

**International Federation of Pharmaceutical  
Manufacturers Associations  
Fédération Internationale de l'Industrie  
du Médicament  
Federación Internacional de la Industria  
del Medicamento**

**IFPMA CODE  
OF PHARMACEUTICAL  
MARKETING PRACTICES  
2006 Revision**

**APPENDIX 1  
OPERATING PROCEDURE OF THE IFPMA CODE**

## **APPENDIX 1**

### **OPERATING PROCEDURE OF THE IFPMA CODE**

#### **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:

IFPMA  
15, chemin Louis Dunant  
P.O. BOX 195  
1211 Geneva 20  
Switzerland  
*Telephone:* +41 (22) 338 32 00  
*Telefax:* +41 (22) 338 32 99  
*IFPMA Web site:* <http://www.ifpma.org>  
*E-mail:* [marketingcode@ifpma.org](mailto:marketingcode@ifpma.org)

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

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

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

IFPMA arranges an annual consultation of the Code Compliance Network.

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