



IFPMA Code Of Pharmaceutical Marketing Practices

2006 Revision



International Federation of Pharmaceutical
Manufacturers & Associations (IFPMA)

Fédération Internationale de l'Industrie
du Médicament (FIIM)

Federación Internacional de la Industria
del Medicamento (FIIM)

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Preamble

- (i) The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and marketing new medicines. Ethical promotion helps to ensure that healthcare professionals have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.
- (ii) IFPMA and its members are committed to educational and promotional efforts that benefit patients and promotional programs and collaborations that enhance the practice of medicine. IFPMA also seeks to preserve the independence of the decisions taken by healthcare professionals in prescribing medicines to patients. The pharmaceutical industry has an obligation and responsibility to provide accurate information and education about its products to healthcare professionals in order to establish a clear understanding of the appropriate use of prescription medicines. Industry relationships with healthcare professionals must support, and be consistent with, the professional responsibilities healthcare professionals have towards their patients. Pharmaceutical companies must maintain high ethical standards when conducting promotional activities and comply with applicable legal, regulatory and professional requirements. Through the promotion of this Code, IFPMA seeks to ensure that ethical promotional practices are established worldwide.
- (iii) The IFPMA Code of Pharmaceutical Marketing Practices (the "IFPMA Code") sets forth standards for the ethical promotion of pharmaceutical products to healthcare professionals, and for member companies' interactions with them. Effective January 1st, 2007, this Code replaces the

IFPMA Code of Pharmaceutical Marketing Practices (Update 2000). Member associations of IFPMA must incorporate this Code into existing national codes no later than January 1st, 2007, subject to the guidance set out in articles (vi) and (vii) below.

- (iv) IFPMA acknowledges the role of relevant codes of ethics developed by the World Medical Association, International Council of Nurses and the International Federation of Pharmacists. IFPMA also recognizes the role of Ethical Criteria for Medicinal Drug Promotion provided by the World Health Organization in 1988.
- (v) The IFPMA Code contains provisions relating to scope, applicability and guiding principles (Articles 1-2), the content of promotional material (Articles 3-6); interactions with healthcare professionals (Articles 7-8); company procedures and responsibilities (Article 9); and operation and enforcement (Article 10). It also includes a Q&A section to assist in interpretation of the IFPMA Code and details the operating procedures for Code complaints (Appendix 1).
- (vi) 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.
- (vii) It is accepted that where there is an established framework of stringent regulatory and/or legal controls which are effectively as comprehensive in their provisions and application as the IFPMA Code, it may be more appropriate for a national member association not to establish new duplicative provisions and procedures. IFPMA also acknowledges that many IFPMA member associations have already established their own codes of conduct, which, together with local laws and regulations, fully embody the principles set forth in the IFPMA Code.
- (viii) IFPMA member companies 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.

- (ix) IFPMA member companies are accountable for addressing and correcting infringements under relevant codes. They should also ensure that internal structures and procedures (including adequate training of employees) are created to ensure responsible and ethical promotional activities. Companies not in membership with IFPMA may elect to be subject to the IFPMA Code and its complaints handling processes.
- (x) The IFPMA is open to receive genuine complaints from any source on any aspect of the IFPMA Code, in accordance with its operating procedures. Where it is determined that there has been a breach of the IFPMA Code, the objective is to correct the matter as rapidly as possible.
- (xi) 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 major global research-based pharmaceutical companies. Companies are committed to the ethical standards set out in this Code.

The IFPMA Code

1. Objective and Scope

1.1 Objective

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

Q&A 1

1.2 Scope

For the purposes of the IFPMA Code:

- “pharmaceutical product” means all pharmaceutical or biological products (irrespective of patent status and/or whether they are branded or not) which are intended to be used on the prescription of, or under the supervision of, a healthcare professional, and which are intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body.

Q&A 2

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

- “member association” means any association that is a member of IFPMA.

1.3 Exclusions

This Code does not seek to regulate the following activities: Promotion of prescription only pharmaceutical products directly to the general public (i.e. direct to consumer advertising).

Q&A 1 and 3

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

Q&A 4

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

Q&A 5

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

Q&A 6

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

Q&A 7

2. General Principles

2.1 Basis of Interaction

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

2.2 Independence of Healthcare Professionals

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

2.3 Appropriate Use

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

2.4 Local Regulations

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

2.5 Transparency of Promotion

Promotion should not be disguised. Clinical assessments, post-marketing surveillance and experience programmes and post-authorization studies must not be disguised promotion. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose. 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.

Q&A 8

3. Pre-Approval Communications and Off-label Use

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

This provision is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences. Nor should it restrict public disclosure of information to stockholders and others concerning any pharmaceutical product, as may be required or desirable under law, rule or regulation.

4. Standards of Promotional Information

4.1 Consistency of Product information

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

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

Q&A 9

4.2 Accurate and Not Misleading

Promotional information should be clear, legible, accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the pharmaceutical product concerned. Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It should not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. Every effort should be made to avoid ambiguity. Absolute or all-embracing claims should be used with caution and only with adequate qualification and substantiation. Descriptions such as 'safe' 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 10 Q&A 11

5. Printed Promotional Material

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

5.1 All Printed Promotional Material, including Advertisements

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

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

Q&A 12

5.2 Reminder Advertisements

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

6. Electronic Materials, including Audiovisuals

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

- the identity of the pharmaceutical company and of the intended audience should be readily apparent;
- the content should be appropriate for the intended audience;
- the presentation (content, links, etc.) should be appropriate and apparent to the intended audience; and
- country-specific information should comply with local laws and regulations.

7. Interactions with Healthcare Professionals

7.1 Events

7.1.1 Scientific and Educational Objectives

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

7.1.2 Events Involving Foreign Travel

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

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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:

- 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) for a pharmaceutical product not registered in the country of the Event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally;
- Promotional material which refers to the prescribing information (indications, warnings etc.) authorized in a country or countries other than that in which the Event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally; and
- An explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.

7.2 Sponsorship

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

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

7.3 Guests

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

7.4 Payments for Speakers and Presenters

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

7.5 Hospitality

7.5.1 Appropriate Venue

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

7.5.2 Limits of Hospitality

Hospitality should be limited to refreshments and/or meals incidental to the main purpose of the Event and should only be provided:

- to participants of the Event and not their guests; and

- if it is moderate and reasonable as judged by local standards.

7.5.3 Guidance from Member Associations

Member associations are encouraged to provide written guidance on the meaning of the terms “moderate”, “modest” and “reasonable”, as used in 7.5.2 and 7.5.4 of this Code, and the meaning of the terms “renowned” and “extravagant” as used in 7.5.1 of this Code. As a general rule, the hospitality provided should not exceed what healthcare professional recipients would normally be prepared to pay for themselves.

7.5.4 Entertainment

No stand-alone entertainment or other leisure or social activities should be provided or paid for by member companies. At Events, entertainment of modest nature which is secondary to refreshments and/or meals is allowed.

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7.6 Gifts and Items of Medical Utility

7.6.1 Cash

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

7.6.2 Personal Gifts

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

7.6.3 Promotional Aids

Promotional aids or reminder items may be provided or offered to healthcare professionals and appropriate administrative staff, provided the gift is of minimal value and relevant to the practice of the healthcare professional.

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7.6.4 Items of Medical Utility

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

7.6.5 Cultural Courtesy Gifts

In some countries, if allowed under local law and in accordance with local practice, an inexpensive gift not related to the practice of medicine may be given on an infrequent basis to healthcare professional in acknowledgment of significant national, cultural or religious holidays.

7.6.6 Guidance on Values

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

- “minimal” value for promotional aids and reminder items in 7.6.3 above;
- “modest value” for items of medical utility in 7.6.4 above; and
- “inexpensive” for customary gifts in 7.6.5 above.

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

8. Samples

8.1 Samples Permitted

In accordance with local laws and regulations, free samples of a pharmaceutical product may be supplied to healthcare professionals in order to enhance patient care. Samples should not 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. Company Procedures and Responsibilities

Companies should establish and maintain appropriate procedures to ensure full compliance with relevant codes and applicable law and to review and monitor all of their promotional activities and materials. A designated company employee, with sufficient knowledge and appropriate scientific or healthcare qualifications should be responsible for approving all promotional communications. Also, a senior company employee could be made responsible, provided that scientific advice is taken.

10. Infringement, Complaints, and Enforcement

10.1 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: Operating Procedures of the IFPMA Code.

10.2 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 Operating Procedure

1. Principles

- 1.1** The IFPMA Code and the operating procedure of the IFPMA Code shall apply directly in territories where no national code has been adopted by the respective member association.
- 1.2** The IFPMA Code and its operating procedure shall also apply in all cases where a member company commits a breach of the IFPMA Code in territories where there are national codes adopted by the respective member association but the member company in alleged breach is not a member of that association.
- 1.3** IFPMA shall ensure that its website contains information on codes and provisions organized by member associations, including details of where case reports may be viewed.
- 1.4** If a complaint is received by IFPMA that is not covered by this operating procedure, IFPMA will refer it to the company concerned. In addition, a copy will be sent to the relevant member association, if the association has a process for complaints.
- 1.5** Should IFPMA receive a complaint about an alleged breach which is already under investigation by one of the member associations (or relevant body thereof or equivalent regulatory body), it will not process the complaint but will inform the sender of the fact that the complaint is being handled elsewhere.
- 1.6** Likewise, if IFPMA during its processing of a complaint is informed that the same alleged breach is being investigated elsewhere, it shall suspend the process and inform the complainant thereof.

2. The Procedure for Code Complaints

2.1 Validation

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

- it appears to be a genuine matter, submitted in good faith;
- there is sufficient information to enable the complaint to be processed (see 3.1 below);
- the alleged breach concerns a country where this operating procedure applies; and
- it is not evident that the same alleged breach is being or has been investigated by a member association (or relevant body thereof).

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

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

2.2 Referral

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

2.3 Non-member Companies

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

2.4 Time Limits

The Letter to the company indicates the time within which a response must be made on the case(s) under investigation. This is normally 30 calendar days from the company's receipt of the documentation. In exceptional circumstances, the Director General of IFPMA may grant an extension to the time limits.

2.5 Company Response

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

2.6 Adjudication

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

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

2.7 Appeal

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

2.8 Ad hoc Groups for Adjudication and Appeal

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

2.9 Publication of the Outcome

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

2.10 Status Reports

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

3. Use of the Complaint Procedure

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

3.1 Submission of Complaints

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

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

All correspondence should be addressed to:

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3.2 Responsibilities of IFPMA

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

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

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

IFPMA arranges an annual consultation of the Code Compliance Network.

Questions & Answers

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 the promotion of pharmaceutical products. Where direct promotion to the public is allowed, this is covered by local laws, regulations and/or relevant codes of practice. Member companies should of course, comply with these local laws, regulations and/or codes.

2. Code Application

Q: To whom does the IFPMA Code apply?

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

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 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 OTC products that may also be prescribed by healthcare professionals?

A: Yes. The IFPMA Code applies to the promotion of 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. Consultancy Agreements

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

A: It is appropriate for consultants who provide services to be offered reasonable compensation for those services and to be offered reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Compensation and reimbursement that would be inappropriate in other contexts can be acceptable for genuine consulting arrangements. Token consulting or advisory arrangements should not be used to justify compensating healthcare professionals. The following factors support the existence of a genuine consulting arrangement (not all factors may be relevant to any particular arrangement):

- a written contract which specifies the nature of the services to be provided and the basis for payment of those services;
- a legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
- the criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;
- the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;
- the retaining company maintains records concerning and makes appropriate use of the services provided by consultants; and
- the hiring of the healthcare professional to provide the relevant service is not an inducement to prescribe a particular product.

7. Non-Promotional Information

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

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

8. Disguised Promotion

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

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

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

A: The clause does not prevent compassionate use programmes which must of course comply with all applicable laws, regulations and codes. Care should be taken to ensure that communications for a compassionate use programme are not, in effect, advertisements for an unlicensed medicine or use.

9. Consistency of Information

Q: What level of detail is required to be included on 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: Where possible and within the context of national requirements, companies should provide the same core product information (such as contraindications, warnings, precautions, side effects and dosage) as it provides in developed countries.

10. Use of Comparisons

Q: Does the 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.

11. 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 clinical investigator or the significance of the underlying work or study.

12. 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 presented to a healthcare professional together with other, company-originated documents, they then become promotional materials. In all cases, where promotion refers to, includes, or is presented together with scientific or medical articles or studies, clear references should be provided. Any reprint of artwork (including graphs, illustrations, photographs or tables) taken from articles or studies and included or presented with promotional materials should clearly indicate the source of the artwork and be faithfully reproduced.

13. Events Involving Foreign Travel

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

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

- (a) A significant proportion of the invited healthcare professionals are from outside of the company's home country, and it makes greater logistical or security sense to hold the event in another country; or
- (b) The relevant resource or expertise that is the object or subject matter of the event is located outside of the company's home country.

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

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

14. Entertainment

Q: The IFPMA Code prohibits stand-alone entertainment, leisure or social activities but allows entertainment of modest nature in conjunction with meals, etc., which is secondary to the main purpose of the event. How should companies interpret this in practice?

A: When a company organizes a meeting and refreshments are provided, e.g., an evening meal for a meeting stretching over more than one day, it would be permitted to provide some background music during the meal or to have an interlude when some local singers perform. However it would not be appropriate for a company to fund attendance at a concert by those same performers as this would be self standing and not incidental to the refreshments and the IFPMA Code also prohibits the purchase of entertainment tickets. A self standing sightseeing tour would not be permitted but this would not prohibit a commentary about sights of interest en-route to a restaurant. The 'modest nature' of the entertainment may be interpreted as prohibiting high profile, inappropriate or expensive entertainers - even if their performance is secondary to a necessary meal. So an appearance by a well known TV or pop star would not be considered as modest whereas a folk dance display or performance by a local singer would be acceptable as entertainment for a meal interlude.

15. Promotional Aids

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

A: Promotional aids should be of minimal value and should be related to the work of the recipient healthcare professional. Possible examples include pens, notepads and surgical gloves. Promotional items intended for the personal benefit of the healthcare professional, such as music CDs, paintings or food baskets would be not be acceptable.

16. Items of Medical Utility

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

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

About the IFPMA

The International Federation of Pharmaceutical Manufacturers & Associations is the global non-profit NGO representing research-based pharmaceutical, biotech and vaccine companies and national industry associations in developed and developing countries. The industry's R&D pipeline contains hundreds of new medicines and vaccines being developed to address global disease threats, including cancer, heart disease, HIV/AIDS and malaria. The IFPMA Clinical Trials Portal (www.ifpma.org/clinicaltrials) and the IFPMA Health Partnerships Survey help make the industry's activities more transparent. The IFPMA strengthens patient safety by improving risk assessment of medicines and combating their counterfeiting. It also provides the secretariat for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).



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