

ECUADOR

IFI-IFPMA

CODE OF GOOD PRACTICES FOR DRUGS PROMOTION

Let's do the right thing

IFI

Research and Innovation Pharmaceutical **Industry**

Promesa

Research and Innovation Pharmaceutical Industry **Foundation**

IFI
RESEARCH AND INNOVATION PHARMACEUTICAL INDUSTRY

IFPMA
INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS
AND ASSOCIATIONS

October 2012

Let's do the right thing
CAMPAIGN FOR ETHICAL PHARMACEUTICAL MARKETING

**CODE OF GOOD PRACTICES FOR DRUGS PROMOTION
2012**

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I. About IFI and IFPMA

IFI

The Research and Innovation Pharmaceutical Industry Corporation (Corporación de la Industria Farmacéutica de Investigación e Innovación—IFI) is an organization founded in the 1980s and which today is representing most of the European and North American research and development, biotechnology and vaccine based pharmaceutical laboratories working in Ecuador.

Its members are integrated on the basis of sound scientific activities, focusing on research and development of new and innovative solutions that provide preventive healthcare and restore the health of persons of all ages and both genders throughout the world.

These companies are currently part of the group spearheading biotechnology research, which is making revolutionary changes in the field of medicine and radically shifting the profile of healthcare treatments.

Ethics, quality, and responsibility with respect to access to pharmaceutical products are the guidelines governing the work of hundreds of Ecuadorians who, every day, ensure that research laboratories are dynamic, productive, socially responsible companies fully committed to the country's health and development.

In this common effort, we are working closely with the medical community and government authorities to promote the suitable supply of high-quality pharmaceutical products, patient safety, access, and information.

As IFI Corporation, we are in charge of conducting reviews and promoting the industrial and trade interests of our members. We also plan and implement major corporate social responsibility projects, in the framework of government health policies and focusing on creating synergies with the most important stakeholders in the sector through our nonprofit foundation called Fundación Promesa IFI (IFI Promise Foundation).

IFI's work is organized with a Board of Directors and Committees in charge of the key issues for the industry, among which ethics.

The Code you are now reading is the outcome of the consensus and commitment achieved by the laboratories that are members of IFI, in a common effort to build up and ensure further transparency of their practices and guarantee ethical marketing and promotion of their pharmaceutical products in the country.

IFPMA

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) is the global nonprofit nongovernmental organization representing research-based pharmaceutical, biotech and vaccine sectors.

The IFPMA brings together national and regional pharmaceutical industry associations throughout the world.

The industry's R&D pipeline contains hundreds of new medicines and vaccines being developed to address global disease threats such as cancer, heart disease, HIV/AIDS and malaria. The new IFPMA Clinical Trials Portal (www.ifpma.org/ClinicalTrials) and information from the recent survey on public and private health partnerships help make the industry's activities much more transparent.

The IFPMA is also committed to patient safety by guaranteeing the quality of medicines and combating their counterfeiting. It also provides the secretariat for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

II. Introduction to the Nationalized IFI-IFPMA Code

All the laboratories that are members of the Research and Innovation Pharmaceutical Industry Corporation (IFI) in Ecuador use the same high ethical standards they apply in all of the countries throughout the world where they work.

These laboratories, focusing on research and development of new and innovative solutions that provide preventive healthcare and restore health, have their own stringent codes guaranteeing ethical conduct with respect to the medical community, government authorities, financial markets, their competency, their clients, their patients and the community at large.

Aware that ethics involves constant reflection and critical examination of the validation of one's conduct, IFI and its members pledged, at the end of 2007, to make an effort to update together the rules for the ethical marketing and promotion of pharmaceutical products to healthcare professionals and thus guarantee that patients will be the principal beneficiaries of their products and that they will be using them adequately.

Thus, IFI and its members worked on revising the nationalized version of the Code of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), which required not only updating the Code but also consolidating it on the basis of concepts and the specification of its scope, thus making the **IFI-IFPMA Code** a version that is more rigorous and with greater applicability in the local context.

Likewise, the mechanisms to prevent, remedy and penalize possible breaches of the Code were drawn up.

This process has been consolidated by providing training on the contents of the **IFI-IFPMA Code** to the staff of each one of member laboratories, which took place with workshops delivered by IFI in each company.

For the purpose of stressing respect for both the spirit and the contents of the **IFI-IFPMA Code**, there is an ongoing process of providing certification to the staff of member laboratories at the level that each one decides (sales force, administrative staff, management, etc.) with online testing of understanding and thorough knowledge about the **IFI-IFPMA Code**.

Throughout 2012, we revised and updated our Code to build up its contents, on the basis of the improvements that were discussed and adopted by IFPMA at the beginning of the year and as a result of the internal reflection and constructive analysis promoted among of member laboratories.

This entire process of drawing up, revising and strengthening the **IFI-IFPMA Code** highlights the concern of all of us who are part of the research and innovation based pharmaceutical industry to duly fulfill our responsibility of providing ethically, completely,

truthfully and objectively information about our pharmaceuticals and promoting their rational use.

III. Preamble to the IFI-IFPMA Code

(i) The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and marketing new medicines. Ethical promotion helps to ensure that healthcare professionals have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.

(ii) The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and each one of its members, among which there is the Research and Innovation Pharmaceutical Industry Corporation (Corporación de la Industria Farmacéutica de Investigación e Innovación—IFI-Ecuador) and each one of its member companies, are committed to educational and promotional efforts that benefit patients and promotional programs and collaborations that enhance the practice of medicine. IFPMA also seeks to preserve the independence of the decisions taken by healthcare professionals in prescribing medicines to patients. The pharmaceutical industry has an obligation and responsibility to provide accurate information and education about its products to healthcare professionals in order to establish a clear understanding of the appropriate use of prescription medicines. Industry relationships with healthcare professionals must support, and be consistent with, the professional responsibilities healthcare professionals have towards their patients. Pharmaceutical companies must maintain high ethical standards when conducting promotional activities and comply with applicable legal, regulatory and professional requirements.

Through the promotion of this Code, IFPMA seeks to ensure that ethical promotional practices are established worldwide.

(iii) The IFPMA Code of Pharmaceutical Marketing Practices (the “IFPMA Code”) sets forth standards for the ethical promotion of pharmaceutical products to healthcare professionals, and for member companies' interactions with them. Effective January 1st, 2007, this Code replaces the IFPMA Code of Pharmaceutical Marketing Practices (Update 2000). Member associations of IFPMA must incorporate this Code into existing national codes, subject to the guidance set out in articles (vi) and (vii) below, as a result of which IFI proceeded to fulfill this mandate.

Therefore, the IFPMA Code was adapted to the country's context by the Research Pharmaceutical Industry Corporation (IFI-Ecuador) and revised in 2008, and thereafter it was referred to as the IFI-IFPMA Code. This Code enshrines the principles set by the IFPMA, while providing it with local elements. The IFI-IFPMA Code came into force on March 4, 2008, and the most recent update of its contents concluded in October 2012.

(iv) IFPMA acknowledges the role of relevant codes of ethics developed by the World Medical Association, International Council of Nurses and the International Federation of

Pharmacists. IFPMA also recognizes the role of Ethical Criteria for Medicinal Drug Promotion provided by the World Health Organization in 1988.

As for the IFI, it recognizes the role of the above-mentioned codes, along with the stipulations regarding this in Ecuadorian law.

(v) The IFI-IFPMA Code contains provisions relating to scope, applicability and guiding principles; the content of promotional material; interactions with healthcare professionals; company procedures and responsibilities; and operation and enforcement. It also includes a Q&A section to assist in interpretation of the Code, describes the procedures for monitoring and providing for penalties on the basis of IFI-IFPMA Code, includes enforceability, takes into account the stipulations of Ecuadorian law, and details the operating procedures for filing Code complaints with the IFPMA (*Appendix 1*).

(vi) It is a requirement of IFPMA membership that member associations, especially the IFI and its member companies, accept the conditions of the IFPMA Code and, subject to local laws and regulations, adopt codes that meet local requirements but are consistent with, and as comprehensive as, the IFPMA Code.

IFI member companies shall be bound by both their own internal codes and the principles set forth in the IFI-IFPMA Code.

(vii) It is accepted that where there is an established framework of stringent regulatory and/or legal controls which are effectively as comprehensive in their provisions and application as the IFPMA Code, it may be more appropriate for a national member association not to establish new duplicative provisions and procedures. IFPMA also acknowledges that many IFPMA member associations have already established their own codes of conduct, which, together with local laws and regulations, fully embody the principles set forth in the IFPMA Code.

The Research and Innovation Pharmaceutical Industry Corporation (IFI-Ecuador) nationalized the IFPMA Code, and its member companies are bound by the principles set forth in the present specific document (IFI-IFPMA Code), enshrining the principles of the IFPMA and providing it with local inputs.

(viii) IFPMA member companies must comply directly with applicable national codes of member associations where such codes exist (the IFI-IFPMA Code in Ecuador). In all other territories, i.e. where there are no local codes or appropriate laws and regulations, or where a member company is not a member of local/regional associations, the IFPMA Code acts as a default code for the activities of member companies and the IFPMA operating procedures apply.

(ix) IFPMA member companies are accountable for addressing and correcting infringements under relevant codes. They should also ensure that internal structures and procedures (including adequate training of employees) are created to ensure responsible and ethical promotional activities. Companies not in membership with IFPMA may elect to be subject to the IFPMA Code and its complaints handling processes.

(x) The IFPMA is open to receive genuine complaints from any source on any aspect of the IFPMA Code, in accordance with its operating procedures. Where it is determined that there has been a breach of the IFPMA Code, the objective is to correct the matter as rapidly as possible.

The operating procedure of the IFPMA Code (*Appendix 1*) provides that said Code and its operating procedure shall be applied in those territories where the respective member association has not adopted a national code. In this regard, the companies grouped together under IFI shall abide by the stipulations of the nationalized IFI-IFPMA Code, as well as by the prevention, complaint reporting and penalty procedure decided on by the IFI Board of Directors and included in the present publication (*Chapter V*).

(xi) The IFPMA is a non-profit, non-governmental organization representing industry associations—among which the IFI—and companies from both developed and developing countries. Member companies of the IFPMA include major global research-based pharmaceutical companies. Companies are committed to the ethical standards set out in this Code. (On application, see chapter VII.)

IV. The IFI-IFPMA Code

1. Objective and Scope

1.1 Objective

The IFI-IFPMA Code sets out standards for the ethical promotion of pharmaceutical products to healthcare professionals to ensure that member companies' interactions with healthcare professionals are appropriate and perceived as such.

Q&A 1 (*question and answer*)

1.2 Scope: for the purposes of the IFPMA Code

- “pharmaceutical product” 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 healthcare 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.

Q&A 2

- “promotion” means any activity undertaken, organized or sponsored by a member company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all media, including the Internet.
- “healthcare professional” means any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product.
- “member company” means any company that is a member of IFPMA (direct member) or a member of any association that is a member of IFPMA (indirect member). “Company” can refer to national companies and/or the worldwide parent company.
- “member association” means any association that is a member of IFPMA, including IFI.

1.3 Exclusions

This Code does not seek to regulate the following activities:

- Promotion of prescription-only pharmaceutical products directly to the general public (i.e. direct-to-consumer advertising).

Q&A 1 and 3

- Promotion of self-medication products that are provided “over-the-counter” (OTC) without prescription.

Q&A 4

- Pricing or other trade terms for the supply of pharmaceutical products.

Q&A 5

- The engagement of a healthcare professional to provide genuine consultancy or other genuine services to a member company.

Q&A 6

- The conduct of clinical trials.
- The provision of non-promotional information by member companies.

Q&A 7

2. General Principles

2.1 Basis of Interaction

Member companies’ relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information and supporting medical research and continuing education. This information shall only be delivered to the healthcare professional by paying him/her a medical visit.

Pharmaceutical companies’ interactions with healthcare professionals must at all times be ethical, appropriate and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence.

2.2 Clinical Research and Transparency

Companies are required to ensure transparency of the clinical trials they sponsor. It is recognized that there are important public health benefits associated with making clinical trial information more publicly available to healthcare practitioners, patients and others. Such disclosure, however, must ensure protection for individual privacy, intellectual property, test data and contract rights, as well as conform to legislation and current national practices in patent law.

Companies may disclose clinical trial information as set out in the “Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases” (2009) and the “Joint Position on the Publication of Clinical Trial Results in the Scientific Literature” (2010) issued by the IFPMA, the European Federation of Pharmaceutical

Industries and Associations (EFPIA), the Japanese Pharmaceutical Manufacturers Association (JPMA), and the Pharmaceutical Researchers and Manufacturers of America (PhRMA).

All human subject research must have a legitimate scientific purpose. Human subject research, including clinical trials and observational studies, must not be disguised promotion.

Clinical studies shall be conducted respecting the rights of persons to not be the target of clinical, laboratory or research tests or trials without their prior written knowledge and consent.

2.3 Support for Continuing Medical Education

Continuing medical education (CME) helps ensure that healthcare professionals obtain the latest and most accurate information and insights on therapeutic areas and related interventions that are critical to the improvement of patient care and overall enhancement of the healthcare system. The main purpose of a continuing medical education meeting must be the enhancement of medical knowledge, and therefore financial support from companies is appropriate.

When 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.

2.4 Interactions with Patient Organizations

The pharmaceutical industry has many common interests with patient organizations. All interaction with patient organizations must be ethical.

When working with patient organizations, companies must ensure that the involvement of the company and the nature of that involvement are clear from the outset. Companies providing financial support to patient organization meetings must have in place written documentation setting out the nature of support, including the purpose of said activities and its events.

Companies may provide financial support for patient organization meetings provided that the primary purpose of the meeting is professional, educational, and scientific in nature, or otherwise supports the mission of the patient organization.

When companies hold meetings for patient organizations, companies must ensure that the venue and location is appropriate for said meeting or event. In addition, any meals or refreshments provided by a company must be modest as judged by local standards.

2.5 Independence of Healthcare Professionals

No financial benefit or benefit-in-kind (including grants, scholarships, subsidies, support, consulting contracts or educational or practice related items) may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would have an inappropriate influence on a healthcare professional's prescribing practices.

2.6 Appropriate Use

Promotion should encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their properties.

Promotion of pharmaceutical products must be in keeping with their true nature, composition, quality or origin, so as to avoid any mistaken idea about their qualities or benefits.

2.7 Local Regulations

In all cases, all relevant laws, local regulations and industry codes must be observed and companies have a responsibility to check local requirements, in advance of preparing promotional material or events in any specific country.

2.8 Transparency of Promotion

Material relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by a company should clearly indicate by whom it has been sponsored and display the authorization which for the purpose is granted by the health authority having jurisdiction if it is so required by legislation currently in force. Promotion should not be disguised.

Q&A 8

3. Pre-Approval Communications and 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.

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 stockholders and others concerning any pharmaceutical product, as may be required or desirable under law, rule or regulation.

4. Standards of Promotional Information

4.1 Consistency of Product Information

It is understood that national laws and regulations usually dictate the format and content of the product information communicated on labeling, packaging, leaflets, data sheets and in all promotional material. Promotion should not be inconsistent with locally approved product information.

Healthcare professionals in developing countries should have access to data similar to those being communicated in developed countries.

Q&A 9

4.2 Accurate and Not Misleading

Promotional information should be clear, legible, accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the pharmaceutical product concerned. Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It should not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. Every effort should be made to avoid ambiguity. Absolute or all-embracing claims should be used with caution and only with adequate qualification and substantiation. Descriptions such as 'safe' or 'no side effects,' 'the most widely chosen product,' 'the only one,' 'recommended most often,' 'famous,' 'completely safe,' 'it's good,' 'new,' among others, should generally be avoided and should always be adequately qualified.

4.3 Substantiation

Promotion should be capable of substantiation either by reference to the approved labeling or by scientific evidence.

Such evidence should be made available on request to healthcare professionals. 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.

Q&A 10 and 11

5. Printed Promotional Material

Where local regulations or codes are in force which define requirements, those take precedence.

5.1 All Printed Promotional Material, including Advertisements

All printed promotional materials other than those covered in 5.2 below must be legible and include:

- the name of the product (normally the brand name);

- the active ingredients, using approved names where they exist;
- the name and address of the pharmaceutical company or its agent responsible for marketing the product;
- date of production of the advertisement;
- “abbreviated prescribing information” which should include an approved indication or indications for use together with the dosage and method of use; and a succinct statement of the contraindications and side effects.

Q&A 12

5.2 Reminder Advertisements

A “reminder” advertisement is defined as a short advertisement containing no more than the name of the product and a simple statement of indications to designate the therapeutic category of the product. For “reminder” advertisements, “abbreviated prescribing information” referred to in 5.1 above may be omitted.

A reminder advertisement can be issued six months after a product has been introduced on the market.

6. Electronic Materials, including Audiovisuals

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; and
- country-specific information should comply with local laws and regulations.

7. Interactions with Healthcare Professionals

7.1 Events

7.1.1 Scientific and Educational Objectives

Symposia, congresses and other meetings for healthcare professionals, whether organized or sponsored by a company, must have an ethical content. These programs are essentially aimed at facilitate continuing learning by healthcare professionals for the ultimate benefit of patients. This funding must not be used to influence or reward the target beneficiary for prescribing or recommending a given pharmaceutical production.

The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an “Event”) for healthcare professionals organized or sponsored by a company must be to inform healthcare professionals about products and/or to provide scientific or educational information.

7.1.2 Events Involving Foreign Travel

No company may organize or sponsor an Event for healthcare professionals that takes place outside of their home country 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.

Companies must not pay any cost stemming from persons accompanying guest healthcare professionals.

Q&A 13

7.1.3 Promotional Information at Events

Promotional information which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in the country where the Event takes place, or which are registered under different conditions, provided that the following conditions are observed:

- Regulations of the host countries allow it;
- The meeting should be a truly international, scientific Event with a significant proportion of the speakers and attendees from countries other than the country where the Event takes place;
- Promotional material for a pharmaceutical product not registered in the country of the Event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally;
- Promotional material which refers to the prescribing information (indications, warnings, etc.) authorized in a country or countries other than that in which the Event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally; and

- An explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.

7.2 Sponsorship

Member companies may sponsor healthcare professionals to attend Events provided such sponsorship is in accordance with the following requirements:

- the Event complies with the hospitality requirements in this Code as described in 7.5;
- sponsorship to healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees;
- no payments are made to compensate healthcare professionals for time spent in attending the Event; and
- any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend or promote any pharmaceutical product.

7.3 Guests

Companies should not pay any costs associated with individuals accompanying invited healthcare professionals.

7.4 Payments for Speakers and Presenters

Payments of reasonable fees and reimbursement of out-of-pocket expenses, including travel and accommodation, may be provided to healthcare professionals who are providing genuine services as speakers or presenters on the basis of a prior written contract with the company at the Event.

7.5 Hospitality

7.5.1 Appropriate Venue

All Events should be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. Companies should avoid using renowned or inappropriate venues, because of their conspicuous luxury or geographical location, for holding Events.

7.5.2 Limits of Hospitality

Hospitality should be limited to refreshments and/or meals incidental to the main purpose of the Event and should only be provided to participants of the Event and if it is moderate and reasonable as judged by local standards.

Domestic transportation, airport taxes, and departure taxes can be covered by the member companies if they decide to do so.

7.5.3 Guidance from Member Associations

As a general rule, the meeting places to be used for this kind of Event should be very similar to those that participants would normally be prepared to pay for themselves.

7.5.4 Entertainment

No entertainment or other leisure or social activities should be provided or paid for by member companies.

No compensation by prescription of any kind should be offered to a healthcare professional.

Q&A 14

7.6 Gifts and Items of Medical Utility

Cash: Payments in cash or cash equivalents (such as gift certificates) must not be offered to healthcare professionals.

7.6.1 Personal Gifts

Gifts for the personal benefit of healthcare professionals (including, but not limited to, music CDs, DVDs, sporting or entertainment tickets, electronic items) must not be provided or offered.

7.6.2 Promotional Aids

Promotional aids may be provided or offered to healthcare professionals, provided they are of minimal value and amount and are relevant to the practice of the healthcare professional.

Q&A 15

7.6.3 Items of Medical Utility

Items of medical utility may be offered or provided free of charge provided that such items are of modest value and are beneficial to the provision of medical services and for patient care.

Offer as a gratuitous loan is permitted when it is required to deliver a major service, such as medicines and similar inputs.

Medical education tools can be provided to healthcare professionals on an ongoing basis, meaning: subscriptions to scientific journals or web portals or others of a similar nature that contribute to the medical readiness of said professionals

Q&A 16

7.6.4 Cultural Courtesy Gifts

An inexpensive gift, equivalent to up to 10% of the consolidated minimum wage, not related to the practice of medicine, may be given on an exceptional basis to healthcare professionals in acknowledgment of national, cultural or religious holidays.

7.6.5 Guidance on Values

Member associations shall provide guidance using local currency, on the precise value for the following:

- “minimal” value for promotional aids and reminder items as indicated above;
- “modest value” for items of medical utility in 7.6.4 above; and
- “inexpensive” for customary gifts in 7.6.5 above.

Member associations shall also clearly define what constitutes significant national, cultural or religious holidays or Events, as referred to in 7.6.5 above.

7.6.6 Local taxes

All amounts envisaged in the present Code do not include local taxes, which must be added respectively and on the basis of the corresponding percentages.

8. Samples

8.1 Samples Permitted

The purpose of providing samples is to “acquaint” the healthcare professional with the product. These samples should not be used for any other reason and must be provided in small amounts.

Free samples of a pharmaceutical product may be supplied to healthcare professionals who are authorized to prescribe this product in order to enhance patient care. Samples must be marked as such so that they cannot be sold or otherwise misused.

8.2 Control and Accountability

Companies should have adequate systems of control and accountability for samples provided to healthcare professionals including how to look after such samples whilst they are in the possession of sales representatives.

8.3 Provision of samples to pharmacy employees

Provision of medical samples to pharmacy employees is forbidden.

9. Company Procedures and Responsibilities

A designated company employee, with sufficient knowledge and appropriate scientific or healthcare qualifications, should be responsible for approving all promotional communications inside the company and with the public health authority having jurisdiction.

10. Infringement, Complaints, and Enforcement

10.1 Complaints

It is urged that genuine complaints regarding infringement of the IFPMA Code be filed with the IFI's Committee on Ethics and Best Marketing Practices.

10.2 Measures to Ensure and Enforce Compliance

Each member association should strongly encourage its member companies to adopt procedures to assure adherence to their national codes.

While strong local legal and regulatory mechanisms and vigorous government enforcement may obviate the need for compliance mechanisms in some countries, member associations are encouraged, where appropriate, to include provisions intended to assure compliance with their national codes. The IFPMA recognizes, however, that local laws and practices vary widely and will affect the types of compliance provisions, if any, that may be adopted.

10.3 Regulations, Monitoring and Penalties

The reporting, monitoring and penalization procedure is set forth in Chapter V of the present Code.

V. Operating Procedure of the IFI-IFPMA Code

COMPLAINTS AND PENALTIES

The Committee on Ethics and Best Marketing Practices of the Research and Innovation Pharmaceutical Industry Corporation (Corporación de la Industria Farmacéutica de Investigación e Innovación—IFI) was established by the General Managers of its member companies at the General Assembly.

Three of these Managers and the IFI Executive Director (acting as head of the Secretariat, but with no right to vote) must be appointed by the IFI Board of Directors to be part of this Committee and are those responsible for making sure that members recognize and abide by the IFI-IFPMA Code and monitor ethical conduct as a key condition for all actions of the member companies.

Thus, the Committee works for the full enforcement of the Operating Procedure of the IFI-IFPMA Code as drawn up and adopted by the General Assembly.

Functioning of the Committee on Ethics and Best Marketing Practices

The Committee shall respond to any report of a breach of the IFI-IFPMA Code by IFI members with the two following instances:

- a) The first entails receiving the reports and settling the complaint by a first hearing comprised of two IFI members and one member of the IFI Board of Directors.
- b) The second entails hearing and settling appeals that are filed by the parties involved with respect to the first-instance ruling. It shall also be comprised of two IFI members and one member of the Board of Directors who have not been involved in the first-instance ruling.

In the event there is a conflict of interest, the member involved in this conflict shall be replaced in both the first and second instances.

The replacing member shall be designated by the Board of Directors, from among any of IFI's members.

The procedure to reach a ruling and impose a penalty for any breach of the standards enshrined in the IFI-IFPMA Code or governing the relationships among the member companies of the institution, shall be followed, handled and resolved by the Committee on Ethics and Best Marketing Practices.

1. FIRST-INSTANCE PROCESSING

- i. The procedure for hearing, ruling and imposing penalties shall begin with the filing of a complaint with the Committee's Secretariat by any IFI member or any individual.

The complaint must obligatorily include the following:

- a) Complete identity of the person filing the complaint.
 - b) Concrete identity of the person being complained about.
 - c) Description of the incidents being reported.
 - d) Clear and accurate identification of the IFI-IFPMA standards being breached.
 - e) Evidence and documents that provide proof of the incidents being reported.
- ii.** The Committee's Secretariat shall notify the Chair of the Committee of the complaint, for the first instance, within three days after the complaint is filed. The Chair must convene the other members of the Committee within eight days as of notification of the complaint in order to hold a first meeting of the Committee.
- iii.** The first meeting of the Committee shall be aimed at checking whether any of the members is hampered from hearing, processing and resolving the complaint, and in addition the contents of the complaint shall be checked to determine whether or not the matter being dealt with is a real issue reported in good faith, whether or not there is enough information and documentation attached to the complaint, whether or not the procedure is applicable and whether or not there has been a prior complaint on the same matter.
- iv.** At the first meeting, the Committee members shall grant 10 days for the above-mentioned checking and request for additional information and evidence.
- v.** After 10 days have elapsed, the Committee shall hold a second meeting, at which time it shall decide whether the complaint is accepted either completely or partially or is turned down; if the latter is decided, the Committee shall order that it be filed away and inform the complainant why it has not accepted to process the complaint.
- If the complaint is accepted for processing, the reported company shall be notified of the complaint within the following five days.
- vi.** With notification of this resolution to the reported company, 10 days shall be given to this company to respond, submit evidence or, if applicable, remedy the reported situation immediately.
- vii.** Ten days after the reported company exercises its right to defend itself, the members of the Committee shall be called to a third meeting, which shall take place within the following eight days and at which time the case shall be settled.
- viii.** The final resolution issued by the Committee shall be notified to the parties within three days after issuance of the ruling, which may include a penalty imposed upon the reported company or acquittal and filing away of the complaint.

II. SECOND AND LAST-INSTANCE PROCEEDINGS

ix. The company penalized or the complainant who believes his/her rights have been undermined by the ruling issued by the Committee in the first instance are entitled to file an appeal regarding the above within five days after being notified of the ruling.

x. The appeal must be filed with the Committee's Secretariat, which in turn shall notify the Chair of the Committee for the second instance, so that he/she can convene the first meeting within the following eight days.

xi. At the first meeting of the Commission's members, they shall review the entire file and if they deem it is necessary, they shall grant 10 days for gathering additional information.

xii. After 10 days have elapsed, a second and last meeting shall be convened, at which time the members of the Committee shall issue a ruling on the appeal, either ratifying the penalty that was imposed or declaring it null and void and ordering that the case be filed away.

III. NATURE OF THE PENALTY

The penalties, as they arise from the enforcement of ethical standards, must also be governed by the same ethical standards, consisting of due publication of the breaches of standards, identification of the offender and the standard being breached on IFI's website. The latter is directly linked to the websites of other regional and world associations, as a result of which a breach of ethics can be checked with only one single search engine or reference to the name of the company in Internet.

IV. ENFORCEMENT OF THE PENALTY

xiii. IFI's Board of Directors shall be responsible for enforcing the penalty, and the Committee that imposed the penalty shall be in charge of monitoring due compliance with the penalty.

All complaints and their respective supporting documents must be addressed to:

IFI

Industria Farmacéutica de Investigación e Innovación
Calle Camilo Destruge N24-633 & Francisco Salazar
INLUXOR Building, 4th floor, Office 402

Quito, Ecuador

Phones: (593-2) 290-8760

(593-2) 290-7441

comunicaciones@ifi-promesa.com.ec

VI. Questions & Answers

1. Communications with the Public

Q: Does IFPMA or IFI regulate communications with the public?

A: No. The Code covers interactions with healthcare professionals and the promotion of pharmaceutical products. Where direct promotion to the public is allowed, this is covered by local laws, regulations and/or relevant codes of practice. Member companies should, of course, comply with these local laws, regulations and/or codes.

2. Code Application

Q: To whom does the IFPMA Code apply?

A: The IFPMA Code applies to IFPMA's member associations and companies. Pharmaceutical companies that are members of neither IFPMA nor its affiliated member associations fall outside the reach of the IFPMA Code. IFPMA encourages such companies—and other organizations marketing healthcare products or services to healthcare professionals—to follow ethical promotion standards similar to those set forth in the IFPMA Code (see Chapter VII).

The IFI-IFPMA Code and its procedures are applicable to all companies that are members of IFI-Ecuador.

3. Disease Awareness Campaigns

Q: Why does the Code not cover public disease awareness campaigns?

A: The Code covers interactions with healthcare professionals and the promotion of pharmaceutical products. A public disease awareness campaign targeted at the public must not promote specific pharmaceutical products. Whilst not covered by the IFPMA Code, disease awareness campaigns must of course comply with local laws, regulations, and/or codes.

4. Self-Medication Products

Q: Are there self-regulatory codes of practice relating to the promotion of self-medication products directed to consumers? Where can I find information on this?

A: Yes, there are self-regulatory codes of practice on this topic in many countries. You should consult the industry association in the relevant country, details of which are provided on the IFPMA website.

Q: Does the Code apply to the promotion and marketing of over-the-counter (OTC) products that may also be prescribed by healthcare professionals?

A: Yes. The Code applies to the promotion of over-the-counter (OTC) products directed towards healthcare professionals. However, the promotion of OTC products to consumers falls outside the scope of this Code.

5. Pricing and Terms of Trade

Q: Does the Code prohibit member companies from giving its customers discounts or other favorable trade terms for the supply of pharmaceutical products?

A: No. The Code does not restrain or regulate commercial trade terms for the supply of pharmaceutical products. The IFPMA encourages fair competition among companies.

Q: Does the Code apply to the promotion and marketing of pharmaceutical products to commercial customers who are also practicing healthcare professionals, such as a pharmacist who operates his/her own practice.

A: The Code does apply to the promotion and marketing of pharmaceutical products to such a customer. However, the Code does not restrain or regulate commercial trade terms for the supply of pharmaceutical products to customers. In any dealings with such a customer, companies should respect the customer's role as a healthcare professional and, if applicable, comply with the requirements of the Code.

Q: Does the Code apply to the promotion and marketing of pharmaceutical products to commercial customers who are not healthcare professionals? What if the customer is a healthcare professional by qualification but is not practicing?

A: No. The Code only applies to interactions with practicing healthcare professionals. Promotion and marketing to commercial customers (whether or not they are healthcare professionals) may of course be governed by other laws and regulations, such as those that restrict or prohibit inaccurate, misleading or deceptive advertising and promotion or restrict or prohibit the giving of inducements to public officials or employees.

Q: Does the Code cover price lists or other documents describing terms of trade?

A: No.

Q: Could a false price claim or a misleading price comparison in promotional material be processed under the Code?

A: Yes, this is possible when a company is inappropriately using pricing information in its promotional materials or activities in a country in which the IFPMA complaints procedure applies. Among the companies affiliated to IFI-Ecuador, the complaint procedure is implemented with the IFI Committee on Ethics and Best Marketing Practices.

6. Consultancy Agreements

Q: In the absence of any formal industry guidelines or local laws, how should companies interact with healthcare professionals who are offering legitimate consultancy services?

A: Healthcare professionals may be hired as consultants or advisors for professional services, such as speaking and/or moderating at meetings or Events; development or other services involving scientific/medical studies, clinical trials or training services; participating in advisory meetings; and participation in market research, where said participation entails compensation. Agreements covering these genuine consulting arrangements or other services must, to the extent relevant to any particular arrangement, meet the following criteria:

- a written contract or arrangement must be agreed upon ahead of time at the onset of the services provided, specifying the nature of the services to be provided and the basis for payment of those services;
- a legitimate need for the services must be identified and documented in advance of requesting the services;
- the criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service;
- the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;
- the hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, provide and/or administer a particular product; and
- financial compensation for the services must be reasonable and reflect the fair market value of services rendered.

7. Non-Promotional Information

Q: What are the examples of non-promotional information that is not covered by the Code?

A: Correspondence, possibly accompanied by material of a nonpromotional nature, needed to answer a specific question about a particular medicinal product is not covered by the Code.

Non-promotional, general information about companies (such as information directed to investors or to current/prospective employees), including financial data, descriptions of research and development programs, and discussion of regulatory developments affecting the company and its products, is also not covered by the Code.

8. Disguised Promotion

Q: Is it ever appropriate for a company to publish promotional materials that appear to be independent editorial content?

A: No. Where a company finances or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial matter.

Furthermore, in compliance with the IFI Code, the laboratory that is funding or hiring the publication must be acknowledged in the publication.

Q: How does the prohibition of pre-approval promotion affect compassionate use programs?

A: The clause does not prevent compassionate use programs which must of course comply with all applicable laws, regulations and codes.

Care should be taken to ensure that communications for a compassionate use program are not, in effect, advertisements for an unlicensed medicine or use.

9. Consistency of Information

Q: What level of detail is required to be included on labeling, packaging, leaflets, data sheets and all other promotional material in a developing country where there are no or very limited national laws and regulations regarding the form and content of such product information?

A: Where possible and within the context of national requirements, companies should provide the same core product information (such as contraindications, warnings, precautions, side effects and dosage) as it provides in developed countries.

10. Use of Comparisons

Q: Does the Code allow for comparisons between different products to be included in promotional materials?

A: Yes. Any comparison made between different pharmaceutical products should be based on relevant and comparable aspects of the products and be capable of substantiation, backed by technical expertise in the event of a dispute. Comparative advertising should not be misleading.

11. Use of Quotations

Q: Does the Code allow for quotations to be included in promotional materials?

A: Yes. Quotations from medical and scientific literature or from personal communications should be faithfully reproduced (except where adaptation or modification is required in order to comply with any applicable codes, in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources clearly identified. Quotations should not change or distort the intended meaning of the author or clinical investigator or the significance of the underlying work or study.

12. Reprints

Q: Are reprints considered as promotional material under the Code?

A: No. Reprints of scientific and medical articles, when used as standalone documents, are not developed by pharmaceutical companies and as such cannot be considered as promotional materials. If, however, they are presented to a healthcare professional together with other, company-originated documents, they then become promotional materials. In all cases, where promotion refers to, includes, or is presented together with scientific or medical articles or studies, clear references should be provided. Any reprint of artwork (including graphs, illustrations, photographs or tables) taken from articles or studies and included or presented with promotional materials should clearly indicate the source of the artwork and be faithfully reproduced.

13. Events Involving Foreign Travel

Q: When is it appropriate and justified for a company to organize or sponsor an event for healthcare professionals outside of their home country?

A: A company can only organize events involving travel if it is justified, i.e.:

(a) A significant proportion of the invited healthcare professionals are from outside of the company's home country, and it makes greater logistical or security sense to hold the event in another country; or

(b) The relevant resource or expertise that is the object or subject matter of the event is located outside of the company's home country.

Q: What is considered as the home country of a healthcare professional?

A: Under the Code, the home country of a healthcare professional is the country in which he/she practices.

14. Entertainment

Q: The Code prohibits entertainment, leisure or social activities for healthcare professionals and other stakeholders. Are there any exceptions to this rule?

A: No. When a company organizes a meeting, refreshments and/or meals associated with the Event's main purpose can be provided. It would not be appropriate for a company to fund attendance at a concert, purchase tickets for shows or pay any other type of entertainment. Background music or a local show, however, may be allowed at the venue where the Event is being held, as long as it is not paid by a pharmaceutical company.

15. Promotional Aids

Q: What kinds of items are permissible as promotional aids?

A: Promotional aids should be of minimal value and should be related to the work of the recipient healthcare professional. Possible examples include pens, notepads and surgical gloves.

Promotional items intended for the personal benefit of the healthcare professional, such as music CDs, paintings or food baskets would be not be acceptable.

16. Items of Medical Utility

Q: What kinds of items are envisaged as being items of medical utility?

A: Items might include an anatomical model for use in an examination room, or medical textbooks, as they are of modest value and both primarily involve a patient benefit. A VCR or CD player however would not be permissible. Items should not be offered on more than an occasional basis, even if each individual item is appropriate.

VII. Who is the Code applicable to?

The IFPMA Code is applicable to all IFPMA member associations and companies. The pharmaceutical companies that are not IFPMA members or member associations affiliated to IFPMA shall be outside the reach of the IFPMA Code.

Members of the IFPMA are national or regional pharmaceutical industry associations, headquartered in more than 60 different countries, in both the industrialized and developing world, and research-based pharmaceutical, biotechnology and vaccine companies.

Up to 2011, associations from Latin American countries belong to IFPMA as a result of their membership in the regional organization FIFARMA. As of 2012, however, most Latin American associations are direct members of IFPMA, among which IFI.

The Federation's membership requirements include commitment by the association, on behalf of its members, to adopt Best Manufacturing Practices and to accept the principles of the IFPMA Code of Pharmaceutical Marketing Practices.

The companies are subject to the IFPMA Code in all the countries where they are working as a result of their direct or indirect membership in the IFPMA (that is, being a member of at least one affiliated association).

IFPMA members are located throughout the world, in more than 60 countries of the Americas, Asia, Europe, the Middle East and Africa.

IFPMA member companies

Abbott Laboratories
Almirall
Amgen Inc.
Astellas Pharma
AstraZeneca
Bayer AG
Boehringer Ingelheim
Bristol-Myers Squibb
Chugai Pharmaceutical
Daiichi Sankyo Co.
Eisai Co., Ltd.
Eli Lilly & Co.
Esteve
F. Hoffmann-La Roche AG
GlaxoSmithKline
Johnson & Johnson
Lundbeck
Menarini S.A.
Merck & Co., Inc.

Merck KGaA
Nicholas Piramal India
Novartis Pharma AG
Otsuka Pharmaceuticals Co., Ltd.
Pfizer Inc.
Pfizer / Wyeth
Piramal Healthcare Ltd.
Quifatex
Roche Ecuador
Sanofi
Schering-Plough
Servier
Takeda Pharmaceutical Co., Ltd.

IFI-IFPMA CODE

Although the IFPMA Code governs all the companies associated with the Research and Innovation Pharmaceutical Industry Corporation (IFI-Ecuador), since its original publication, the nationalized IFI-IFPMA Code and its respective procedures must be complied with and enforced obligatorily for all and each and every IFI member as of 2008.

IFI Member companies

Abbott
Baxter
Bayer
B. Braun
Boehringer-Ingelheim
GlaxoSmithKline
Grunenthal Ecuatoriana
Janssen-Cilag
Merck Ecuador
Merck Sharp & Dohme/Schering-Plough
Pfizer / Wyeth
Quifatex
Roche Ecuador
Sanofi

VIII. What does Ecuadorian law say?

REGULATIONS CURRENTLY IN FORCE REGARDING THE MARKETING OF PHARMACEUTICAL PRODUCTS

1. Basic Law on Health
2. Regulations for the Health Registration of Medicines in General, Medical Devices and Cosmetics.
3. Law on Generic Drugs for Human Use
4. Regulations for the Law on Generic Drugs for Human Use

1. BASIC LAW ON HEALTH (OFFICIAL REGISTER, SUPPLEMENT 423, DECEMBER 22, 2006)

Article 143. Advertisement and marketing of products requiring health registration must be in line with the true nature, composition, quality or origin of the product, so as to prevent any mistaken conception of its qualities or benefits, which shall be monitored by the national health authority.

Advertisement for prescription-only medicines is forbidden.

Article 160. For the purpose of setting and revising the prices of medicines for human use and ingestion, advertising and marketing expenses shall be regulated in keeping with the law and regulatory framework currently in force so that access to medicines and consumers rights are not affected.

Article 168. Physicians, dentists, and obstetricians are professional healthcare professionals authorized to issue prescriptions for medicines.

2. REGULATIONS FOR THE HEALTH REGISTRATION OF MEDICINES IN GENERAL (OFFICIAL REGISTER NO. 335, December 7, 2010)

Article 31. Outside and inside labels must be in the Spanish language and in clearly legible and indelible print and must state the following:

- a) Name of product;
- b) Generic name (D.C.I.);
- c) Pharmaceutical form;

d) Net content of the container expressed in international system units or conventional units of active ingredients when there is none of the above and number of units of the pharmaceutical form.

e) Qualitative and quantitative formula. It must state the percentage concentration of the active ingredient(s) per unit of dose, depending on the case, stated with the generic name. When the product requires it, the concentration of the active ingredients shall be stated in biological units with their equivalent in units of weight, if possible. For antibiotics, the equivalence compared to its base. Abridged or abbreviated chemical formulas must not be used. Inside labeling must state the name and concentration of the active ingredient.

f) How to administer, although it can be excluded from the inside label, except for intravenous medicines, vaginal ovuli and tablets.

g) Batch number or code.

h) Single medicine code;

i) Pediatric use if required by the product;

j) Storage temperature;

k) Name of the manufacturing laboratory, city and country of origin under license, monitoring and others determining the responsibilities for the manufacture, monitoring and marketing of the product. In the case of products that are packaged by a company other than the manufacturer, the name of each one has to be stated, indicating how each has participated. On the inside label, the logo of the manufacturer is acceptable and the name of the city can be omitted.

l) Name of the pharmaceutical chemist or pharmaceutical biochemist in charge of the laboratory holding the license for the product (this may be excluded from the inside label).

m) Date of manufacture and expiry clearly legible and identifiable (the date of manufacture may be omitted from the inside label, but inclusion of the date of expiry is mandatory).

n) Health registration number corresponding to the registration or re-registration. In the latter case, the number corresponding to its registration shall be kept, but followed by a digit indicating the number of times the product has been re-registered.

o) Sale condition: over the counter, medical prescription, controlled prescription, or restricted distribution (may be excluded from the inside label).

p) For over-the-counter products, the following shall also be stated:

- Instructions and how to use

- Dosage
- Warning: “If symptoms persist, consult your physician.”
- Contraindications.

q) In the case of medical samples, inside and outside labels must also include the caption: “Medical sample not for sale.”

Article 32. If the primary container is too small to include on its label all the information stipulated in the preceding article, the container shall state the following: name of the product, name or logo of the laboratory responsible and batch number or code, concentration of the active ingredient(s), date of expiry, and public health registration number. In the case of intravenous products, the initials of the route of administration and the content of the container must also be included. For vaginal ovuli and tablets, the route of administration must also be provided.

Article 33. Labels, packaging and data sheets of new pharmaceutical products that have not met the minimum requirements indicated with respect to pharmacological work must include the following:

1. If the work carried out is incomplete, they must bear the following warning: “This product must not be administered during pregnancy or when pregnancy is suspected.”
2. If the stakeholders have not provided any of the teratological studies required, the warning must read: “Contraindicated in case of pregnancy or when pregnancy is suspected.”
3. If the product has turned out to be teratogenic for any of the animal species envisaged in the teratological studies, the warning must read: “Contraindicated in case of pregnancy and when pregnancy is suspected.”

Article 34. When requesting public health registration of a product, the petitioner shall submit the draft of the labels. Once the public health registration has been processed and approved, within ninety (90) days at the latest, the definitive labels with the public health registration printed on them, which is mandatory to market any pharmaceutical product, shall be submitted.

Article 35. In the container of every product must be included a foldout addressed to the user, which must be in line with international pharmacological standards and scientific reports currently in force. The text of the foldout shall be submitted for approval as part of the pharmacological documentation supporting its public health registration and must include the following condensed data of the profile and up-to-date basic information on the product.

- a) Identification of the product and warnings needed to consult a physician if there is any other concern.
- b) Active ingredients expressed in terms of quality and quantity and list of excipients expressed in terms of quality.
- c) Pharmaceutical form and content.
- d) Name and address of the manufacturer and/or distributor.
- e) Pharmaco-therapeutic group or type of activity in terms that are easy to understand for the patient.
- f) Therapeutic instructions.
- g) Information needed before taking the product, contraindications, precautions when using, interactions, special warnings (for example, pregnancy, pediatric or geriatric use, precautions when driving a motor vehicle or operating machinery).
- h) Appropriate instructions for use, with emphasis on the dosage, method and frequency of administration and the need to complete treatment, action to take in case of overdose, etc.; limitations on use; and time if it is an over-the-counter product.
- i) Undesirable effects that may appear under conditions of normal use and, if necessary, what actions to take.
- j) Storage conditions and the warning: "All medicines must be kept out of the reach of children."

3. LAW ON GENERIC DRUGS FOR HUMAN USE (OFFICIAL REGISTER NO. 162, DECEMBER 9, 2005)

Article 12. The National Health Council shall draw up and publish the National Therapeutic Register periodically. It must be updated on an ongoing basis and shall contain the description of all generic drugs, both domestic and imported, whose use is authorized in the country, with a description of their properties, generic name and brand-name equivalents.

Article 13. The Ministry of Public Health shall disseminate on an ongoing basis the National Therapeutic Register among medical professionals and the staff working in pharmaceutical establishments. With the cooperation of the mass media, broadcasting campaigns shall be made on the advantages that this Law has for consumers.

Article 14. In the performance of their duties in hospitals, clinics and dispensaries, and public and private medical offices, healthcare professionals are required to include on their

prescriptions the name of the brand-name medicine and the respective generic name, except in cases of medical emergencies.

Article 15. Those establishments authorized to market and sell to the public medicines for human use are required to offer for sale the generic equivalent of the brand-name drug being requested by the user.

Article 16. National pharmaceutical laboratories must produce at least 20% generic drugs in line with their specialty.

Article 17. It is forbidden to do any kind of negative advertising on generic drugs, whether directly or indirectly.

4. REGULATIONS FOR THE LAW ON GENERIC DRUGS FOR HUMAN USE (OFFICIAL REGISTER NO. 84, MAY 24, 2000)

Article 26. The National Health Council, via the Pharmacology Committee, shall periodically draw up and publish the National Therapeutic Register, which is an academic instrument providing pharmaco-clinical information with a description of all the medicines appearing on the National Basic Medicines Table, with reference to kinetic properties, dynamics, pharmaco-pathologies, dosage, contraindications, administration of medicines, treatment for intoxication, and trade names sold in Ecuador.

REGULATIONS ON ADVERTISING AND PROMOTING MEDICINES IN GENERAL, PROCESSED NATURAL PRODUCTS FOR MEDICINAL USE, HOMEOPATHIC MEDICINES AND MEDICAL DEVICES (OFFICIAL REGISTER No. 416, MARCH 30, 2011)

Article 7. The contents of advertisement or promotion of: medicines, processed natural products for medicinal use, homeopathic medicines, and medical devices sold over the counter must meet the following requirements:

- a) Advertisement must promote the rational use of medicines;
- b) It must provide the therapeutic indications and uses of the medicine, which must be written in the Spanish language using clear wording so as not to confuse users;
- c) In the case of advertisement for medical devices, indications on how to use them must be in the Spanish language with clear wording so as not to confuse users.
- d) The information that is provided must be reliable, accurate, true, up-to-date and in line with therapeutic indications.

e) It must correspond to the contents of the provisions appearing in the public health registration certificate, as well as in the pharmacological report, issued by the INH during the processing of said public health registration.

f) Advertising must not induce indiscriminate, unnecessary, incorrect or inappropriate use of medicines, processed natural products for medicinal use, homeopathic medicines, and medical devices.

g) The use of phrases and pictures must be in line with the attribution or use of the product pursuant to the pharmacological report adopted by the INH during processing of the public health registration to foster better understanding by the public in general.

h) Information contained in the advertising materials must not lead to mistaken interpretations capable of leading to a false, mistaken, and/or confused interpretation about the medicine, processed natural product for medicinal use, homeopathic medicine and medical device.

i) Advertising must not use expressions that might cause fear or anxiety or suggest that health may be affected if the medicine is not used.

j) It must not be misleading, subliminal or unfair toward competitor companies.

k) When advertising takes place audiovisual media or print such as data sheets, leaflets or foldouts, the content of the advertisement must be easy to read in a color that stands out from the background of the announcement.

l) It must transmit messages clearly and at a measured pace when broadcasting over radio.

m) Advertising on billboards located in the street, outdoor advertisement or other similar media must use, for the information on dosage, precautions about use, contraindications and warnings, a letter size that is easy to read.

n) In movies, television, audiovisual media and other similar media, this information must be visible for a sufficient amount of time to allow full reading of the requirements set forth in Article 5, paragraph d) of the present regulations. The contrast of the letter should be such as to enable reading regardless of the color of the background.

18. Advertising is forbidden in the following cases:

a) Advertising of medicines, processed natural products for medicinal use, homeopathic medicines, and medical devices sold on the basis of a doctor's prescription;

b) Campaigns aimed at the general public inducing the use of medicines sold with a doctor's prescription.

- c)** Advertising on containers, labels, signs, packages, inserts or data sheets of other products that come with over-the-counter medicines, processed natural products for medicinal use, homeopathic medicines and medical devices.
- d)** Offensive comparison with other brands, products, services, companies or organizations.
- e)** Inducing the indiscriminate use of the product or responses that are not scientifically proven or suggesting that the product should be taken permanently.
- f)** That the product has healing properties for chronic illnesses.
- g)** Suggesting that the product prevents illness and recommending its use by healthy persons to improve their condition.
- h)** Inducing the interpretation that the product being used is the only alternative stating phrases and/or slogans that are not supported by the corresponding public health registration, such as: “the most widely chosen product,” “the only one,” “the most frequently recommended,” “the best,” “completely reliable,” “the most effective,” “famous,” “totally safe,” “it’s good,” “new,” among others.
- i)** Including children in the contents of the advertisement, except for those medicines that are aimed at children, and that said children have due written authorization from their parents, in accordance with the provision of the Code for Children and Adolescents, Article 52, item 1.
- j)** Including phrases such as: “proven in clinical trials,” “clinically tested,” and “recommended by experts and/or institutions.” If these phrases are used, technical scientific information substantiating their use and duly approved by the INH in the processing of the public health registration, must be attached to the petition.
- k)** Including messages such as “authorized by the National Health Authority” or “Ministry of Public Health.”
- l)** For the advertisement to induce the use and consumption of medicines, processed natural products for medicinal use, homeopathic medicines, and medical devices on the basis of offerings of promotions and prizes, including associations with other products.
- m)** Using censored images (nudes or semi-nudes) to promote the purchase of the products.
- n)** Using pictures and names of healthcare professional to recommend use of the medicine.
- o)** Advertising directly used in shopping malls, sports events, public entertainment events, and other similar events.

- p)** When it affects the image of other products and undermines the reputation of products or the reputation of third parties.
- q)** When it attempts to foster the rejection of products belonging to competitors or their users.
- r)** When it mentions active ingredients that are not part of the product being advertised.
- s)** When it mentions possible adverse or collateral effects stemming from active ingredients that are not part of the product being advertised.
- t)** Advertising of medicines, processed natural products for medicinal use, homeopathic medicines, and medical devices by the pharmaceutical and marketing establishments for these products, without due authorization granted by the Directorate-General for Health through its Department for Monitoring and Improving Healthcare Surveillance.

Appendix 1

IFPMA PROCEDURE

IFPMA Code Operating Procedure

1. Principles

1.1 The IFPMA Code and the operating procedure of the IFPMA Code shall apply directly in territories where no national code has been adopted by the respective member association.

1.2 The IFPMA Code and its operating procedure shall also apply in all cases where a member company commits a breach of the IFPMA Code in territories where there are national codes adopted by the respective member association but the member company in alleged breach is not a member of that association.

1.3 IFPMA shall ensure that its website contains information on codes and provisions organized by member associations, including details of where case reports may be viewed.

1.4 If a complaint is received by IFPMA that is not covered by this operating procedure, IFPMA will refer it to the company concerned. In addition, a copy will be sent to the relevant member association, if the association has a process for complaints.

1.5 Should IFPMA receive a complaint about an alleged breach which is already under investigation by one of the member associations (or relevant body thereof or equivalent regulatory body), it will not process the complaint but will inform the sender of the fact that the complaint is being handled elsewhere.

1.6 Likewise, if IFPMA during its processing of a complaint is informed that the same alleged breach is being investigated elsewhere, it shall suspend the process and inform the complainant thereof.

2. The Procedure for Code Complaints

2.1 Validation

When a complaint, alleging a breach of the IFPMA Code, is received by the IFPMA Secretariat, it is first validated to ensure that:

- it appears to be a genuine matter, submitted in good faith;
- there is sufficient information to enable the complaint to be processed (see 3.1 below);

- the alleged breach concerns a country where this operating procedure applies; and
- it is not evident that the same alleged breach is being or has been investigated by a member association (or relevant body thereof).

If the complaint cannot be validated, it will not be processed under this operating procedure and, where possible and/or appropriate, the complainant will be notified accordingly. In appropriate cases, IFPMA may refer the complainant or forward the complaint to an appropriate member association.

A single complaint may cover more than one “case”, e.g. the complaint may refer to several advertisements from different companies and/or for different products. Each “case” is handled separately by IFPMA under the main complaint reference. The first action in each case is to identify the company cited in the case and the head office or parent company, and its location, if different.

2.2 Referral

The complaint, including a copy of any supporting evidence (e.g. a copy of the advertisement alleged to be in breach of the IFPMA Code), together with an accompanying letter from IFPMA (the “Letter”), is sent to the senior management of the company, at its headquarters and at local level within 5 working days from its receipt by IFPMA.

2.3 Non-Member Companies

When a case refers to a company that is not subject to the IFPMA Code, the case cannot be processed formally. Companies are subject to the IFPMA Code, in every country in which they operate, by virtue of direct or indirect (i.e. membership in at least one affiliated member association) membership of IFPMA.

2.4 Time Limits

The Letter to the company indicates the time within which a response must be made on the case(s) under investigation.

This is normally 30 calendar days from the company’s receipt of the documentation. In exceptional circumstances, the Director General of IFPMA may grant an extension to the time limits.

2.5 Company Response

Where the company acknowledges that it has acted in breach of the IFPMA Code, the response should indicate what action has been taken or will be taken to remedy the matter. Where the allegations are rejected, the reasons for rejection must be clearly stated and, where appropriate, supporting data (e.g. scientific evidence to support claims which have been questioned) must be provided.

2.6 Adjudication

Where the company disputes the allegation, IFPMA will rule on the case. IFPMA normally decides cases within 30 days from receipt of the company's response. If necessary, IFPMA can ask the complainant or the affected company for additional information or argumentation, in which case the timelines may be extended.

The IFPMA Director General refers complaints to an ad hoc group of three individuals experienced in the application of national codes and selected from member associations. In addition, expert medical or technical advice will be sought by IFPMA when the complaint warrants this, e.g. when the validity of a medical claim is challenged. Decisions are made by simple majority, with the IFPMA Director General having a casting vote.

2.7 Appeal

Where the company or complainant disagrees with the decision of the IFPMA, they may, within 30 days, request a second instance ruling. If new facts or arguments are put forward, the other party is invited to provide comments within 30 days. The IFPMA Director General refers the complaint to an ad hoc group of five individuals experienced in the application of national codes and selected from member associations (other than the individuals participating in the first instance ruling). The final decision is made by this group, by simple majority, without participation of any members of the IFPMA staff. The decision is communicated to the IFPMA Director General.

2.8 Ad hoc Groups for Adjudication and Appeal

The IFPMA Director General appoints 3 and 5 members of the ad hoc groups for adjudication and appeal respectively for a one-year period.

2.9 Publication of the Outcome

When a complaint is upheld and a breach of the IFPMA Code is determined, or non disputed by the company, information identifying the company (and product, where relevant) concerned, the country in which the incident took place, the complainant, and providing a summary of the key facts of the case, is immediately made public by publication on the IFPMA website.

Likewise, information may be made public in cases where the company fails to respond within the specified time limit.

2.10 Status Reports

IFPMA will issue annually a Status Report on the IFPMA Code, summarizing its operation, related IFPMA activities and recent industry developments in the area of self-regulation. The report is published and given wide circulation to government health departments, WHO, the technical press and leading medical journals, and to member associations of IFPMA.

3. Use of the Complaint Procedure

The IFPMA Code complaint procedure is open to any healthcare professional, a company or member of the public, acting in good faith within the spirit and intentions of the IFPMA Code.

3.1 Submission of Complaints

Complaints must be in writing or by e-mail and include:

- Complainant details: The identity of the complainant, with a full mailing address (including fax number and e-mail, if possible) for correspondence. On the request of the complainant, the identity of the complainant can be kept confidential to all parties outside the IFPMA Secretariat.
- Company: For each case, the identity of the company which is alleged to be in breach of the IFPMA Code, and the name of any product or products which are specifically involved.
- Reference material: For each case, a specific reference to the source of the advertisement/activity which is the subject of the complaint, of printed material or other evidence. Wherever possible a copy of the material in question should be provided.
- Date: The date, where relevant, of the alleged breach of the IFPMA Code.
- Summary: For each case, a brief description of the complaint with, if possible, a specific reference to the part of the IFPMA Code under which the complaint is being made (section and paragraph number(s)).

All correspondence should be addressed to:

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3.2 Responsibilities of IFPMA

IFPMA designates a member of its staff to undertake all necessary activities in relation to this operating procedure. IFPMA also establishes the IFPMA Code Compliance Network, comprised of individuals experienced in the application of industry codes from member companies and associations. This network has the following roles:

- to exchange best practices in code compliance and implementation;
- to facilitate prevention of breaches by encouraging communication and networking among companies and associations officers;
- to create a forum for positive communication around industry self-regulation activities;
- to create a resource pool of experts in code compliance for needs of the IFPMA complaints procedure as described in 2.6 and 2.7 (only experts from associations); and
- to stimulate discussions about new challenges related to industry's promotion and marketing practices.

Periodic reports on the operation of the IFPMA Code are submitted to the IFPMA Council.

IFPMA arranges an annual consultation of the Code Compliance Network.

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