



Code of Practice

*Upholding ethical standards
and sustaining trust*

2019



IFPMA

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Foreword

*A letter from our
Director General*

“Trust is the basis of reputation and essential for innovation. There is no true innovation without ethical decision making.”



Foreword

Our research-based biopharmaceutical industry is unlike any other – our products can prolong and save lives. Because of the very nature of our business, society's expectations of our industry are high and criticism is harsh when we do not meet these expectations. There is no doubt that this industry brings great value to society in helping to improve global health but we are deeply conscious we can never rest on our laurels. All who work in it, over two million employees, are properly held to higher standards than most because the very nature of our business requires us to win and retain patient trust. Trust is the life-blood of our industry. It goes without saying that key ethical and safety values must be embedded within this highly regulated industry.

Today, as societal expectations step up several gears within a world of ever faster, more and more interconnected change, how we earn and keep the trust is critical. Trust is the basis of reputation and essential for innovation. There is no true innovation without ethical decision making. Doing the right thing creates

a competitive advantage and therefore increases shareholder value. Ethical business conduct remains a constant challenge. In a fast-changing world, what was acceptable business practice a few years ago may no longer be adequate today. Thus, IFPMA's mission which rests on the establishment and promotion of ethical principles for the industry as a whole, has to adapt to societal expectations of ever higher standards.

Our Code of Practice was first drawn up in 1981, and it was the first one of its kind for any sector. Initially, correct information on the effects and side effects of medicines were at the core of the Code. Today, through periodic updates, expectations regarding compliance are much more comprehensive. Updated and revised over the decades, the Code sets out a rules-based compliance framework for clinical research, fees for services, support for continuing medical education, to name but a few. Many local and regional associations rely on the IFPMA Code as guidance for their own codes of conduct.

The last Code revision in 2012 saw its scope expanded beyond marketing practices to cover all interactions with healthcare professionals, medical institutions and patient organizations.

Now, with the new Code, we are setting the bar higher. We are placing a global ban on gifts for any company that is a member of IFPMA, and for all those firms that are members of our regional and national associations. This new revised Code is more principles-based and seeks to embody a deeper and broader appreciation of business integrity.

Do we and will we get it right 100 percent of the time? No, our member organizations are comprised of fallible human beings who make mistakes. With this new Code, we reaffirm our commitment to take action when mistakes occur. We take these matters seriously because in healthcare, trust is at the center of all we do, and that trust is built up over time by deeds. A company's reputation can vanish overnight, and in doing so, can tarnish the reputation of an entire industry.

At IFPMA, across our member companies and throughout our national member associations, we need to champion integrity, ethics, and compliance. Implementing the new and revised Code in full is about walking the talk, about earning our license to operate. As with all things, it is work in progress and I am sure more needs to be done. But we will never stop trying to improve.

Thomas Cueni

Director General, IFPMA



Our Ethos

Building a culture of trust



The Ethos underpins the rules of the IFPMA Code of Practice and provides a framework to behave with integrity no matter how testing the circumstances.

R&D-based biopharmaceutical member companies of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) are responsible for the discovery of most new medicines and vaccines, which they go on to develop, promote, sell and distribute in an ethical manner and in accordance with all the rules and regulations for medicines and healthcare. In doing so, they provide the healthcare community with the latest scientific and educational information to improve understanding of treatment options available to patients and support high-quality patient care.

IFPMA has taken a new approach and moved from a Code based on rules to a culture grounded in integrity, values and principles – and, most importantly, patient trust. The Ethos is the foundation that shapes how the R&D based biopharmaceutical industry sustains trust based on the core values of care, fairness, respect and honesty in line with ever-changing society's expectations. The Ethos serves to instill a culture of ethics and integrity needed to guide our business behaviours and interactions between IFPMA members and the healthcare community.

The Ethos underpins the rules of the IFPMA Code of Practice and provides a framework to behave with integrity no matter how testing the circumstances.

The pharma industry is unlike any other. Its innovations can prolong and save lives.

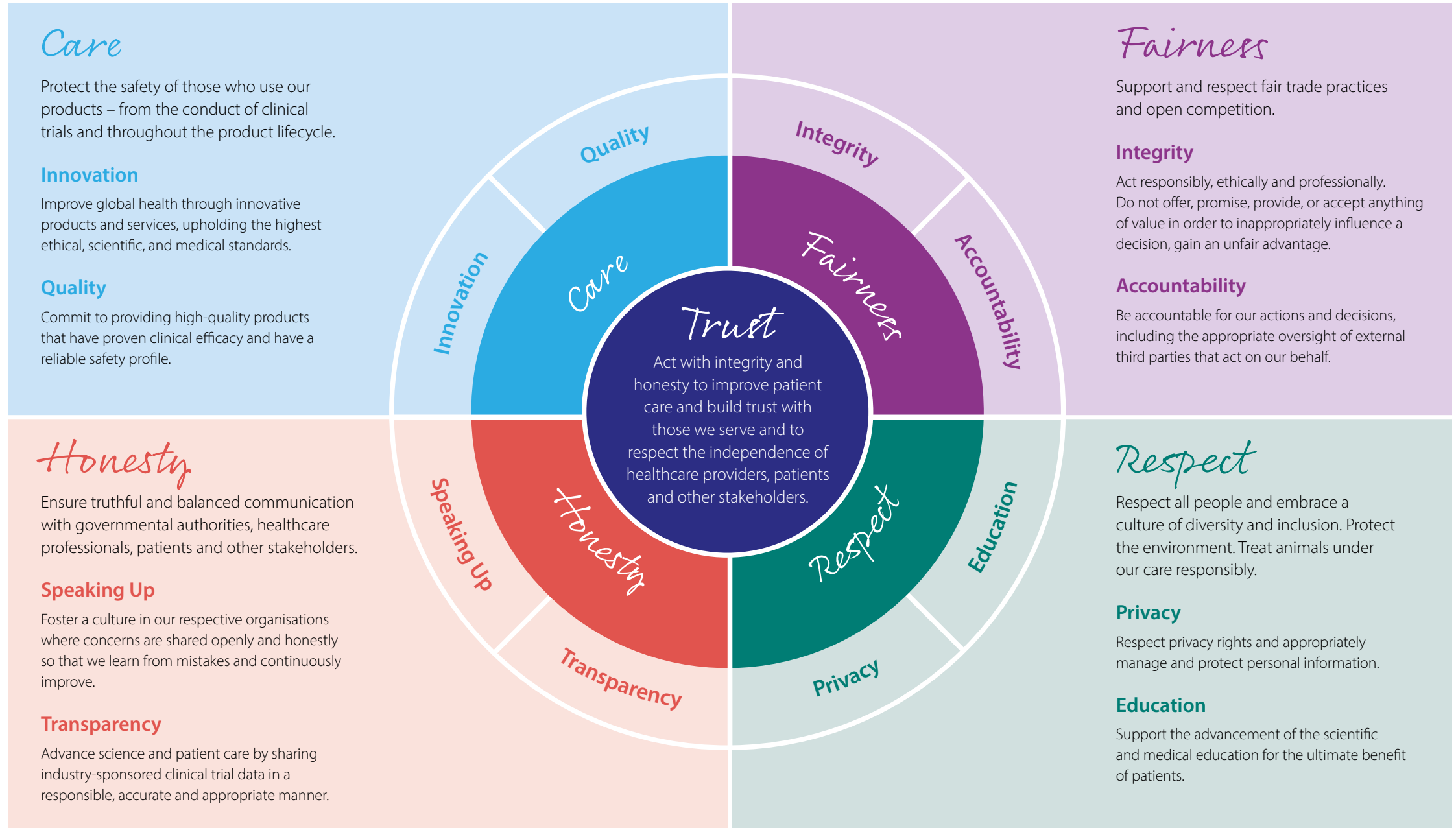
We hold ourselves to higher standards than other industries. We owe it to the patients who rely on our medicines.

Patient trust is the lifeblood of our industry: we must take every opportunity to earn, sustain and grow that trust.

See our Ethos



Our Ethos *Building a culture of trust*





Code of Practice

*Upholding ethical standards
and sustaining trust*

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 (HCPs) 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 HCPs and helps ensure that member companies' interactions with HCPs 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 anyone acting on their behalf 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.

The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and promoting new medicines.

- 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 January 2019, the IFPMA Code of Practice replaces the 2012 IFPMA Code of Practice. Member associations of IFPMA must incorporate this Code into existing national codes no later than 1st January 2019, 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 HCPs, 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 46-49)

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 HCP, 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 HCPs to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all methods of communications, including the internet.
- **“Healthcare Professional (HCP)”** 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, sell 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/or caregivers.
- **“medical institution”** means typically an organization that is comprised of HCPs 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 HCPs and other stakeholders are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing HCPs 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 49)



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 labelling, 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, HCPs in developing countries should have access to similar data to those being communicated in developed countries.

Q&A 8 (see page 50)

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 HCPs. 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 50)

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;
- **“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 51)

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 HCPs organized or sponsored by a company should be to provide scientific or educational information and/or inform HCPs about products.

7.1.2 Events Involving Foreign Travel

No company may organize or sponsor an Event for HCPs (including sponsoring individuals to attend such an Event as described in Article 7.2) that takes place outside of the HCP's country of practice 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 51)

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 51)

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 HCPs 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 HCPs is limited to the payment of travel, meals, accommodation and registration fees;
- No payments are made to compensate HCPs for time spent in attending the Event; and
- Any sponsorship provided to individual HCPs must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.

7.3 Guests

Companies must not pay any costs associated with individuals accompanying invited HCPs, except in cases of medical necessity.

7.4 Fees for Services

HCPs 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. The compensation arrangement may include reimbursement of reasonable expenses including travel, meals and accommodation.

7.5 Gifts and Other Items to Healthcare Professionals

Items in this section, where permissible, must never constitute an inducement to prescribe, recommend, purchase, supply, sell or administer a pharmaceutical product.

7.5.1 Gifts and Promotional Aids

7.5.1.1 Prohibition of Gifts

Gifts for the personal benefit (such as sporting or entertainment tickets, electronics items, social courtesy gifts, etc.) of HCPs (either directly or through clinics and institutions) are prohibited. Providing or offering cash, cash equivalents or personal services is also prohibited. For these purposes, personal services are any type of service unrelated to the HCP's profession and that confer a personal benefit to the HCP.

7.5.1.2 Promotional Aids

A promotional aid is a non-monetary item given for a promotional purpose (which does not include promotional materials as defined in Articles 5 and 6). Providing or offering them to HCPs in relation to the promotion of prescription-only medicines is prohibited.

Promotional aids of minimal value and quantity may be provided or offered to HCPs solely for the promotion of over-the-counter medicines if relevant to the practice of the HCP.

Q&A 14 (see page 52)

7.5.2 **Items of Medical Utility to enhance the Provision of Medical Services and Patient Care**

Items of medical utility may be offered or provided by member companies 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.

They should not be offered on more than an occasional basis, even if each individual item is appropriate.

Items of medical utility can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

Q&A 15 (see page 52)

7.5.3 **Informational or Educational Items that enhance Patient Care**

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

These informational and educational items can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

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

7.5.4 **Guidance on Values**

Member associations shall provide guidance using local currency, on acceptable monetary amounts for the following:

- **"minimal value"** for promotional aid items;
- **"modest value"** for items of medical utility and informational & educational items;
- **"reasonable value"** for scientific books & journal subscriptions

Q&A 16 (see page 52)

8. Samples

8.1 Samples

In accordance with local laws and regulations, free samples of a pharmaceutical product may be supplied to HCPs 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 HCPs 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, with minor revisions as of January 15, 2018)* and the *Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (2010, with minor revisions as of October 30, 2017)* 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 HCPs 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 17 (see page 55)

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.

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 Procedures.

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, which 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 is also applicable if and as far as the code adopted by the respective member association is not fully compliant with the IFPMA Code (unless required by national laws and regulations).
- 1.3** 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.
- 1.4** The IFPMA website shall contain links to information on codes and provisions organized by member associations, including links where case reports may be viewed.
- 1.5** 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.
- 1.6** 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 and appeal 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 and in a timely manner;
- 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 by the IFPMA Secretariat, it will be referred to the Appeal Group for a second review. If the Appeal Group is also unable to validate the complaint, the complaint will be dismissed and the complainant will be notified accordingly. In appropriate cases, IFPMA may refer the complainant or forward the complaint to an appropriate member association. If the Appeal Group deems the complaint to be valid, the procedure stated below will proceed.

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 the place where the alleged breach took place without undue delay, preferably 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 within 30 working 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 20 working 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 written reasons for its decision to the IFPMA Secretariat which will provide the decision to the parties and advise them of the appeal process.

2.6 Appeal

When the respondent company or the complainant disagrees with the first decision it either may, within 20 working days of receipt of the decision from the IFPMA Secretariat, request a second instance ruling. If new facts or arguments are put forward, the other party is invited to provide comments within 20 working days. The IFPMA Secretariat refers the matter to an ad hoc appeal group of five individuals experienced in the application of national codes and selected from member associations (which will not include any individuals participating in the first instance ruling). In addition, expert medical or technical advice can be sought by the IFPMA Secretariat. Following the request of either

the complainant or the company, the IFPMA Secretariat will organise an oral hearing. The final decision is made by this group, by simple majority, without participation of any members of the IFPMA staff. This group provides written reasons for its decision to the IFPMA Secretariat which provides the decision to the parties.

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 two-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 HCP, 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 should 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.

4.2

Anonymous Complaints

Although anonymous complaints are accepted it is preferable if complainants from outside the industry provide a name, contact details, and relevant information about their interests in the matter of complaint.

All correspondence should be addressed to:

IFPMA

Chemin des Mines 9
P.O. BOX 195
1211 Geneva 20
Switzerland

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

Appendix 2

IFPMA Secretariat Standard Operating Procedures

Action list for the processing of complaints by IFPMA

A Validation of Complaints 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.** If a complaint cannot be validated by the IFPMA Secretariat or is not covered by the IFPMA operating procedure, it will be referred to the Appeal Group for a second review. If the Appeal Group is also unable to validate the complaint, the complaint will be dismissed 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. If the Appeal Group deems the complaint to be valid, the complaint will be processed as stated in the Procedure.

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 the place where the alleged breach took place 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 working 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 20 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

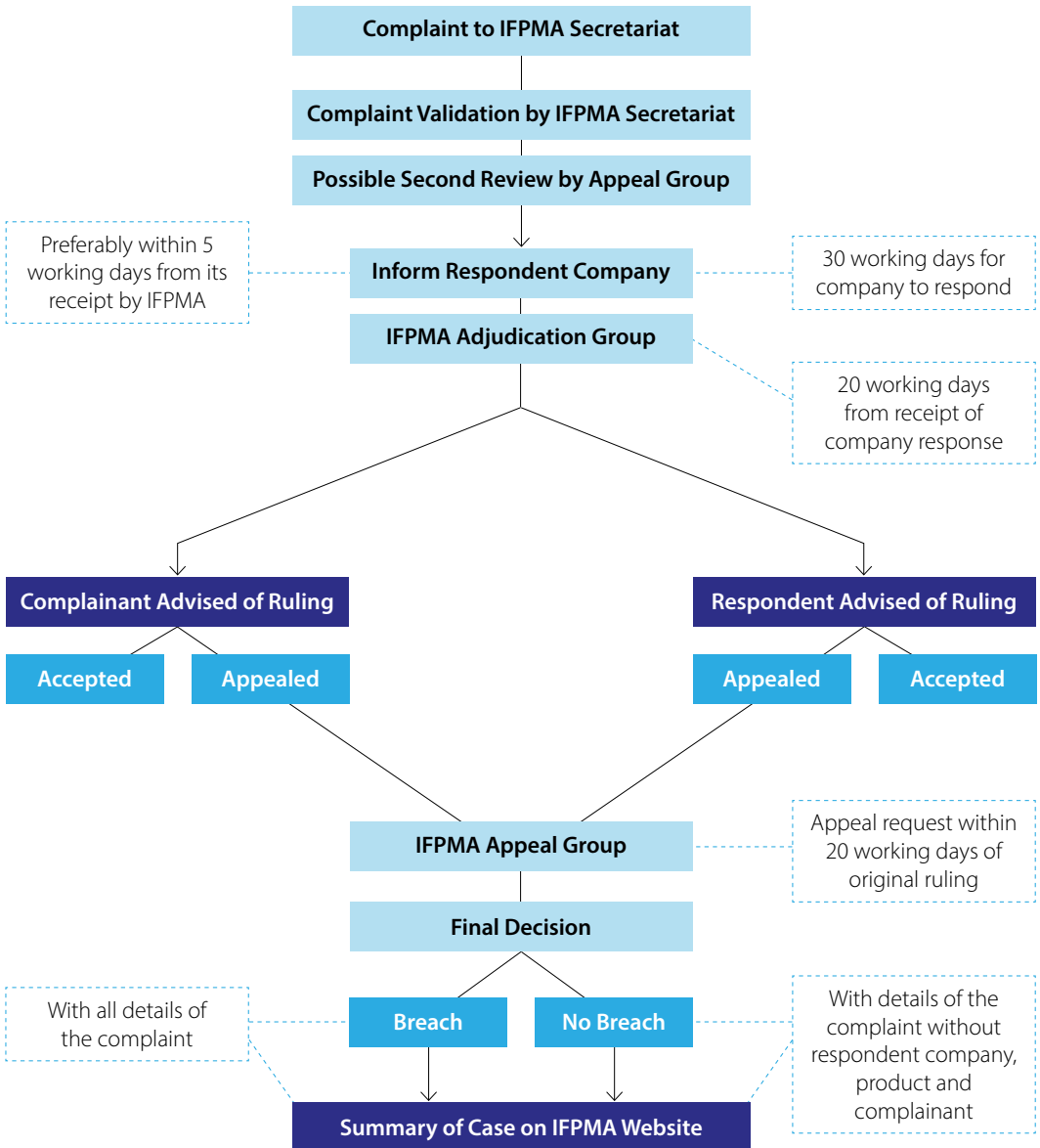
- 1.** The complainant or a company ruled in breach may, within 20 working days, appeal against the ruling. If new facts or arguments are put forward, the other party has 20 working days in which to comment on them.
- 2.** IFPMA Secretariat must refer the matter to an ad hoc group of five individuals 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 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.

Complaint Procedure





Appendix 3

IFPMA Procedural Requirements

5. 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 Ethics and Business Integrity Committee (eBIC), 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 eBIC. Periodic reports on the operation of the IFPMA Code are submitted to the IFPMA Council.

6. 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.





Questions & Answers

*Providing clarity on the scope
and provisions of our Code*

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 1.1 Does the IFPMA Code regulate communications with the public?

A 1.1 No. The IFPMA Code covers interactions with HCPs 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 2.1 To whom does the IFPMA Code apply?

A 2.1 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 HCPs, or those having interactions with HCPs, medical institutions and patient organizations — to follow ethical standards for promotion and interactions, similar to those set forth in the IFPMA Code.

Q 2.2 Which interactions or activities of pharmaceutical companies are specifically outside the scope of the IFPMA Code?

A 2.2 This Code specifically does not seek to regulate the following activities:

- Promotion of prescription only pharmaceutical products directly to the general public (e.g. direct to consumer advertising);
- Promotion of self-medication products that are provided “over-the-counter” (OTC) directly to consumers without prescription; (see also question 4.2)
- 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 3.1

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

A 3.1

The IFPMA Code covers interactions with HCPs, 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 4.1

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 4.1

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 4.2

Does the IFPMA Code apply to the promotion and marketing of over-the-counter (OTC) products that may also be prescribed by HCPs?

A 4.2

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

5.

Pricing and Terms of Trade

Q 5.1

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

A 5.1

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 5.2

Does the IFPMA Code apply to the promotion and marketing of pharmaceutical products to commercial customers who are also practicing HCPs, such as a pharmacist who operates his/her own practice?

A 5.2

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 HCP and, if applicable, comply with the requirements of the IFPMA Code.

Q 5.3

Does the IFPMA Code apply to the promotion and marketing of pharmaceutical products to commercial customers who are not HCPs? What if the customer is a HCP by qualification but is not practicing?

A 5.3

No. The IFPMA Code only applies to interactions with practicing HCPs. Promotion and marketing to commercial customers (whether or not they are HCPs) 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 5.4 Does the IFPMA Code cover price lists or other documents describing terms of trade?

A 5.4 No.

Q 5.5 Could a false price claim or a misleading price comparison in promotional material be processed under the IFPMA Code?

A 5.5 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 6.1 What are the examples of non-promotional information that are not covered by the IFPMA Code?

A 6.1 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 7.1 Is it ever appropriate for a company to publish promotional materials that appear to be independent editorial content?

A 7.1 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 7.2 How does the prohibition of pre-approval promotion affect compassionate use programs?

A 7.2 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 8.1

What level of detail is required to be included on labelling, 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 8.1

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 9.1

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

A 8.1

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 10.1

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

A 10.1

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 11.1

Are reprints considered as promotional material under the IFPMA Code?

A 11.1

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 HCP 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 12.1

When is it appropriate and justified for a company to organize or sponsor an event for HCPs outside of the company's home country?

A 12.1

A company can only organize or sponsor events involving travel if it is justified, e.g.

- a) A significant proportion of the invited HCPs 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) In exceptional circumstances where the relevant resource or expertise that is the object or subject matter of the event is located outside of the company's home country.

13. Entertainment

Q 13.1

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

A 13.1

No. 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.

14. Promotional Aids

Q 14.1

Section 7.5.1.2 prohibits promotional aids for prescription-only medicines. Does this also apply to the provision of pens and notepads in the context of company organized events?

A 14.1

No, pens and notepads can be provided to HCPs in the context of company organized events for the purpose of taking notes during the meeting. They must not bear the name of any medicine but may bear the name of the company providing them. In addition they must be of minimal value and only the necessary quantity are distributed. Examples of banned promotional aids include sticky notes, mouse pads, calendars, etc.

15. Items of Medical Utility

Q 15.1

What are examples of items of medical utility which offset business practices?

A 15.1

Items such as stethoscopes, surgical gloves, blood pressure monitors and needles are examples of routine business expenses, and they are expected to be supplied by the HCPs themselves or their employers.

16. Informational or Educational items that enhance Patient Care

Q 16.1

What are examples of informational or educational items?

A 16.1

For example, memory sticks pre-loaded with educational or informational data may be appropriate if the storage capacity is commensurate with the materials provided, whereas tablet computers may have independent value to a HCP and must not be provided, even if they could also be used to deliver education to patients.

Q 16.2

Which criteria should be considered when assessing “reasonable value” for scientific books and journal subscriptions?

A 16.2

The provision of scientific books and journal subscriptions can be an important component of improving patient care by keeping HCPs up to date on the most recent scientific developments. However, these publications are frequently expensive, and therefore their provision should be kept to a minimum. Consideration should be given both to the cost of an individual book or subscription as well as the overall benefit to an individual HCP in a given year and on an ongoing basis.

17.

Interactions with Patient Organizations

Q 17.1

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

A 17.1

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.





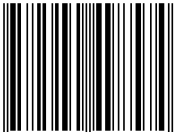
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