

International Federation
of Pharmaceutical
Manufacturers & Associations

IFPMA
Code of
Practice

2012



IFPMA

Foreword



Advancing medical knowledge and improving global public health depend on information-sharing interactions by the entire medical community - from researcher to attending physician and nurse to patient – and integrity is essential to these exchanges. Fundamentally, there must always be confidence that prescription decisions are made on an ethical and patient-focused basis.

In these interactions, it is essential that governments, the healthcare community and patients are confident that pharmaceutical companies, wherever they operate in the world, act in an ethical and professional manner. Such ethical practices should apply not only to the promotion of medicines but more broadly to all interactions with the healthcare community. This is the commitment that we, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) representing the research-based pharmaceutical industry, make in our recently-revised Code of Practice.

Since its initial adoption in 1981 as the foundation of a global self-regulatory approach, the Code has been regularly updated and strengthened to adapt to changing needs. The scope of the 2012 revision extends this already high standard of pharmaceutical industry practice beyond marketing practices to cover all interactions with healthcare professionals, medical institutions and patient organizations.

Success of the Code requires high awareness levels of both the standard itself as well as the established procedures for registering complaints. IFPMA member companies are committed to informing all their 1.3 million employees about the Code as well as to providing thorough training. While our industry holds itself accountable to conduct business with the highest possible ethics, we encourage others – doctors, pharmacists, nurses, academicians, patients and consumers – to become aware of this new benchmark and to ensure equally high ethical practice throughout the healthcare sector.

Focused on serving the best interests of patients, we have a moral obligation to communicate and participate in all relationships with integrity, accuracy and clarity. The IFPMA Code of Practice is a tangible example of the research-based pharmaceutical industry's commitment to making a strong contribution to global public health while adhering to the highest standard of practice.

A handwritten signature in black ink that reads "Eduardo Pisani". The signature is fluid and cursive, with a large, stylized initial 'E'.

Eduardo Pisani

Director General

International Federation of Pharmaceutical
Manufacturers and Associations (IFPMA)

Table of Contents

Page		Page	
2	IFPMA Guiding Principles on Ethical Conduct and Promotion	10	Samples (Article 8)
		8.1	Samples
		8.2	Control and Accountability
3	Preamble		
4	Scope and Definitions (Article 1)		Clinical Research and Transparency (Article 9)
1.1	Scope	9.1	Transparency
1.2	Definitions	9.2	Distinction from Promotion
	Basis of Interactions (Article 2)		Support for Continuing Medical Education (Article 10)
2.1	Basis of Interactions		
2.2	Transparency of Promotion		
5	Pre-Approval Communications and Off-Label Use (Article 3)	11	Interactions with Patient Organizations (Article 11)
		11.1	Scope
		11.2	Declaration of Involvement
		11.3	Written Documentation
		11.4	Events
	Standards of Promotional Information (Article 4)		Company Procedures and Responsibilities (Article 12)
4.1	Consistency of Product Information	12.1	Procedures
4.2	Accurate and Not Misleading	12.2	Training
4.3	Substantiation	12.3	Responsibilities for Approving Promotional Communications
6	Printed Promotional Material (Article 5)	12	Infringements, Complaints and Enforcement (Article 13)
5.1	All Printed Promotional Material including Advertisements	13.1	Complaints
5.2	Reminder Advertisements	13.2	Measures to Ensure and Enforce Compliance
	Electronic Materials, including Audiovisuals (Article 6)	13	IFPMA Code of Practice Operating Procedure (Appendix 1)
7	Interactions with Healthcare Professionals (Article 7)	16	IFPMA Secretariat Standard Operating Procedures (Appendix 2)
7.1	Events and Meetings		
7.1.1	Scientific and Educational Objectives		
7.1.2	Events Involving Foreign Travel		
7.1.3	Promotional Information at Events		
7.1.4	Appropriate Venue		
7.1.5	Limits		
7.1.6	Entertainment		
7.1.7	Guidance from Member Associations		
7.2	Sponsorships		
7.3	Guests		
7.4	Fees for Services		
7.5	Gifts and Other Items		
7.5.1	Prohibition of Cash and Personal Gifts		
7.5.2	Promotional Aids		
7.5.3	Items of Medical Utility		
7.5.4	Guidance on Values		
		18	Questions & Answers

IFPMA Guiding Principles on Ethical Conduct and Promotion

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) member companies engage in medical and biopharmaceutical research in order to benefit patients and support high-quality patient care. Pharmaceutical companies, represented by IFPMA, promote, sell and distribute their products in an ethical manner and in accordance with all the rules and regulations for medicines and healthcare.

The following Guiding Principles set out basic standards to inform the 2012 IFPMA Code of Practice which applies to the conduct of IFPMA Member Companies and their agents. This helps ensure that their interactions with stakeholders are appropriate.

- 1** The healthcare and well-being of patients are the first priority for pharmaceutical companies.
- 2** Pharmaceutical companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities.
- 3** Pharmaceutical companies' interactions with stakeholders 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.
- 4** Pharmaceutical companies are responsible for providing accurate, balanced, and scientifically valid data on products.
- 5** Promotion must be ethical, accurate, balanced and must not be misleading. Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use.
- 6** Pharmaceutical companies will respect the privacy and personal information of patients.
- 7** All clinical trials and scientific research sponsored or supported by companies will be conducted with the intent to develop knowledge that will benefit patients and advance science and medicine. Pharmaceutical companies are committed to the transparency of industry sponsored clinical trials in patients.
- 8** Pharmaceutical companies should adhere to both the spirit and the letter of applicable industry codes. To achieve this, pharmaceutical companies will ensure that all relevant personnel are appropriately trained.

Preamble

- i** The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and promoting new medicines. Ethical promotion helps to ensure that healthcare professionals globally 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 IFPMA is a non-profit, non-governmental organization representing industry associations and companies from both developed and developing countries. Member companies of the IFPMA include global research-based pharmaceutical companies. Companies are committed to the ethical standards set out in this Code.
- iii** The IFPMA Code includes standards for the ethical promotion of pharmaceutical products to healthcare professionals and helps ensure that member companies' interactions with healthcare professionals and other stakeholders, such as medical institutions and patient organizations, are appropriate and perceived as such.
- iv** It is a requirement of IFPMA membership that member associations 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.
- v** 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 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.
- vi** IFPMA member companies and their agents must comply directly with applicable national codes of member associations where such codes exist. 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 association), the IFPMA Code acts as a default code for the activities of member companies and the IFPMA operating procedures apply.
- vii** IFPMA member companies are accountable for addressing and correcting infringements under relevant codes. Companies not in membership with IFPMA may elect to be subject to the IFPMA Code and its complaints handling processes.
- viii** The IFPMA is open to receive 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.
- ix** IFPMA acknowledges the role of relevant codes of ethics developed by the World Medical Association, the 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.
- x** Effective 1st September 2012, the IFPMA Code of Practice (Updated 2011) replaces the 2006 IFPMA Code of Pharmaceutical Marketing Practices. Member associations of IFPMA must incorporate this Code into existing national codes no later than 1st September 2012, subject to the guidance set out in Articles (iv) and (v) above.

1 Scope and Definitions

1.1 Scope

The IFPMA Code covers interactions with healthcare professionals, medical institutions and patient organizations, 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.

[Q&A 1-6 \(see pages 18-19\)](#)

1.2 Definitions

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.
- “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 methods of communications, 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.
- “patient organization” means typically a not-for-profit institution that primarily represents the interests and needs of patients, their families and and/or caregivers.
- “medical institution” means typically an organization that is comprised of healthcare professionals and/or that provides healthcare or conducts healthcare research.
- “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.

2 Basis of Interactions

2.1 Basis of Interactions

Member companies’ relationships with healthcare professionals and other stakeholders are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about medicines, providing scientific and educational information and supporting medical research and education.

2.2 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. Promotion should not be disguised.

[Q&A 7 \(see page 19\)](#)

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.

Respecting the requirement that promotion should be consistent with the label and approved uses locally, healthcare professionals in developing countries should have access to similar data to those being communicated in developed countries.

[Q&A 8 \(see page 19\)](#)

4.2 Accurate and Not Misleading

Promotional information should be clear, legible, accurate, balanced, fair, 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" and "no side effects" 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 9-10 \(see page 19\)](#)

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 Article 5.2 below, must 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; and
- “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, precautions, and side-effects.

[Q&A 11 \(see page 19\)](#)

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 Article 5.1 above may be omitted.

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 and Meetings

7.1.1 Scientific and Educational Objectives

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 should be to provide scientific or educational information and/or inform healthcare professionals about products.

7.1.2 Events Involving Foreign Travel

No company may organize or sponsor an Event for healthcare professionals (including sponsoring individuals to attend such an Event as described in Article 7.2) 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.

[Q&A 12](#) (see page 20)

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:

- Host country regulations should permit such an arrangement;
- 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 (excluding promotional aids as described in Article 7.5.2) 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.

7.1.4 Appropriate Venue

All Events must be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. Companies must avoid using renowned or extravagant venues. The additional requirements set forth in Article 7 of this Code also apply accordingly.

7.1.5 Limits

Refreshments and/or meals incidental to the main purpose of the Event can only be provided:

- exclusively to participants of the Event; and
- if they are moderate and reasonable as judged by local standards.

7.1.6 Entertainment

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

[Q&A 13 \(see page 20\)](#)

7.1.7 Guidance from Member Associations

Member associations are encouraged to provide written guidance on the meaning of the terms “renowned” and “extravagant” as used in Article 7.1.4 of this Code, and the meaning of the terms “moderate” and “reasonable”, as used in Article 7.1.5 of this Code. As a general rule, the hospitality provided must not exceed what participants would normally be prepared to pay for themselves.

7.2 Sponsorships

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

- The Event complies with the requirements in this Code as described in 7.1;
- 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, purchase, supply, administer or promote any pharmaceutical product.

7.3 Guests

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

7.4 Fees for Services

Health care professionals may be engaged as consultants and advisors for services such as speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration. The arrangements which cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfill all the following criteria:

- a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services;
- a legitimate need for the services must be clearly identified and documented in advance;
- 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, supply, and/or administer any medicine; and
- the compensation for the services must be reasonable and reflect the fair market value of the services provided.

[Q&A 14 \(see page 20\)](#)

7.5 Gifts and other Items

7.5.1 Prohibition of Cash and Personal Gifts

Payments in cash or cash equivalents (such as gift certificates) must not be provided or offered to healthcare professionals. Gifts for the personal benefit of healthcare professionals (such as sporting or entertainment tickets, electronics items, etc.) must not be provided or offered.

[Q&A 15 \(see page 20\)](#)

7.5.2 Promotional Aids

Promotional aids of minimal value and quantity may be provided or offered to healthcare professionals if relevant to the practice of the healthcare professional.

[Q&A 16 \(see page 20\)](#)

7.5.3 Items of Medical Utility

In accordance with local laws and regulations, items of medical utility may be offered or provided if such items are of modest value, do not offset routine business practices and are beneficial to enhancing the provision of medical services and patient care.

[Q&A 17 \(see page 20\)](#)

7.5.4 Guidance on Values

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

- “minimal value” for promotional aid items in Article 7.5.2 above;
- “modest value” for items of medical utility in Article 7.5.3 above.

8 Samples

8.1 Samples

In accordance with local laws and regulations, free samples of a pharmaceutical product may be supplied to healthcare professionals authorized to prescribe that product in order to enhance patient care. Samples should be marked as such so that they cannot be resold 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 possession of medical representatives.

9 Clinical Research and Transparency

9.1 Transparency

Companies are committed to the transparency of clinical trials which 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 maintain protection for individual privacy, intellectual property and contract rights, as well as conform to legislation and current national practices in patent law.

Companies 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 Research and Manufacturers of America (PhRMA).

9.2 Distinct from Promotion

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

10 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 primary purpose of an educational 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.

Companies must follow Article 7 of the IFPMA Code where applicable.

11 Interactions with Patient Organizations

11.1 Scope

The pharmaceutical industry has many common interests with patient organizations. All interactions with patient organizations must be ethical. The independence of patient organizations must be respected.

11.2 Declaration of Involvement

When working with patient organizations, companies must ensure that the involvement of the company and the nature of that involvement is clear from the outset. No company may require that it be the sole funder of the patient organization or any of its programs.

[Q&A 18](#) (see page 20)

11.3 Written Documentation

Companies that provide financial support or in-kind contribution to patient organizations must have in place written documentation setting out the nature of support, including the purpose of any activity and its funding.

11.4 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 and conducive to informational communication. In addition, any meals or refreshments provided by a company must be modest as judged by local standards.

12 Company Procedures and Responsibilities

12.1 Procedures

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.

12.2 Training

Companies should also ensure that relevant employees receive training appropriate to their role.

12.3 Responsibilities for Approving Promotional Communications

A designated 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.

13 Infringement, Complaints, and Enforcement

13.1 Complaints

Genuine complaints relating to infringements of the IFPMA Code are encouraged. Detailed procedures for complaints and the handling of complaints (including the respective roles and jurisdiction of IFPMA and member associations) are set out in Appendix 1: IFPMA Code of Practice Operating Procedure.

13.2 Measures to Ensure and Enforce Compliance

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

Appendix 1

IFPMA Code of Practice Operating Procedure

1. Principles

1.1 The IFPMA Code of Practice (“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 Pharmaceutical companies are encouraged to report potential violations of this Code to the compliance department of the company alleged to be in breach, prior to submitting a complaint to the IFPMA.

2. The Procedure for Code Complaints

2.1 Role of the IFPMA Secretariat

The IFPMA is responsible for administering complaints to ensure that they are progressed as required by this operating procedure and the agreed IFPMA Secretariat Standard Operating Procedure (Appendix 2). This includes validation of the complaint, preparing the papers for the adjudication groups and advising the parties of the outcome. The IFPMA Secretariat has no role in deciding whether or not there has been a breach of the Code.

2.2 Validation

When a complaint, alleging a breach of the IFPMA Code, is received by the IFPMA Secretariat, it is first validated in line with the IFPMA Secretariat Standard Operating Procedure which ensures that:

- it appears to be a genuine matter, submitted in good faith;
- there is sufficient information to enable the complaint to be processed;
- the alleged breach concerns a country where this operating procedure applies; and
- it is not already under investigation by one of the member associations (or relevant body thereof or equivalent regulatory body).

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.

2.3 Inform

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 by the IFPMA Secretariat to the senior management of the company, at its headquarters and at local level within 5 working days from its receipt by 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 IFPMA Secretariat may grant an extension to the time limits.

2.5 Adjudication

When the company response is received the IFPMA Secretariat will send the case for adjudication. Cases are normally decided within 30 days from receipt of the company's response. If necessary, IFPMA Secretariat can ask the complainant or the respondent company for additional information, in which case the timelines may be extended.

The IFPMA Secretariat 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 can be sought by IFPMA Secretariat. Decisions are made by simple majority without participation by any members of the IFPMA staff. This group provides details of its decision with reasons to the IFPMA Secretariat which will advise the parties of the outcome and the appeal process.

2.6 Appeal

When the respondent company or complainant disagrees with the first decision either 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 Secretariat refers the matter 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). In addition, expert medical or technical advice can be sought by IFPMA Secretariat. The final decision is made by this group, by simple majority, without participation of any members of the IFPMA staff. This group provides details of its decision with reasons to the IFPMA Secretariat which will advise the parties of the outcome.

2.7 Sanctions

If a company is found in breach of the IFPMA Code, the company has 10 working days to provide written details of the action taken to comply with the ruling ("the Compliance Statement"). As a minimum, the respondent company will be asked to confirm that the activity or use of the material in question, and any similar material if not already discontinued or no longer in use, will cease immediately and that all possible steps will be taken to avoid a similar breach of the Code in the future. The Compliance Statement must be signed or authorized by a senior employee and must include the date on which the material was finally used or appeared and/or the last date on which the activity took place.

The details of the case are published by the IFPMA as set out in Section 2.8.

2.8 Publication of the Outcome

Where a breach is ruled a summary of the case will be published on the IFPMA website. The information to be disclosed includes the identity of the company in breach, the name of any product, where relevant, the country in which the breach took place, and a summary of the key facts.

Where no breach is ruled a summary of the case will be published on the IFPMA website. The information disclosed will include the relevant country and a brief summary of the key facts. The respondent company, the complainant, and product(s) are not named.

Information may also be made public in cases where a company fails to respond within the specified time limit.

3. Composition of the Adjudication and Appeal Groups

The IFPMA Secretariat recommends individuals from member associations for the ad hoc groups for adjudication and appeal, respectively for a one-year period. Individuals are chosen based on their expertise and geographical representation is also taken into account. Interested individuals can also volunteer to serve on either group. All appointments must be approved by the IFPMA Council.

4. 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.

4.1 Submission of Complaints

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

- Complainant details: The true 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, if not from a pharmaceutical company, can be kept confidential to all parties outside the IFPMA Secretariat and the Adjudication Groups;
- 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;
- 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));
- 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; and
- Date: The date, where relevant, of the alleged breach of the IFPMA Code.

All correspondence should be addressed to:

IFPMA

Chemin Louis-Dunant 15
P.O. BOX 195
1211 Geneva 20
Switzerland

Tel: +41 22 338 32 00
Fax: +41 22 338 32 99
Email: code@ifpma.org

www.ifpma.org

4.2 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 (CCN), 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 2.5 and 2.6 (only experts from associations); and
- To stimulate discussions about new challenges related to industry's promotion and marketing practices.

IFPMA arranges regular consultations of the IFPMA Code Compliance Network.

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

4.2.1 Status Reports

IFPMA will regularly issue 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, World Health Organization (WHO), the technical press and leading medical journals, and to member associations of IFPMA.

Appendix 2

IFPMA Secretariat Standard Operating Procedures

Action list for the processing of complaints by IFPMA

A) Validation of a Complaint

Considerations by IFPMA Secretariat

- 1) Unless there is clear evidence to the contrary, a complaint shall be deemed by the Secretariat to be a genuine complaint submitted in good faith.
- 2) Is it clear who or what the complainant is? Is there a full contact address?
- 3) Is it clear which company is alleged to have breached the Code?
- 4) Does the alleged breach relate to a country where the IFPMA Code operating procedure applies?
- 5) Is the company alleged to be in breach a member of the IFPMA? If not is it a company that is covered by the IFPMA by its membership of one of IFPMA member associations?
- 6) Has sufficient information been provided by the complainant to allow the complaint to proceed? Does the complaint name the product or products (if any) involved? Is it clear which material or activity is at issue? Has the matter of complaint been made clear? Have copies of relevant promotional or other materials been provided? If relevant, has the date of the alleged breach been given?
- 7) If the complaint is from a pharmaceutical company is it signed by a senior employee and does it state the sections of the Code alleged to have been breached?

B) Invalid Complaints

Procedure for IFPMA Secretariat

- 1) If a complaint cannot be validated because the information provided is inadequate, the complainant must be given an opportunity to provide the additional information needed.
- 2) If a complaint is not covered by the IFPMA operating procedure, the IFPMA must refer it to the company concerned. In addition, a copy must be sent to the relevant member association.
- 3) Except as dealt with above, if a complaint cannot be validated it must not be processed and, where possible, the complainant must be notified accordingly. (The complainant would normally be advised). In appropriate cases, IFPMA can refer the complainant, or forward the complaint, to an appropriate member association.

C) Processing a Valid Complaint

Procedure for IFPMA Secretariat

- 1) The complaint and supporting evidence must be sent to the senior management of the company alleged to be in breach at its headquarters and at the local level within 5 working days of its receipt by IFPMA.
- 2) In an accompanying letter IFPMA must state the time within which a response must be received. This will normally be 30 calendar days from the company's receipt of the documentation. In exceptional cases the IFPMA Secretariat can grant an extension to the time allowed. If the complaint is from outside the pharmaceutical industry the IFPMA Secretariat may suggest the sections of the Code to be addressed in the response.
- 3) The respondent company must be asked if a similar complaint is under investigation by a member association (or relevant body thereof or equivalent regulatory body).
- 4) The respondent company must be asked for full details if it rejects the allegations, the reasons must be clearly stated and, where appropriate, supporting data must be provided.
- 5) The respondent company must be informed that if it acknowledges that it has breached the IFPMA Code it must indicate what action has been taken or will be taken to remedy the matter.

D) Adjudication

Procedure for IFPMA Secretariat

- 1) The case must normally be decided within 30 working days from the receipt of the company's response. Following a request from one of the adjudication bodies, the IFPMA Secretariat can ask the complainant or the company alleged to be in breach for additional information or arguments. In such circumstances the time limit can be extended.
- 2) Upon receipt of the response from the company the IFPMA Secretariat must refer the complaint to an ad hoc group of three individuals experienced in the application of codes and selected from member associations. Decisions are made by a simple majority without participation by any members of IFPMA staff. The adjudication group can ask the IFPMA Secretariat to obtain expert advice.
- 3) The adjudication group must decide whether consideration of the complaint can proceed. If the complaint is under investigation by a member association (or relevant body thereof or equivalent regulatory body) then the adjudication group cannot consider the case and it must so inform the IFPMA Secretariat so that the case can be suspended. In such circumstances the IFPMA Secretariat informs the complainant that the case is being considered elsewhere.
- 4) The adjudication group will provide the IFPMA Secretariat with its decision and reasons for it.
- 5) The IFPMA Secretariat will contact the parties with details of the decision and inform the parties of the process for accepting that decision including the provision of a Compliance Statement where required or the process for appealing the first decision.

E) Appeals

Procedure for IFPMA Secretariat

- 1) The complainant or a company ruled in breach may, within 30 calendar days, appeal against the ruling. If new facts or arguments are put forward, the other party has 30 days in which to comment on them.
- 2) IFPMA Secretariat must refer the matter 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).
- 3) Decisions are taken by simple majority without participation by any member of IFPMA staff. The appeal group can ask the IFPMA Secretariat to obtain expert advice.
- 4) The appeal group will provide the IFPMA Secretariat with its decision and reasons for it.
- 5) The IFPMA Secretariat will contact the parties with details of the decision and inform the parties of the process for accepting that decision including the provision of a compliance statement where required.

F) Publication of the Outcome

Procedure for IFPMA Secretariat

- 1) Where a breach is ruled a summary of the case must be made public immediately on the IFPMA website. The information to be disclosed is the identity of the complainant, the identity of the company in breach of the IFPMA Code, the names of the product or products where relevant, the country in which the breach took place and a summary of the key facts.
- 2) Where no breach is ruled a summary of the case must be made public immediately on the IFPMA website. The information to be disclosed is the country in which the activity took place and a brief summary of the key facts. The respondent company, the product and the complainant are not named.
- 3) Information may also be made public in cases where a company fails to respond within the specified time limit.
- 4) A copy of the material to be published is provided to the respondent company for information only.

Questions & Answers

The questions and answers section has been developed to provide clarity on the scope and provisions of the IFPMA Code. The content in this section is binding.

1 Communications with the Public

Q: Does the IFPMA Code regulate communications with the public?

A: No. The IFPMA Code covers interactions with healthcare professionals and other stakeholders, such as medical institutions and patient organizations, 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, or those having interactions with healthcare professionals, medical institutions and patient organizations — to follow ethical standards for promotion and interactions, similar to those set forth in the IFPMA Code.

Q: Which interactions or activities of pharmaceutical companies are specifically outside the scope of the IFPMA Code?

A: This Code specifically 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);
- Promotion of self-medication products that are provided "over-the-counter" (OTC) directly to consumers without prescription;
- Pricing or other trade terms for the supply of pharmaceutical products, including promotion and marketing of pharmaceutical products to commercial customers;
- Certain types of non-promotional information or activities; and
- Promotion of medical devices.

3 Disease Awareness Campaigns

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

A: The IFPMA Code covers interactions with healthcare professionals, medical institutions and patient organizations, 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 IFPMA Code apply to the promotion and marketing of over-the-counter (OTC) products that may also be prescribed by healthcare professionals?

A: Yes. The IFPMA 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 IFPMA Code prohibit member companies from giving its customers discounts or other favorable trade terms for the supply of pharmaceutical products?

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

Q: Does the IFPMA 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 IFPMA Code does apply to the promotion and marketing of pharmaceutical products to such a customer. However, the IFPMA 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 IFPMA Code.

Q: Does the IFPMA 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 IFPMA 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 IFPMA 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 IFPMA 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.

6 Non-Promotional Information

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

A: Correspondence, possibly accompanied by material of a non-promotional 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 program, and discussion of regulatory developments affecting the company and its products is also not covered by the Code.

7 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.

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.

8 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.

9 Use of Comparisons

Q: Does the IFPMA 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. Comparative advertising should not be misleading.

10 Use of Quotations

Q: Does the IFPMA 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 identified. Quotations should not change or distort the intended meaning of the author or the significance of the underlying work or study.

11 Reprints

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

A: No. Reprints of scientific and medical articles, when used as stand-alone documents, are not developed by pharmaceutical companies and as such cannot be considered as promotional materials. If, however, they are proactively 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.

12 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 IFPMA Code, the home country of a healthcare professional is the country in which he/she practices.

13 Entertainment

Q: The IFPMA Code prohibits companies from providing entertainment, leisure and social activities to healthcare professionals and other stakeholders. Are there exceptions to this rule?

A: No. When a company organizes a meeting, refreshments and or meals incidental to the main purpose of the event can be provided. It would not be appropriate for a company to fund attendance at a concert, purchase of entertainment tickets or pay for entertainment in any form. However, if there is background music or a local performance at the venue where the event is taking place, which is not paid for by a pharmaceutical company, this may be permitted.

14 Fees for Services

Q: When a health professional is employed by a company to speak at a meeting can that company reimburse out of pocket expenses including travel and accommodation?

A: Yes. This should be included in the compensation arrangements.

15 Cash and Personal Gifts

Q: What are the exceptions to the requirements in the IFPMA Code concerning offering or providing cash and personal gifts to healthcare professionals?

A: In some countries, if allowed under local law and in accordance with local practice, an inexpensive customary gift not related to the practice of medicine may be given on an exceptional basis to a healthcare professional in acknowledgment of significant national, cultural or religious events. However, even in these circumstances such gifts may not be provided on occasions when it could be perceived as interfering with the independence of a healthcare professional's decision to prescribe, recommend or purchase medicines.

16 Promotional Aids

Q: What can be given as a promotional aid?

A: A promotional aid is a non-monetary item given for a promotional purpose. Promotional aids can only be given to healthcare professionals as defined in Article 1.2. Promotional aids must be related to the work of the recipient healthcare professionals and should be of minimal value and quantity. Possible examples include inexpensive pens and notepads. Promotional items intended for the personal benefit of the healthcare professional, such as music CDs, paintings or food baskets are not acceptable. Promotional literature such as detail aids, leave-behind pieces, booklets, etc. are not considered to be promotional aids as meant in Article 7.5.2.

17 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 both primarily involve a patient benefit. A DVD 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.

18 Interactions with Patient Organizations

Q: What happens if only one pharmaceutical company wishes to support a particular patient organization. Is this allowed?

A: Yes. Many patient organizations are supported by a number of pharmaceutical companies. There may, however, be situations where only one pharmaceutical company wishes to support a particular patient organization or one of its activities. It would be acceptable under the IFPMA Code for that pharmaceutical company to be the only pharmaceutical company providing funding as long as that company did not make its support conditional on it being the sole funder.

**International Federation
of Pharmaceutical
Manufacturers & Associations**

Chemin Louis-Dunant 15
P.O. Box 195
1211 Geneva 20
Switzerland

Tel: +41 22 338 32 00
Fax: +41 22 338 32 99
Email: code@ifpma.org

www.ifpma.org



ISBN 978-2-940498-01-7



9 782940 498017 >