Promotion" means any activity undertaken, organized or sponsored by a Member Company which is directed at Health Care Providers to promote the prescription, recommendation, supply, administration or consumption of its Pharmaceutical Product(s) through all methods of communications, including the Internet and other available platforms to Member Company. The terms "Promotional Activity" and "To Promote" have the same meaning as "Promotion".

"Health Care Provider" is any person or group of people who provide some type of health care service. In countries covered by Fedefarma, these people include medical

practitioners, dentists, pharmacists, nurses, microbiologists, nutritionists, therapists or any other similar person, who in the course of their activities may in some way participate in the prescription, recommendation, purchase, supply or administration process of a pharmaceutical product or therapeutic activity, and thus recognized by local regulations. For the purposes of this Code, the following categories are identified:

a) **"**Health Care Professionals with Prescriptive Authority" is any person that, through formal education and training is certified and legally authorized to prescribe medication and medical devices. In countries covered by Fedefarma, these professionals are doctors and dentists, except for such specific cases where local regulations have provided otherwise.

b) **"**Health Care Professionals WITHOUT Prescriptive Authority" is any person that, through formal education and training, is certified and legally authorized to administer prescribed medication, to carry out or assist in prescribed treatments or to supply medication. In countries covered by Fedefarma, these are Nursing, Pharmacy, Nutrition and Supportive (Physical, Respiratory, etc.) Therapy professionals, except for such specific cases where local regulations have provided otherwise.

c) "Medical Support Personnel" (MSS) is any person that, through education or training, is qualified to supply or deliver medication or to collaborate in health-related activities, under the supervision of an accredited professional. In countries covered by Fedefarma, these individuals are pharmacy assistants and/or attendants, nursing assistants or technicians in a range of diagnostic and therapy activities, except for such specific cases where local regulations have provided otherwise.

"Pharmaceutical Products" means all pharmaceutical or biological products (irrespective of patent status and/or whether they are branded or not) which are intended to be used on the prescription of, or under the supervision of, a Health care Professional, and which are intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body. For the purposes of this Code, the term "medication" is equivalent to "pharmaceutical product".

"Regulations" are laws, rules, statutory provisions, health standards, handbooks, codes, and other guidelines issued by government departments and agencies.

2. 2. Promotion of Pharmaceutical Products

2.1 Key Principles

1. Fedefarma member companies must comply with all local regulations and adhere to high ethical standards with regards to all Activities and/or Promotional Materials provided either face-to-face or online.
2. A pharmaceutical product cannot be promoted for use prior to the granting of the marketing authorization allowing its commercialization in the country where promotion is to take place.
3. Pharmaceutical products shall not be advertised to Healthcare Professionals who have clearly made a statement to the effect that he or she does not wish to receive such pharmaceutical promotion.
4. Promotional material must not be disguised All communications must clearly state the name of member company responsible.
5. Pharmaceutical Advertisements cannot be disguised through the use of clinical assessments, post-marketing

surveillance, experience programs or non-intervention studies (NIS). Such assessment programs and studies are only conducted when a primary scientific or educational purpose exists.

6. All promotional communications, whether it be oral, written, or electronic, both in-person or online, must be clear, specific, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value and properties of the pharmaceutical product concerned.

7. All promotional communications must be based on up-to-date evaluation of all relevant scientific evidence, and reflect that evidence clearly. Promotion should encourage the proper use of pharmaceutical products. It must not lead to confusion through distortion, exaggeration, undue emphasis, omission or in any other way. Every effort must be made to avoid ambiguity. No absolute or superlative claims should be made which may lead to unfair competition unless reliable evidence exists to prove such claims.

8. Promotion must be supported by prescribing information approved by the respective Ministries of Health or by scientific evidence supporting claims included in the pharmaceutical product information. Such evidence should be made available upon request to Health Care Provider, in accordance with their degree of responsibility and as provided in the relevant articles of this Code. Member Companies should deal objectively with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry.

9. Recognized sources to support medical-scientific claims should be scientific information published or available to the public, such as:

- Publications in peer-reviewed journals (or articles accepted for publication in peer-reviewed journals).
- Official conference documents.
- Published presentations or posters of medical-scientific events.
- Web publications (e.g., clinical outcome record).
- Data on files approved for disclosure.

10. Quotations from medical and scientific literature or from personal communications, should be faithfully reproduced, and must accurately reflect the meaning of the author. The precise source of the quotation must be identified.

11. Regarding advertising comparisons, promotion must focus on advantages of the advertised product and not on its competitor's weaknesses. Comparison shall be acceptable provided such are objective, truthful and do not contain statements that unjustifiably affect the good name of third parties.

2.2 Promotional materials

2.2.1 Definition and scope

Promotional material, within the meaning of this Code, is any promotional item or communication mentioning the name of a pharmaceutical product, containing information about it, or medical information, with the intention of being used or disseminated to Health Care Providers and which objective is to increase the scientific knowledge about a product and ensure the adequate prescription of the advertised promotional products.

The provision of non-promotional information is not considered advertisement. The principles specified herein also apply to public promotions of prescription drugs, where legally accepted. Where any adaptation is necessary for the promotion to the public of over-the-counter medicines, local regulations should apply.

Promotional material includes, but is not limited to:

- Visual aids.
- Giveaway materials
- Event invitations.
- Event brochures
- Magazine ads (including reminder advertisement).
- Promotional websites, e-mails and other use of electronic media for advertising.
- Other items that make statements about a pharmaceutical product.

Where reference to the pharmaceutical product is made by an external speaker in his or her presentation, whether of a promotional or non-promotional nature, rules set forth in Section 5.1.3 herein shall apply. Reprints of medical and scientific items not developed by the pharmaceutical member company are not considered promotional materials. However, if accompanied by item or communication mentioning the name of a pharmaceutical product or containing information about the product, such shall be considered promotional materials.
Sin embargo, si son acompañados por cualquier artículo promocional o comunicación que mencione el nombre de un producto farmacéutico o contenga información de éste, serán considerados como materiales promocionales.

2.2.2 General Principles

1. All promotional materials are approved by Member Company pursuant in-house authorization procedures.
2. Quotations, illustrations, graphs and tables taken from scientific publishedstudies, or statements from third parties, should be faithfully reproduced, and must accurately reflect the meaning of the author. The precise source of the quotation must be identified.
3. Product promotion personnel are responsible for ensuring the use of up-to-date promotional materials duly approved by the appropriate internal authorities, including the Medical Department.
4. Promotional material may not be used without the approval of the Authorized Signatory. Under no circumstances shall an employee be able to:

- Use home-made materials or modify approved materials (including cutting or pasting approved materials).
- Use or distribute unapproved journal articles or reference texts.
- Use or provide approved material outside the scope of its intended use and target audience (country, Medical Specialty, etc.) to Health Provider.
- Draft notes, letters or other communications to Health Providers with medical-scientific information, without the approval of the Authorized Signatory.

5. The same requirements shall apply to electronic promotional materials as apply to printed materials. Specifically, in the case of Pharmaceutical Product related websites:

- The identity of the Pharmaceutical Company and of the intended audience should be readily apparent.
- The content should be appropriate for the intended audience.

- The presentation (content, links, etc.) should be appropriate and apparent to the intended audience.
- Country-specific information should comply with local laws and regulations.

6. For the purposes of promotional materials, the word “new” should not be used to describe a pharmaceutical product, a new presentation or indication that has been available in the local market for more than 12 months.

2.2.3 Required information for printed materials

The following requirements apply and are subject to local regulations or codes describing mandatory information requirements:

1. All advertisements appearing electronically and in print (including audiovisual materials) other than reminder advertisements (material where no prescription information is provided for product) and scientific items, must be legible and include:

- The name of the product (usually the brand name);
- The active ingredients, using an approved name where one exists.
- The name and address of Company responsible for marketing the pharmaceutical product and/or its contacts information.
- Date of production of the advertisement.
- Abbreviated prescribing information (only when required pursuant local legislation) or reference to the technical sheet/monograph of product approved by the local Regulatory Authority, including the date of document approval.
- Internal material identification code.

2. bbreviated prescribing information (where required by local law) must be approved by Authorized Signatory pursuant country-specific guidelines. In any event, the abbreviated prescribing information must include:

- Approved indication or indications for use.
- Dosage and method of use.
- A succinct statement of the contraindications, precautions and side effects.

3. For brand reminder advertisements and promotional items only containing the name of the pharmaceutical product, prescription does not require the abbreviated prescribing information nor reference to the technical sheet/monograph of product approved by the local Regulatory Authority; unless otherwise provided by local legislation.

- A reminder advertisement is defined as a short advertisement containing no more than the name of the pharmaceutical product and a simple statement of indications to designate the therapeutic category of the product. It bears none of the brand’s attributes.

4. Where a particular study or publication is referenced, clear citations should be included for reader to locate original source

- Copyrights and Publisher rights must be respected and the necessary licenses must be obtained, when applicable.

5. Promotional material in active use should be reviewed periodically or when significant changes occur (for example, upon adding a warning or side effect to prescribing information), and thus ensure its continued compliance with relevant local regulations.

6. Appropriate procedures should be established and maintained to ensure full compliance with applicable laws and all information required in the review and monitoring of all promotional materials.
7. For materials used throughout the digital media, such as websites, phone apps, etc., the purpose of which is educational and not advertisement, Member Company must present them before the competent authorities for approval, unless explicitly provided for by local legislation.
8. Any promotional statement must include scientific evidence supporting claims in the references section of such material.

2.3 Promotional Visits

2.3.1 Definition and scope

A promotional visit is any verbal communication with a Heal Care Provider, conducted in person or online, to promote a Federma Member Company pharmaceutical product. Support material for these pharmaceutical product related visits is covered in Section 2.2.

2.3.2 General Principles

1. All product statements must conform to Section 2.1.
2. Promotional visits shall seek to create value for Health Care Provider by providing relevant, up-to-date, accurate, true and precise pharmaceutical information to meet patients´ need.
3. Promotional visit may be conducted in person or online pursuant local regulations, the availability of Health Care Providers and Member Company provisions; always following safety and restriction protocols to reduce risks in unpredictable scenarios or force majeure events.
4. Promotional visits to Health Care Professionals WITHOUT Prescriptive Authority or visits made to Medical Support Staff, specifically pharmacy assistants and/or attendants should not be aimed at encouraging the recommendation or prescription of pharmaceutical products that legally requires a medical prescription.

The payment of “Push Money”, vignettes and/or incentive programs offering cash and/or non-cash awards for the purpose of encouraging the prescription and/or recommendation of pharmaceutical products in pharmacies or dispensing facilities is strictly prohibited.

2.3.3 Handling of questions concerning the unauthorized prescription of pharmaceutical products

No pharmaceutical product shall be promoted for use until the requisite approval is given by health and local authorities.

Responsible advertising personnel should not initiate discussions on pharmaceutical products or the unauthorized use of a product. When unexpected requests for information are made by Health Care Providers regarding pharmaceutical products or the unauthorized use of a product, the sales representative should refer the consultation to the local Medical Department.

The Medical Department may supply Health Care Professionals with Prescriptive Authority with the relevant information or material, provided its unauthorized nature is clarified. Material must be clearly addressed to such professional (i.e., stating his/her name), explicitly indicate its use is not certified and that the company does not

endorse product off-label use. When query is made by Health Care Professionals without Prescriptive Authority or Medical Support Personnel, the Medical Department must specify approved uses and that the company does not endorse product off-label use.

Any verbal, digital or written off-label information provided by the Medical Department, must:

- Be directly relevant to the inquiry and not cover other areas.
- Use clear, scientific and objective language.
- Be factual, objective, and reflect all available published evidence, with the exception of privileged or confidential information.
- Use pharmaceutical product generic name.
- Simply answer the question and not provide any other unrelated product information.
- Clearly state usage is not authorized and that the Member Company does not endorse product off-label use.

2.4 Medical Samples

Pursuant local regulations, during a promotional visit or as a consequence of such visit, medical samples can be provided to Health Care Professionals so that they may familiarize themselves with the medicinal product and acquire experience in dealing with them or upon their request provided sample handling and distribution complies with local regulations.

Medical samples may only be provided to Health Care Professionals who are authorized to prescribe them and should not be sold nor awarded as a bonus, discount or used in any type of commercial transaction that could result in competitive advantage and/or create unfair promotion or competition. Items given to Health Care Professionals with Prescriptive Authority must never constitute an inducement to prescribe, recommend purchase, supply, sell or administer a pharmaceutical product.

Samples shall be prominently labeled, both in the primary and secondary packaging, so as not be resold or used improperly.

Companies must have an appropriate monitoring and accounting system for the samples they distribute to Health Care Professionals with prescriptive authority, including how to look after such samples whilst they are in possession of medical representatives.

Delivery of medical samples must comply with public and private health institution requirements regarding biosafety issues, to reduce risks in unpredictable scenarios or force majeure events. (e.g. pandemics).

Principles set forth herein apply to early experiences of original product presentations.

2.5 Provision of Gifts to Health Care Provider

2.5.1 Definition and scope

A gift is an item provided to an individual free of charge and with no expectation of receiving anything in return.

With regards to Health Care Personnel, the following Prohibition of Gifts apply:

- Offer gifts or other benefits seeking the inducement to prescribe, purchase, recommend or access any product.

- Provide gifts for the personal benefit (such as sporting or entertainment tickets, electronics items, social courtesy gifts, etc.) of Health Care Professionals (either directly or through clinics and institutions).
- Providing or offering cash, cash equivalents or personal services (personal services are any type of service unrelated to the Healthcare Professional's profession and that confer a personal benefit to the Health Care
- Make monetary disbursements or deliver financial benefits in kind, including, but not limited to, benefits that offset and/or subsidize routine business expenses of Health Care Provider.

Printed or online promotional material such as brochures, fliers, stickers, etc., are not considered as gifts.

A promotional aid or memento is a non-monetary item given for a promotional purpose. Providing or offering such promotional aid to Health Care Providers in relation to the promotion of prescription-only medicines is prohibited.

The following may be offered to Health Care Provider:

- Promotional aids in minimal quantity and value solely for the promotion of over-the-counter medicines if relevant to the practice of the Health Care Provider.
- Pens and notebooks may be distributed to event attendees provided such items company branded. Only quantities necessary for event purposes should be distributed and amounts may not exceed a maximum of USD $50 (fifty U.S. dollars).

2.5.2 General Principles

1. Pursuant local regulations and the IFPMA Code, providing or offering financial and/or in-kind benefits (including grants, scholarships, grants, support, consulting agreements, or medical practice-related items that exceed criteria set forth in Section 2.5.1) to Health care Providers conditional upon any obligation to prescribe, recommend, purchase, supply, administer or promote products or for a past or future commitment. Likewise, nothing should be offered or provided in a manner or on conditions that would have an inappropriate influence over the prescribing practices of Health Care Professionals with Prescriptive Authority.
2. Health Care Provider must not be offered or provided as a gift, cash or cash equivalent any redeemable coupons, vouchers, lottery or raffle tickets, etc.).
3. Health Care Provider must not be offered or provided as a gift, cash or cash equivalent any offset of routine business expenses (e.g. utilities, connectivity platforms, membership fees, etc.).
4. Promotional gifts should be oriented to support the work or medical practice of Health Care Provider.

2.5.3 Items of Medical Utility

Items of medical utility are items beneficial to the provision of medical services and for patient care. Member Companies may provide items of medical utility if such items:

- Have maximum value of USD $200 (two hundred U.S. dollars).
- Do not offset routine business expenses.
- Beneficial to enhancing the provision of medical services and patient care.

Examples include:

- Demo units for the use of medical devices.
- Digital storage device of modest value with storage contents suitable for contents.

Items of medical utility should not be offered on more than an occasional basis, even if each individual item is appropriate. Items of medical utility can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

Medical related text or reference books/information, subscription to on-line. journals and other educational materials available through medical institutions or associations may be given by Member Companies if of a reasonable value and subject to the prior approval of Medical Department Any other informational or educational items given to Health Care Provider should be of modest value.

A process should be established to ensure that an individual Health Care Professional does not receive items of this nature on a regular basis.

2.5.4 Informational or Educational Items that enhance Patient Care

Informational or educational items provided to Health Care Professionals for their education or for the education of patients on disease and its treatments may be offered by member companies provided that the items are primarily for educational purposes and do not have independent value.

Informational or educational items provided to Health Care Professionals for patient use can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

The value of books and subscriptions must be reasonable. Other informational or educational items must be of modest value.

2.6 Communications and scientific information on unapproved products or off-label use

No Pharmaceutical Product shall be promoted for use in a specific country until the requisite approval for marketing for such use has been given in that country.

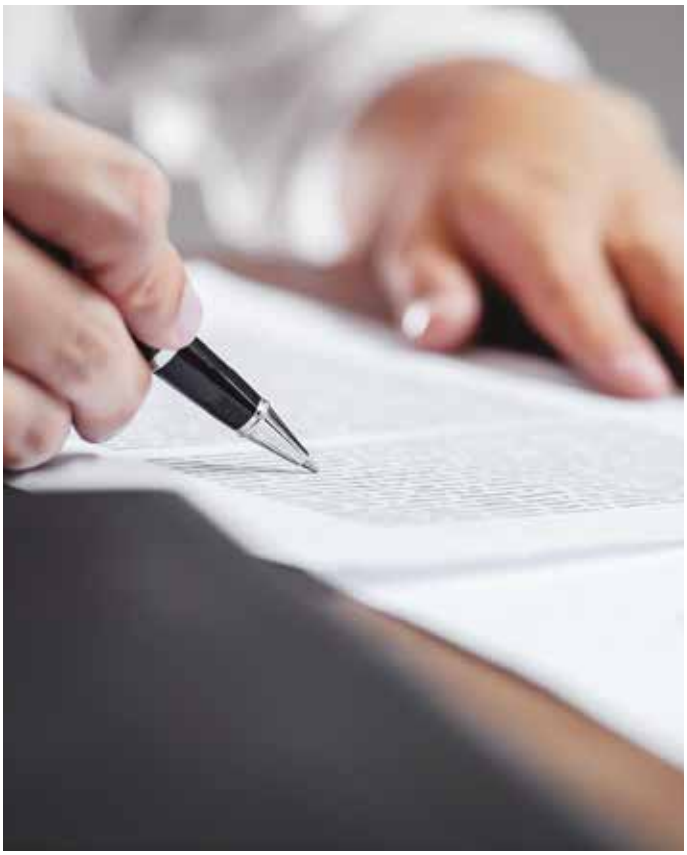
Any query regarding off-label use should be handled by the Member Company Medical Department backed with all relevant medical documents.

This provision is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a Pharmaceutical Product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences.

Nor should it restrict public disclosure of information to stakeholders and others concerning any Pharmaceutical Product, as may be required or desirable under local regulations. In any case, material should clearly indicate that the product is not locally approved for use.

Scientific information may be shared in a non-promotional manner with the intent to:

- Enhance scientific knowledge
- Support the medical community in obtaining information regarding scientific/medical advancements.
- Share information about current medical practices.



Non-promotional scientific information may be shared by authorized qualified personnel, taking into account that it will be directed to public with scientific/educational interest (scientific community, Health care Providers, regulatory bodies) and with no promotional interests. These situations are:

- As part of an approved pre-launch communication, for example, on diagnostic or epidemiology matters.
- In response to specific questions from Heath care Providers.
- As part of a scientific event.
- As part of normal conversations and communications regarding clinical research activities as provided by Medical Department personnel.

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

- If material makes unfounded claims about therapeutic implications.
- If material does not use clear, scientific and objective language but instead uses language of a promotional nature.
- If the material is not factual, objective nor reflects available published and unpublished evidence.
- If material uses the pharmaceutical brand name instead of its generic name.

Section 2.3.3 shall apply for handling questions regarding off-label use.

3. Promotion of over-the-counter pharmaceutical products (OTC)

3.1 Definición y Alcance

This section covers the voluntary implementation of ethical principles for medicines and products, such as cosmetics, personal hygiene products, medical devices, nutritional supplements, and natural products marketed by Fedefarma Member Companies throughout Central America and the Dominican Republic as:

- Nonprescription sales,
- Over-the-counter sales and/or
- Sales to the public in general.

Concepts are defined as follows:

1. Non-prescription products: For the purposes of this document, drugs, devices, supplements, cosmetics or other products that, pursuant local regulations, are authorized for sale without the need of a prescription. In some countries non-prescription products are exclusively sold at pharmaceutical facilities.
2. Over-the-counter products: In some countries this definition is used as a synonym for non-prescription products. It refers to non-prescription drugs which can also be sold at NON-pharmaceutical facilities. In Panama, it is a synonym for non-prescription products.
3. Consumables: For the purposes of this document, products subject to specific health regulations, such as food, dietary and nutritional supplements, hygiene products, devices, etc.
4. Promotional or advertising materials: It refers to consumer-directed techniques, informative activities and materials that seek to inform, disseminate and influence the acquisition and use of a pharmaceutical product.
5. Reminder advertisement: Promotional items given to consumers free of charge, containing the name of pharmaceutical product, Member Company brand or product claims.
6. Health Organization: A public or private organization, institution, or association offering healthcare services or consisting of Health care Professionals.

Member Companies are responsible to ensure compliance with the Code, including actions performed by third parties, such as distributors or companies contracted by Member Companies.

3.2 Objective

- Asegurar que las actividades comerciales, de información e interacción con consumidores, clientes, Personal de Salud, autoridades sanitarias y público en general, se realizan de manera responsable, ética, profesional y en cumplimiento con las regulaciones vigentes en cada país.

3.3 Promotion and Advertising General Provisions

Member Companies must comply with the following provisions regarding the promotion and advertising of pharmaceutical products:
1. Promotion and advertisement must observe relevant internal and external regulations (e.g. local regulations, internal standards, Industry and Fair Competition Code).
2. Pursuant country-specific regulations, no pharmaceutical product shall be promoted nor advertised for use in a specific country until the requisite approval for marketing for such use has been given in that country.
3. All information must be consistent with use indications approved by health authorities, i.e. not include off-label uses not approved by the relevant authorities.
4. The use of items which exert an inappropriate influence upon prescribing, recommendation, acquisition, supply, dispensing, or administrative decisions regarding products is strictly forbidden.
5. Members must observe and comply with health regulations and consumer related information and protection regulations.
6. It is further required that products include security information, (such as warnings and precautions, including contraindications interactions, etc.), necessary for the correct dosage of such

products, whether in product packaging or package inserts pursuant local regulations.
7. Promotional information must be clear, legible, up-to-date, accurate, fair, objective and balanced.
8. Advertisement must be based on relevant evidence and/or sufficiently complete in order for the target audience to be able to form their own opinion on the given pharmaceutical product.
9. Comparative information may be used in countries where local regulations allow its use, provided product evidence is provided and product qualities description be objective and be presented in a fashion excluding the possibility of misleading the advertising audience, as well as observe third party intellectual property and unfair competition related practices.

Promotional and/or advertising information should not be:

- Misleading; e.g. through suggestion, omission, exaggeration, false statement ambiguity or other distortion of information.
- Suggest a cure for a condition that requires treatment under the supervision of a Health Care Professional.
- Offensive, dismissive, obscene, repulsive, rude, discriminatory or inspiring violence.
- Should not incite the indiscriminate use of medicines.

3.3.1 Promotion and Advertising General Provisions

Promotion and advertising to the public must comply with Promotion and Advertising General Provisions.

As provided under local regulations, the following is allowed: Price promotions, gifts with purchases, brand reminders, award promotions, and distribution of medical samples for product familiarization and usage.

- Giving away of samples to consumers as an inducement to purchase product is prohibited.
- These promotions are allowed and can be offered as discount coupons, vouchers, loyalty cards and discounted prices.
- Gifts with the purchase of non-prescription or over-the-counter Products must be related to Product use.
- Reminder advertisements are to be given free of charge and do not entail the obligation to purchase product.

Delivery of medical samples to consumers must comply with public and private health institution or facility requirements regarding biosafety issues, to reduce risks in unpredictable scenarios or force majeure events. (e.g. pandemics).

3.3.2 Promotion directed to Customers

La promoción dirigida a clientes (por ejemplo, distribuidores, mayoristas, farmacias, detallistas) debe cumplir con las disposiciones generales de Promoción y Publicidad. Así mismo deben entenderse y manejarse adecuadamente los riesgos de corrupción y soborno; y cumplir con las leyes de competencia y regulaciones locales en lo que respecta a precios y descuentos.

3.3.3 Promotion directed to Health Care Professionals

The purpose of promotional actions directed at Health Care Professionals is to proactively provide information regarding

member company products and about diseases that are prevented or treated with their pharmaceutical products.

Members must ensure that personnel responsible for promotions directed to Health Care Professionals comply with the following:

- Receive appropriate training and knowledge on the pharmaceutical product regarding approved indications and safety profile, thus ensuring that off-label uses are not endorsed.
- Have the qualification and profile required by country-specific regulations.
- Promotional information to Health Care Professionals may include: disease information, clinical trial data, or comparative statements.
- Samples of non-prescription products may be provided to Health Care Professionals or directly to the consumer, provided delivery is allowed local regulations, for product familiarization and usage. Pursuant local regulations, product shall be prominently labeled with “Free sample – not for sale” (or similar phrase).
- Promotional events for Health Care Professionals, must attract attendees through its scientific/educational program.
- Incidental entertainment and recreational activities are permitted provided such are associated with an educational and/or scientific activity and that the latter is the priority.
- Invitations to continuing education activities shall only be provided to Health Care Professionals, and shall not include relatives or companions.

3.4 Recruitment and support for Health Care Professionals

Health Care and Health Organization Professionals may be involved in services such as the creation of marketing materials for experts, consultancies, public relations activities, advisory boards, product registration assistance for specialists, regulatory support and consulting services.

Health Care Professionals who are considered public officials with decision-making powers in public institutions will not be paid for lectures, regardless of the subject matter.

Health Care Professionals and Health Organizations are third parties at risk and their recruitment must comply with anti-bribery and anti-corruption standards. An agreement must be properly signed before commencement of activities.

4. Meetings

Meetings with Health Care Providers include member company meetings, sponsored meetings, or sponsorship for Health Care Providers to attend international meetings.

4.1 Member Company Meetings

4.1.1 Definition and scope

A member company meeting is defined as a meeting organized and managed by the company between several (three or more) Health Care Providers and one or more company employees.

A meeting is not considered a member company meeting when:

- The meeting is only being funded and such funds are received by a medical association, health institution, or other organization that brings together Health Care Providers or people with scientific interests.
- The meeting agenda is not detailed or managed by the member company.

This section applies to all external meetings held in person and/or online, either locally or internationally, such as:

- Own meetings.
- Congresses and symposia.
- National and regional meetings.
- Meetings with an external speaker.
- Meetings conducted by sales representatives (for example, round table meetings).
- Continuing medical education activities.
- Clinical Study Meetings.
- Advisory Board meetings.
- Medical congresses, hospital workshops, company sessions, etc.

4.1.2 General Principles

1. Meeting organized must have a scientific or educational purpose and be relevant to the proper practice or use of medicines. Meetings with Health Care Providers of a purely social nature, should not be organized, sponsored or co-sponsored.
2. Participants must not be paid for their attendance or time spent in meetings unless providing a service at that meeting, in which case provisions set forth in Section 5 herein shall apply.
3. Fedefarma Member Companies are responsible for ensuring compliance with all relevant regulations when organizing activities and meetings with Health Care Providers and, in the event of delegating the organization or indirectly participating, it will continue to be liable, inform the organizers and ensure that these regulations are respected and complied with.
4. Events that takes place outside of attendee's country of practice should not be organized unless it is appropriate and justified to do so from the logistical or security point of view. International scientific congresses and symposia that derive participants from many countries are therefore justified and permitted. These meetings can be organized and conducted in person or online, and must comply with the same principles.
5. For international in person meetings, the national codes of participants must be respected, as must the code of the nation in which the meeting is held and the national code of the country from which it is organized. In such cases, the strictest rules shall apply to the fullest extent.
6. For online international meetings, the national codes of participants must be respected. The nation where the event is organized is hereby considered herein to be the country where the organizing company is legally incorporated.

4.1.3 Contents of meeting

All materials submitted must be relevant and internally approved by the member company, which must be clearly identified in such materials, and must observe relevant local regulations.

This requirement must be met for in person and/or online meetings, and for all countries in which the member company has an interest in disseminating meeting contents.

4.1.3.1 Lectures with External Speakers

External speakers should be appropriately informed so as they cannot incur in a breach of local regulations and requirements detailed in this Code.

Promotional meetings should not include information on unauthorized pharmaceutical products or off-label use.

Non-promotional meetings may include scientific/educational information provided by external speakers that, subject to local regulations, may include references to unauthorized pharmaceutical products and/or off-label use. If such a reference is made, the speaker should be asked to clearly state that the information is about an unauthorized pharmaceutical products and/or off-label use.

Discussions should be strictly limited to a legitimate exchange of medical/scientific information. Meetings designed to promote off-label uses are not permitted.

Meetings where reference is made to pharmaceutical products or off-label uses may not include support personnel at the medical activity, only Health Care Professionals.

4.1.3.2 International Events

Promotional materials distributed to participants could relate to pharmaceutical products not registered in the country of some participants, provided that it is truly an international scientific meeting and an explanatory statement is made specifying that registration conditions differ from one country to another.

Additionally, pursuant meeting contents, any rules set forth in any relevant Industry Code must be complied with by Health Care Providers or others in a relevant professional field. Invitations will be extended to the relevant Health Care Providers, pursuant meeting contents and objectives.

For online meetings, invitations shall be extended to Health Care Providers who have given their consent to be contacted online by the organizing Member Company.

No companions, spouses, family members or partners shall be invited. In special circumstances and upon evaluation of the particular case - which will be taken under exceptional circumstances - as a medical necessity, the assistance of support staff for attendees displaying difficulty or physical limitation (caretakers, LESCO interpreters, etc.) must be justified. Organizing Member company shall not cover third party expenses when an in person international or local meetings requiring the overnight stay of participants, such participants arrive with a non-justified companion.

Support and attendance at both in person and online meetings should be based on the scientific and educational value of event, taking into account the program, contents, overall cost, nature of the audience, cybersecurity and privacy agreements, and assessing the general impression of all agreements between the parties.

The possibility of categorizing participants is important during online meetings so that measures are taken to restrict materials and/or information to the Health Providers for which such materials were approved. In addition, it should be considered that attendees may consent to terms and conditions of online activity, when this is a local requirement or a requirement of event organizer.

4.1.4 Venues

The following should be considered for venues of meetings organized by member companies:

- Must be appropriate and conducive to the main purpose of meeting.
- Lavish, inappropriate or seemingly extravagant venues must not be used.
- Venues that are renowned for their leisure and entertainment facilities should be avoided unless no other meeting place is available due to capacity, facilities, etc.
- Should be logistically appropriate, to ensure easy access and facilitate travel for all participants.
- Must comply with applicable local regulations.

Meetings in which the majority of participants are from a single country should not be held outside that country unless the relevant source or experience constituting the object or subject matter of the meeting is located outside such territory, for example, visits to a specific clinic, manufacturing facilities, laboratory, due to expert accessibility or safety issues.

This provision does not apply to online events, which always assumes connectivity of participants from their base locations.

4.1.5 Hospitality, lodging and travel

Subject to strict compliance with industry codes and local regulations, member companies may provide meeting attendees with the following, within referenced limits:

- Appropriate air or ground transportation, provided meeting location distance so warrants.
- Lodging.
- Registrations for applicable cases.

Meetings may include hospitality for guests, as are snacks, incidental to the meeting's main purpose.

Should be moderate and reasonable as judged by local standards. Meals shall not be provided at expensive or luxurious locations.

Hospitality shall be exclusively provided or covered for meeting attendees and should always be secondary to the main purpose of the meeting. Hospitality must comply with local regulations.

No stand-alone entertainment or other leisure or social activities may be provided or paid for. However, entertainment of a modest nature which is secondary to refreshments and/or meals is allowed during Events. (e.g. ambient music).

Lodgings may be offered provided attendees have traveled a reasonable distance and when the duration of the meeting is sufficient to justify the overnight stay.

Stay should be pursuant meeting agenda and should not be anticipated or extended beyond what is reasonable to ensure the participation of meeting attendees.

Not to be provided:

- Travel in first class.
- Business class travel for short-haul flights, for example, less than the hours specified by each member company or pursuant local regulations.
- Luxury hotels (no more than the local equivalent of a 4-star hotel (except when one must resort to a higher category hotel due to the magnitude of event).

- Fancy meals (no more than a medium quality local restaurant), no expensive/fancy spirits or wines.

If attendees wish to extend their stay beyond the time required to participate in meeting, such individual must cover all additional costs on their own. Invitations and entertainment programs should not be extended or arranged for companions, who should not attend any activity, including but not limited to scientific meetings and business dinners.

4.1.5.1 Hospitality for online meetings

In certain circumstances, modest and incidental hospitality for online commitments is acceptable in order to ensure Health Care Providers use their time in the most efficient manner and to support patient care.

Online events where food is provided must be of scientific or educational nature and such hospitality must be appropriate and incidental to event program. Factors such as length of meeting, number of participants, time of day meeting is held (e.g. breakfast or lunch) and type of hospitality to be provided should always be considered.

Hospitality should be appropriate at all times (e.g. refreshments).

The same high standards of in person interactions should apply to online interactions, including the following:

- Hospitality may only be provided at the office, institution or official health center where Health Provider works, and never sent to residences or other specific place outside the work environment.
- Ensure compliance with local protocols and restrictions, e.g., measures dictated by emergency declarations.
- At least one representative of organizing member company will be present online to participate during the entire debate.
- Organizing member companies can only provide meals if they reasonably expect Health Care Provider will remain present throughout the whole event.
- Member companies may not reimburse Health care Providers for meal costs at a meeting. Hospitality coordination should only be carried out directly by the organizing member company.

4.1.6 Control, Follow-Up and Documentation

Fedefarma member companies shall be responsible for implementing the appropriate Health Care Provider meeting and activity approval, control and follow-up systems.

These procedures should be aligned with this Code and should take into account local regulations to which event attendees belong to. Relevant authorization levels must be included and sufficient descriptive elements must be provided to understand the magnitude of activity, the conditions under which it will develop and its compatibility with this Code.

Information regarding all meetings should be documented e.g. agenda, lecture, etc. Documentation must at least include the following:

- List of attendees, date, subject, speaker.
- Related service agreements.
- Internal approvals.
- Approval of external bodies, when required by local regulations.

4.2 Sponsored Events

4.2.1 Definition and scope

This section applies to all meetings not under the control of member company but funded in whole or in part by such company. In other words, the member company does not control:

- the agenda
- the event venue
- invited speakers
- selection of participants.

Typical examples are scientific meetings or congresses held by medical associations or providers of medical services.

Where member company controls or significantly partakes in drafting the agenda, choosing the venue or inviting speakers, Section 4.1 should apply.

4.2.2 General Principles

1. Sponsored meeting must have a scientific or educational purpose and be relevant to the proper 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 meetings deemed acceptable with regards to venue, hospitality, accommodations and other arrangements, as detailed in Section 4.1, should be sponsored.
4. Member company associates can actively seek sponsorship opportunities as well as respond to sponsorship requests. However, approval must be obtained before any formal agreement can be made.
5. A written agreement for any sponsorship commitment must exist which includes the agreed amount and consideration for sponsorship. Agreement needs to define the use of funds provided. The inclusion of all necessary elements to ensure the organizer's actions do not put the company at risk of infringing applicable codes or regulations.
6. Sponsorship to attend a sponsored meeting may be provided to delegates (see Section 4.3).

4.2.3 Scope of sponsorship

Sponsorship for meetings, both in-person and online, have monetary or non-monetary value, but should only cover relevant or auxiliary items for meetings, including connectivity platforms for online sessions.

Sponsorship should be associated with a relevant scientific activity, to medical associations, healthcare institutions, scientific facilities and entities renowned for their scientific, education and health work.

The level of funding should represent fair market values with regards to meeting costs.

4.2.4 Control, Follow-Up and Documentation

Fedefarma member companies shall be responsible for implementing the appropriate third-party meeting and activity sponsorship approval, control and follow-up systems. These procedures should be aligned with provisions included in this Code and should take into account local regulations to which event organizing company belongs to.

Relevant authorization levels must be included and sufficient descriptive elements must be provided to understand the magnitude of activity, the conditions under which it takes place and its compatibility with this Code.

Documented information should conform to the following as minimum:

- Receiver.
- Amount of money or type of material provided.
- Use of funds.
- Event agenda (identifying scientific content and any additional activities taking place during the event, including entertainment activities).

4.3 Sponsorship of Health Care Providers to attend external meetings

Sponsorship may be provided to individuals to attend external independent meetings, provided:

- Meeting is clearly of a medical or scientific nature.
- Meeting is widely accepted and accredited by the medical/scientific community.
- Meeting contents must always be relevant to the practice of Health Care Provider.
- Sponsorship of delegates to attend meetings complies with industry codes and local regulations.

Sponsorship of Health Care Providers to participate in external meetings must never constitute an incentive or inducement to prescribe, recommend purchase, supply, sell or administer a pharmaceutical product.

Only attendance to meetings deemed acceptable with regards to venue, hospitality, accommodations and other arrangements, as detailed in Section 4.1, should be sponsored.

Sponsorship is limited to the payment of:

- Registration/participation fee; paid, when possible, directly to organizer and not to sponsored individual.
- Travel expenses, pursuant Section 4.1 requirements and in compliance with industry codes and any in-house limits.
- Accommodation expenses, pursuant Section 4.1 requirements and in compliance with industry codes and any in-house limits.
- Meal expenses, pursuant Section 4.1 requirements and in compliance with industry codes and any in-house limits.

Member Company reimbursement to sponsored individual is subject to filing proof of payment for all such sponsored expenses.

In any case, all payment stubs for incurred expenses must be properly guarded. Travel, accommodation and the payment or reimbursement of other expenses for individual accompanying guest are not allowed.

4.4 Support for Continuing Medical Education

Continuing Medical Education (CME) helps ensure that Health Care Providers obtain the latest and most accurate information and insights on therapeutic areas and related interventions, of the essence to the improvement of patient care and overall enhancement of the healthcare system.

The primary purpose of an educational meeting must be the enhancement of medical knowledge and therefore financial support from Member Companies is appropriate.

When Member Companies provide content to CME activities and programs, such material must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognized opinions.

Content must consist of medical, scientific or other information that can contribute to enhancing patient care Member Companies must follow Article 3.1 herein, where applicable.

5. Participation of Health Care Providers and organizations in contracted services

5.1 Key principles for service agreements

5.1.1 Definition and Scope

This section applies to all activities where payments are made to Health Care Providers in exchange for services to Member Companies, including, but not limited to:

- Speaking at and chairing events.
- Involvement in medical/scientific studies
- Provide training services.
- Provide consulting services.
- Participation at advisory board meetings.
- Draft educational materials.

The following activities are not included within the scope of this section:

- Sponsorship of meetings (see Section 4.2).
- Sponsorship of individuals to attend meetings (see Section 4.34.3).
- Donations (See Section 7.1).
- Health Care Provider Expenses (see Section 4.3).

5.1.2 General Principles

1. Member Company may not engage or pay a Health Care Provider for access or the right to promote a product.
2. The hiring of Health care Provider to provide the relevant service must not be an inducement to prescribe, recommend,

purchase, supply, and/or administer any pharmaceutical product.

3. Meetings with consultants should be deemed acceptable with regards to venue, hospitality, accommodations and other arrangements, as detailed in Section 4.1.

4. If required by local regulations, authorization must be obtained from the public employer before hiring an employee Health Care Provider.

5.1.3 Selecting Consultants

The criteria for selecting a Health care Provider must be directly related to the expertise necessary to provide the service; Selection criteria includes, but is not be limited to:

- Experience with product, therapy and subject-matter in question;
- Scientific reputation.
- Publication of abstracts or articles directly related to the therapeutic field, illness or subject matter in question.
- Objectively proven equivalent experience in the subject-matter in question.
- Being affiliated to a university/research facility associated with the subject-matter at hand;
- Having experience as a lecturer or similar participation in a relevant scientific program.

5.1.4 Compensation

Compensation for Contractor services should be reasonable, agreed upon in advance, based on the fair market value of services to be provided and must reflect the time required to perform such service.

Fair Market Value means a price based on the relevant Health Care Provider's typical compensation levels; it should consider:

- Required preparation and execution time.
- Experience, reputation and seniority of Health Care Provider (e.g., a regional, national, or international opinion leader)
- Widely accepted honorarium rates at the local level

5.1.5 Recruitment

It is necessary to conclude a written agreement between the member company and the contractor for each service agreement. It must be signed by both parties and, at a minimum, contain the following:

- A detailed description of the service being provided.
- Delivery date.
- Amount and the basis for payment of such services.
- Other benefits, including travel, meals, accommodation, etc.
- Employment terms and conditions.

5.2 Total individual payments to Health Care Provider

It is important member company is not perceived as having undue influence, be it real or perceived, over Health Care Provider, with regards to the total level of payments individually received by such Health Care Provider. Therefore, internal controls should be implemented to receive knowledge of such 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 is achieved through a statement in meeting materials, stating the meeting has been organized by such company. In meetings organized by third

parties, organizers should be agreed to include an appropriate statement in meeting materials, specifying the meeting is endorsed by the member company.

5.2.2 Documentation

The following information should be documented:

- Proof that contracted service has been performed.
- Compensation levels and justification.

6. Market Research

6.1 6. Market Research

6.1.1 Definition and scope

For the purpose of this Code, Market Research is defined as any form of data collection (typically statistical in nature) that includes prescribers or patients, to better understand the preference of Health Care Professionals with prescriptive authority and patients, with regards to a product, service or practice. This section includes all types of Market Research, whether performed by third parties on behalf of member company or the latter executes direct agreements with Health Care Providers and/or patients. In any event, a Fedefarma member company must inform the contracted Market Research firm of principles and standards contained in this chapter, and its responsibility for compliance.

6.1.2 General Principles

1. The objective of any Market Research should be to obtain qualitative or quantitative data on the market environment and to understand trends and conditions of illnesses, therapies, preferences and treatment usage methods.
2. Retrospective in nature, Market Research is not conditioned by a prescription as a requirement to perform he study.
3. Market Research must have no promotional intent or effect and, when in doubt, the Authorized Signatory must be asked to review the project. Only materials relevant to research objectives should be used as part of market research. This should never be a form of concealed advertising.
4. Applicable data privacy regulations should be complied with at all times when conducting any type of Market Research. These regulations may depend on country-specific rules, for both the country where data is collected as the country where such data is stored and used.

6.1.3 Compensation

When Market Research is conducted through an agency, participants must be paid directly by the agency. Market Research agencies must comply with the national code of practice regarding compensation levels, as specified in agreement with agency or as directly set forth in contract for such purposes. Payment and reimbursement to participants for services rendered should be reasonable, based on the fair market value, and must reflect the time required to perform such service.

7. Donations and Sponsorships

7.1 Donations

7.1.1 Definition and scope

Donations are monetary or material contributions to entities, for which Fedefarma and/or its member companies do not require anything in return.

This section applies to donations given by Fedefarma and/or its member companies in favor of external recipients, which may include medical societies, local community groups, medical research charities, educational charities, public health institutions, etc., and are legally incorporated pursuant local regulations. It does not include contributions provided to commercial organizations or contributions provided in exchange for services rendered.

7.1.2 General Principles

1. Donations are not conditional on services rendered or the provision of any other type of benefit to Fedefarma and/or member companies in exchange for the contribution provided. In particular, donations should not be linked to past or future pharmaceutical product sales or prescriptions.
2. Potential donation beneficiaries should be charities, non-profit organizations or public institutions meeting the following criteria:

- Must be a private foundation, company or association established for research or charitable purposes (e.g., public hospitals, universities, etc.).
- Public health institutions (e.g., ministries of public health, social insurance funds, etc.).
- Be legally incorporated and authorized to operate pursuant local regulations where it conducts its activities.
- Donations to such entities should be permitted by local regulations.

3. Fedefarma and/or its member companies can actively seek and respond to donation related requests.
4. Donations may be monetary and material in nature, including medicines, medical equipment, diagnostic materials, etc., found in excellent conditions for use and pursuant applicable regulations for the awarding member company.
5. Requests from public or private institutions seeking to improve medical research or create medical facilities for patients:

- Must be supported by the proper documentation, clearly stating such donation meets complies with guidelines.
- It must not be linked to the inclusion of a pharmaceutical product on the National Therapeutic Form, nor other past or future turnover report.

7.2 Sponsorships

7.2.1 Definition and scope

This section applies to all types of sponsorship provided by Fedefarma and/or its member companies. Sections 4.2 and 4.3 provide further details regarding the sponsorship of meetings and the sponsorship of Health Care Professional attendance of meetings.

Sponsorship is defined as the monetary or non-monetary contribution of an activity or initiative where:

- Name of Fedefarma and/or its member companies are linked to the activity.
- Contribution is destined to a certain predefined initiative or activity.

Examples of sponsorship activities or initiatives potentially funded by Fedefarma and/or its member companies include:

- Sponsorship of educational programs.
- Sponsorship of research activities.
- Sponsorship of websites.

- Sponsorship of public information programs.

7.2.2 General Principles

1. In addition to the sponsorship of meeting, it is acceptable for Fedefarma and/or its member companies to provide funding in the form of sponsorship to initiatives and activities implemented by third parties for scientific or educational purposes, relevant to the medical practice, the usage of medicine, or beneficial to patient care.
2. Sponsorship may only be provided for predefined initiatives or activities.
3. Promotional opportunities are not included and, if included, a specific contract or procedure must be executed separately.
4. Sponsorships should only be provided to legally incorporated institutions, groups or entities working in the healthcare field, or that indirectly have an impact on health environment. Sponsorship should not be provided to individual Health care Providers.
5. Contribution levels should not be excessive and should be proportional to the cost of initiative.
6. Fedefarma and/or its member companies must ensure, as part of the sponsorship agreement, that organizers of sponsored meetings undertake not to perform activities that could place the company in a state of non-compliance with relevant industry codes and regulations.

7.2.3 Documentación

The following information regarding sponsorships should be documented:

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

8. Interaction with the Public, Patients and Groups of Patients

8.1 General Principles

1. Where it is permitted by law to communicate directly with patients regarding their prescription pharmaceutical product, all such information should be accurate, fair, non-misleading and in accordance with local regulations. Country-specific regulations should be consulted for further information.
2. Member Companies that are sent to the public can provide non-promotional information on treatments, diseases and health to improve quality of life, health knowledge and support the safe and effective use of pharmaceutical products.
3. Member Companies can assist in the conduct of public/patient disease awareness programs, to meet growing social demands for more information and to increase public understanding, by providing information on, signs and symptoms of medical conditions, illnesses, and available treatments. Such activities must adhere to the highest standards and must support the role of Health Care Providers.
4. The company is responsible for information about pharmaceutical products released by public relations agencies. The Authorized Signature must be obtained for such purposes.

8.2 Direct-to-Consumer Advertising

Where legally permitted, the direct-to-consumer advertising of prescription pharmaceutical products must strictly adhere to local regulations in compliance with this Code. Likewise, when the member company non-prescription pharmaceutical products directly to consumers, it must strictly adhere to all applicable local regulations in compliance

with this Code.
Patient-oriented educational materials must contain the following text: “EDUCATIONAL MATERIAL COURTESY OF (name of the member company)” and the text “CONSULT YOUR PHYSICIAN”. Where not permitted by local regulations, these materials may not contain prescription information, logo and/or claims regarding any prescription pharmaceutical product.

8.3 Interactions with Patient Groups

8.3.1 Definition and scope

“Support” means any assistance provided to Patient Groups and, eventually, to family members who may be linked to the treatment of the patient at any given time. This includes, but is not limited to, donations, monetary and in-kind payments for specific projects or unconditional donations, payment of agency accounts (e.g., public relations agencies), providing qualified personnel to work on projects and to render services (e.g., web page design). “Support” does not include informal discussions or the provision of information, either proactively or in response to a request.

8.3.2 General Principles

1. Support to Fedefarma member company should be directed solely to improving the welfare of the Patient Group and should never be provided as an incentive or reward for prescribing, administering, recommending, buying, paying for, reimbursing, authorizing, approving or providing any product or service sold or provided by the Fedefarma member company, or to obtain any inappropriate advantage in favor of such Fedefarma member company.
2. Support should not be given to promote the pharmaceutical products of Fedefarma member company and should never be conditional on Patient Groups making positive statements regarding products. Exclusive agreements that prevent or inhibit a party from working with others are not permitted.
3. The relationship must be based on transparency and trust and, agreements and expectations of parties should be completely clear. Patient Groups should be urged to be transparent regarding the support received. This includes statements on web pages and specific productions.
4. All support given to Patient Group should:

- Be covered by a written agreement or consent.
- Be formally approved by the Authorized Signatory, in writing.

5. Independence of Patient Group should not be jeopardized. Fedefarma member companies should not attempt to influence the content of Patient Group material sponsored by member companies.
6. Support agreements must not damage the reputation of Fedefarma member company or Patient Group.
7. Support agreements must always comply with local regulations.

8. Non-promotional health, disease and drug information may be provided to Patient Groups in which Fedefarma member company has editorial involvement or responsibility and, such information should be formally reviewed and approved by the Authorized Signature.
9. No support should be given to events of a purely social nature. Hospitality support may be provided in the framework of 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 people with disabilities).
10. Any meeting with Patient Groups should be guided by the principles set forth in Section 4 herein.
11. Fedefarma member companies shall not make use of the logo or material owned by a Patient Group without the prior written consent of such organization.
12. The Patient Group must be legally incorporated pursuant regulations of the country to which it belongs. Regional Patient Groups shall be governed by regulations of the country where the Group is domiciled or the country where the Group President is located at.

8.3.3 Documentation

Fedefarma member company must keep an annual list of Patient Groups with local support and the dollar amounts provided to them. This should include a brief description of the nature of support.

8.4 Patient Support Programs

8.4.1 Definition and scope

The Patient Support Program is an action or set of actions designed to improve or facilitate compliance with drug therapy or therapy persistence of patients with chronic illnesses requiring long-term or life-long treatment with any Fedefarma or member company product. Actions promoting medications and discounts granted to patients by a Fedefarma member company or by third parties are excluded from this definition.

8.4.2 Program Manager

1. A contract must exist between the Fedefarma member company and the patient program management entity.
2. Such contract must clearly specify activities to be carried out by the Manager and include which practices or activities are not permitted.
3. Contract must include a clause granting the Fedefarma member company the right to audit and review Manager´s operations regarding Program.
4. No company may request to be the exclusive provider of funds for Patient Groups or any of their programs.

8.4.3 Patient Information

1. Neither the Fedefarma member company nor any of its business or sales employees may in any way (directly or indirectly) explicitly request the personal data (first and last name, telephone, address, prescribed medication, etc.) of a patient enrolled in the Program for purposes other than medical, educational or statistical use or that the patient explicitly decides to share.
2. All information managed by the Fedefarma member company regarding patients enrolled in the Program must be handled in a statistical and anonymous manner, so as not to allow the individual identification of patient. Only the member company Medical Department may set forth the rules to access and analyze this information.

3. No direct or indirect contact should exist, for either commercial or promotional purposes, between the Fedefarma member company and patients. This measure seeks to minimize the risk of direct-to-patient advertising and the risk of patient information privacy violations. Patient educational support and/or therapy follow-up programs are excluded.
4. All material produced for patients must comply with country specific rules and regulations. This must be educational in nature and by no means promotional. It should not refer to uses or features of a pharmaceutical product, except those requiring specific instructions for use.
5. For transparency purposes, all patient materials must bear the name of Fedefarma member company.
6. All patient support must be covered by their informed consent.
7. No pharmaceutical product should be provided without the prescription attending physician.
8. Only where explicitly provided by local regulations, patient support programs should be submitted to the competent authorities for approval. If such programs are not covered by regulations, the member company is not liable when prior approval is not requested.

8.4.4 Educational activities

Within the framework of Programs, it is possible to hold exhibitions and educational workshops for Patients and Patient Groups. The content of educational activities is informative with regard to the general pathology of patients, their possible treatment (including dietary and lifestyle measures, as well as pharmacological therapies), and the importance of compliance with the chronic pharmacological treatment.

9. Clinical Research and Transparency

9.1 Objective

Research with human beings must have a legitimate scientific objective. This research, including clinical trials and observational studies, should not constitute a disguised promotion.

9.2 Transparency

Member Companies are committed to the transparency of clinical trials which they sponsor.

Admittedly, important health benefits exist with regard to making the information on clinical trials more publicly available to Health Care Providers, patients, and other interested parties.

Such disclosure, however, must maintain protections for individual privacy, intellectual property and contract rights, as well as conform to legislation and current national practices in patent law.

Member companies will disclose information on clinical trials as set forth in the joint position on disclosure of clinical trial information through clinical trial records and databases (2009) and the joint position on publication of clinical trial results in scientific literature (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 Pharmaceutical Research and Manufacturers of America (PhRMA).

10. Member Company Procedures and Responsibilities

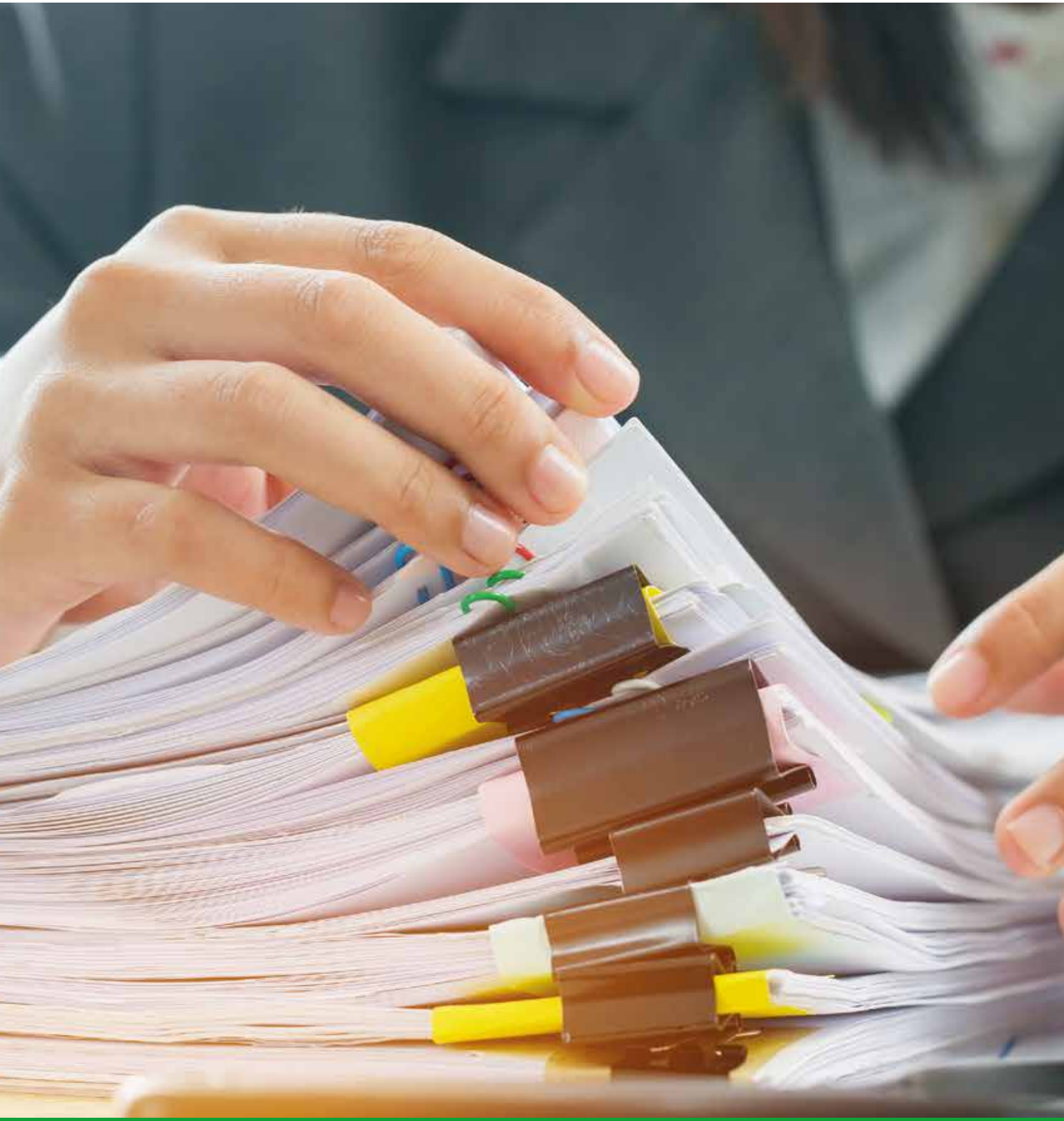
1. Member Companies should establish and maintain appropriate procedures to ensure compliance with relevant codes and applicable laws and to review and monitor all of their activities and materials in that regard.
2. Member Companies should also ensure that relevant employees receive training appropriate to their role.
3. A designated Member Company employee with sufficient knowledge and appropriate qualifications should be responsible for approving all promotional communications. In the alternative, a senior company employee(s) could be made responsible provided that he or she receives scientific advice on such communications from adequately qualified scientific personnel.

10.Subsequent obligations

Fedefarma and its member companies undertake to draft an annual calendar, which includes, but is not limited to, the following activities:

- Code disclosure and publication.
- The effective application and enforcement of the Fedefarma Code of Good Practices and, where necessary, the adaptation of each Fedefarma member company's in-house policies to such effect.
- Draft a schedule containing a compilation and regular updating of the local applicable regulations relevant to subject-matter referred to herein, which have been issued in, and are binding to, each country where Fedefarma member companies conduct their commercial business.
- The effective and coordinated application of obligations arising from Code by each Fedefarma member company.

The issuance by each Fedefarma member company of an annual statement of commitment and compliance with the Fedefarma Code.



SCHEDULES

Schedule A:
Glossary of Used Terms

1. "Items of Medical Utility": Medical items are items beneficial to the provision of medical services and for patient care. Generally unbranded, but may include an acknowledgment of company.

2. "Regulatory Authorities": regional or local authorities with regulatory oversight of Fedefarma member company activities, and those of others in the Pharmaceutical Industry.

3. "Promotional Items": brand reminder items seeking to promote a Fedefarma member company product (e.g., pens, notebook, etc.).

4. "Industry Codes": any Code of industry practices which applies to the marketing, sales or promotion practices of Fedefarma member companies at the international, regional or national level.

5. "Informed Consent": Refers to the document where guidelines, requirements and exclusions of a support program are detailed to Patient or Patient Group. Such document must be signed by Patient or Patient Group, or an official representative with sufficient Patient Group authority, before any program action is performed. This consent must imply the acceptance of program guidelines indefinitely, or its automatic renewal if patient does not explicitly revoke his/her consent, or its acceptance for a specific period of time as stated in the consent, or the alternative that best adapts to local laws.

6. "Pharmacy Assistant and/or Dependent": a Medical Support Personnel Member, an employee of a pharmacy that works under the orders of a pharmacist responsible for such pharmacy and who dispatches, sells, or delivers pharmaceutical products to the public.

7. "Donations": monetary or material contributions to entities, for which Fedefarma and/or its member companies do not receive a service or benefit in return.

8. "Market Research Studies": a study aimed at collecting and analyzing information to better understand the preference of researcher or patient with regard to a product, service or practice. A Market Research study is usually conducted through group sessions, interviews, or database analysis. Retrospective by nature, these studies should not be directly assessing behaviors at the time of prescription.

9. "Hospitality": includes accommodation, refreshments, food and other subsistence support.

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

11. "Venue" or "Location": geographic and physical location (e.g. hotel, conference facilities) used for an event.

12. "Promotional Materials" any promotional items or communications mentioning the name of a pharmaceutical product or containing medical or product information, pharmaceutical product information, intended to be used by or disclosed to Health care Providers in a promotional manner.

13. "Prescription Drugs": Medications that must be prescribed to patient only and exclusively by a physician, and which has been explicitly authorized as such by the competent authority.

14. "Over-the-counter or OTC Medication": Freely distributed medication authorized for

sale by the competent authority without the need of a prescription.

15. "Patient": Any person who requests medical and/or pharmaceutical care; who requires and obtains the provision of health care; whether or not hospitalization is needed.

16. "Sponsorship" is defined as the monetary or non-monetary contribution of an activity or initiative where:

- Name of Fedefarma or any of its member companies is linked to the activity.
- Contribution is destined to a certain predefined initiative or activity
- Fedefarma or any of its member companies may receive opportunities to elevate their reputation.
- The activity or initiative has a scientific or educational purpose, is relevant to the practice or use of medicine, or is beneficial to patient care.

17. "Health Care Provider" is any person that provide some type of healthcare service. In countries covered by Fedefarma, these people include medical practitioners, dentists, pharmacists, nurses, nutritionists, therapists or any other similar person, who in the course of their activities may in some way participate in the prescription, recommendation, purchase, supply or administration process of a pharmaceutical product or therapeutic activity, and thus recognized by local regulations. For the purposes of this Code, the following categories are identified:

- "Health Care Professionals with Prescriptive Authority" is any person that, through formal education and training is certified and legally authorized to prescribe medication and medical devices. In countries covered by Fedefarma, these professionals are doctors and dentists, except for such specific cases where local regulations have provided otherwise.
- "Health Care Professionals WITHOUT Prescriptive Authority" is any person that, through formal education and training, is certified and legally authorized to administer prescribed medication, to carry out or assist in prescribed treatments or to supply medication. In countries covered by Fedefarma, these are Nursing, Pharmacy, Nutrition and Supportive (Physical, Respiratory, etc.) Therapy professionals, except for such specific cases where local regulations have provided otherwise.
- Medical Support Personnel is any person that, through education or training, is qualified to supply or deliver medication or to collaborate in health-related activities, under the supervision of an accredited professional. In countries covered by Fedefarma, these individuals are pharmacy assistants and/or attendants, nursing assistants or technicians in a range of diagnostic and therapy activities, except for such specific cases where local regulations have provided otherwise.

18. "Pharmaceutical Product" or "Product" means all pharmaceutical or biological products (irrespective of patent status and/or whether they are branded or not) which are intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body.

19. "Non-Medicinal Products" means all products of a non-medicinal nature which may be marketed by member companies. These include cosmetics, food, nutraceuticals, veterinary and agricultural products, medical devices, laboratory reagents, orthosis and prosthesis.

20. "Promotion" means any activity undertaken, organized or sponsored by a Fedefarma Member Company which is directed at Health Care Provider to promote

the prescription, recommendation, supply, administration, sale or consumption of its Pharmaceutical Product(s) through all methods of communications, including the Internet and other available platforms to Member Company.

21. "Public": An individual or group of people who receive information about medication, illnesses, preventing illnesses, disease prevention, symptoms, and signs of medical conditions.

22. "Gifts": items, monetary advantages and financial benefits of any kind, including, but not limited to, Promotional Items and Medical Utility Items. Promotional material such as brochures, fliers, stickers, etc., are not considered as gifts.

23. "Regulations": laws, rules, statutory provisions, health standards, handbooks, codes, and other guidelines issued by government departments and agencies.

24. "Fedefarma Meeting": A meeting organized by Fedefarma or any member company, regardless of where it is held, between several Health Care Providers and one or more Fedefarma employees or employees of any of its member companies. A meeting is not considered a meeting of Fedefarma or of its member companies when Fedefarma or its member company is financing the meeting but does not control the agenda, invites, venue, etc.

25. "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 (e.g. a promotional kiosk). However, Fedefarma or its member company does not manage a sponsored meeting, does not control the drafting of the agenda and does not choose the venue, lecturers nor speakers.

26. "Promotional Visits": any verbal communication (e.g., discussions, details) with a Heal Care Provider to promote a Federma Member Company pharmaceutical product.

Schedule B:
Protocol for Donation Delivery

The following recommendations are proposed to ensure safe and healthy conditions for donor representatives and donor entity and, to ensure compliance with Central American and Dominican Republic country-specific health authority rules and regulations. These recommendations are for informative purposes and designed to ensure a safe and healthy environment for the delivery of in-kind contributions, or for ceremonies held to receive monetary donations to help improve care conditions for the most vulnerable inhabitants, such as those in unpredictable scenarios or force majeure events. (e.g. a pandemic).

1. The minimum number of representatives in attendance for parties involved in donation delivery and acceptance should be ensured.

2. All event participants must wear personal protective equipment (PPE) - including gloves, goggles, face shields, face masks and respiratory protection (where applicable) - as set forth by health authorities and pursuant the situation at hand.

3. Open and well-ventilated venues should be chosen to carry out the donation delivery and acceptance protocol in order for all attendees to keep safe distant from one another.

4. Whenever possible, donation deliveries should be carried out without contact between participants, by placing donation in an appropriate area from where it may be received, thus limiting all unnecessary contact to the maximum extent possible.

5. Physical contact, such as shaking hands or hugging, is not recommended as a sign of appreciation, even if parties involved are protected by personal protective equipment, as this sends a contradictory message regarding good practices.

6. Ceremony should be short, only covering donation delivery.

7. Donor is recommended to perform a proper disinfection of goods delivered, before entering such in-kind donation at any facility.

Donations are initiatives for social benefit with the only purpose of providing aid during critical times. Even though it would be desirable to capitalize on these opportunities for networking, we should not lose sight of the fact that, in times of force majeure, this may represent an increase in risk. Social networks and press releases should be used for these purposes.

Fedefarma

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