

Organisation of Pharmaceutical Producers of India

OPPI Code of Pharmaceutical Marketing Practices 2010



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Introduction

Since the OPPI Code of Pharmaceutical Marketing Practices is based on the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code, we provide brief introduction to the IFPMA Code.

The IFPMA Code has been in operation for the last two decades with the objective of ensuring that promotion of all products is backed by adequate, unbiased and truthful technical data. It defines universally applicable baseline standards for marketing practice and applies to all promotional communications from the pharmaceutical industry to the medical profession. This includes visual aids, flip charts, leave-behinds, advertisements, gifts and audio-visuais. This code has been revised in 2006 to cover additional aspects of Industry relationship with healthcare professionals. These revisions have been made to ensure that IFPMA and its member associations including OPPI are committed to educational and promotional efforts that benefit patients, and promotional programs and collaborations that enhance the practice of medicine. The Code therefore applies to the practice of organizing events like scientific symposia or seminars by pharmaceutical companies and extending hospitality to doctors. The Code introduces clearer and more restrictive rules for Companies interactions with healthcare professionals, including organization of events involving travel, company sponsorship, hospitality, entertainment and gifts.

The IFPMA Code is a 'Model Code'. It is not intended to be a detailed operating procedure, covering every eventuality. The Code sets certain principles considered basic to ethical behaviour in pharmaceutical marketing. It is designed to be adopted by more than 51 member countries with transcultural and language barriers.

It is noteworthy that the IFPMA Code applies to the scientific as well as the non-scientific aspects of promotion. Its implementation can be meaningful and total only with co-ordinated and coherent efforts by the medical and the marketing personnel of the industry with co-operation from the medical fraternity. Through the promotion of this Code, IFPMA seeks to ensure that ethical promotional practices are established worldwide.

OPPI is a signatory to the Code and hence it is obligatory on the Member Companies to adhere to the principles enshrined in this code. As suggested by the IFPMA code, OPPI has adapted the code to provide specific local guidelines.

This publication contains the OPPI Code followed by an Appendix that details the Operating Procedure for the implementation of the code. In the end, the constitution and procedure for the Code of Practice Committee of the OPPI for the implementation of the OPPI Code is given as Appendix.

The final responsibility of implementation of the Code is a matter of self-regulation and self-discipline.

1. **OBJECTIVE AND SCOPE:**

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

1.2 **Scope:** For the purposes of the Code:

- “pharmaceutical product” means all pharmaceutical or biological products (irrespective of patent status and/or whether they are branded or not) which are intended to be used on the prescription of, or under the supervision of, a healthcare professional, and which are intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body.
- “promotion” means any activity undertaken, organised 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 **and mobile SMS etc.**
- “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.
- **“company” means any pharma company that is a member of OPPI that agrees to abide by this code**

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).
- Promotion of self-medication products that are provided “over the counter” without prescription.
- Pricing or other trade terms for the supply of pharmaceutical products.
- The engagement of a healthcare professional to provide genuine consultancy or other genuine services to a member company.
- The conduct of clinical trials (which are governed by separate GCP guidelines).
- The provision of non-promotional information by member companies.

2. **GENERAL PRINCIPLES :**

2.1 **Basis of Interaction:** 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 or would influence their professional integrity and autonomy or will compromise patients' interest in any manner.

Healthcare professionals should not be influenced to endorse any drug or product of any pharmaceutical company publicly.

2.3 **Appropriate Use:** Promotion should encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their properties.

2.4 **Regulations:** In all cases, all relevant laws and regulations must be observed and companies have a responsibility to check requirements, in advance of preparing promotional material or events.

2.5 **Transparency of Promotion:** Promotion should not be disguised. Clinical assessments, post-marketing surveillance and experience programmes and post-authorisation 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.

3. **Pre-approval Communications and Off-Label Use:**

No pharmaceutical product shall be promoted for use until the requisite approval for marketing for such use has been given.

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 approved product information.

Healthcare professionals in India should have access to similar data to those being communicated by the same company in other countries.

- 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.

5. **Printed Promotional Material:**

Where 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; and
- “abbreviated prescribing information” which should include an approved indication or indications for use together with the dosage and method of use, and a succinct statement of the contraindications, precautions and side effects.

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 applied 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
- Information should comply with Drugs & Magic Remedies Act.

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 organised or sponsored by a company should be to inform healthcare professionals about products and/or to provide scientific or educational information.

7.1.2 **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.) authorised 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 **Travel Facilities:** No travel facilities to be extended to a healthcare professional as a delegate, inside the country or outside, including rail, air, ship, cruise tickets, paid vacations, etc. for self and family members for vacation or for attending conference, seminars, workshops, CME programme, etc.

7.3 **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, other than delegates.

7.4 **Affiliation :** A healthcare practitioner may work for the pharmaceutical company in advisory capacities as consultants, as researchers, as treating doctors or any other professional capacity. Such affiliation would ensure the following:

- (i) Professional integrity and freedom of healthcare professionals are maintained.
- (ii) Patients' interest are not compromised in any way.
- (iii) Such affiliations are within the Law and fully transparent and disclosed.

7.5 **Hospitality:** No hospitality, like hotel accommodation, for self and family members under any pretext to be provided to a healthcare professionals other than as mentioned in sections 7.3 and 7.4

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. The additional requirements set forth in Article 7 of this Code also apply accordingly.

7.5.2 **Limits of Hospitality:** Hospitality, wherever applicable, 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.
- As a general rule, the hospitality provided should not exceed what healthcare professional recipients would normally be prepared to pay for themselves.

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

7.6. **Cash, Gifts and Promotional Aids:**

7.6.1 **Cash:** No cash or monetary grants for individual purpose in individual capacity under any pretext to be provided to healthcare professionals. Funding for medical research study, etc. can only be given through approved institutions by modalities laid down by law / rules / guidelines adopted by such approved institutions in a transparent manner and as mentioned in section 7.4

7.6.2 **Gifts:** Gifts to the 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, relevant to the practice of the healthcare professional.

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 Code are encouraged. Detailed procedures for complaints and the handling of complaints are set out in Appendix : Operating Procedures of the Code.

10.2 **Measures to Ensure and Enforce Compliance:** OPPI strongly encourage their members to adopt procedures to assure adherence to the Code.

APPENDIX

OPERATING PROCEDURE OF THE CODE

1. **The Procedure For Code Complaints :**

1.1 Validation: When a complaint, alleging a breach of the Code, is received by the OPPI 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;
- 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.

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 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.

- 1.2 **Referral:** The complaint, including a copy of any supporting evidence (e.g. a copy of the advertisement alleged to be in breach of the Code), together with an accompanying letter from OPPI (the “Letter”), is sent to the senior management of the company within 5 working days from its receipt by OPPI.
- 1.3 **Non-member Companies:** When a case refers to a company that is not subjected to Code, the case cannot be processed formally.
- 1.4 **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 OPPI may grant an extension to the time limits.
- 1.5 **Company Response:** Where the company acknowledges that it has acted in breach of the 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.
- 1.6 **Adjudication:** Where the company disputes the allegation, OPPI will rule on the case. OPPI normally decides cases within 30 days from receipt of the company's response. If necessary, OPPI can ask the complainant or the affected company for additional information or argumentation, in which case the timelines may be extended.

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

- 1.7 **Appeal:** Where the company or complainant disagrees with the decision of OPPI, 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 Director General or his nominee refers such complaint to a group of five individuals experienced in the application of ethical marketing codes and selected from member companies (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 Association staff. The decision is communicated to the Director General of OPPI.

- 1.8 **Groups for Adjudication and Appeal:** The OPPI Director General or his nominee appoints 3 and 5 members of the groups for adjudication and appeal respectively for a one-year period comprised of individuals as given below.

Adjudication Group consists of a member from Medical, Marketing and Legal Committees.

Appeal Group consists of 2 members from Medical Committee and one each from Executive, Marketing and & Legal Committees.

- 1.9 **Publication of the Outcome:** When a complaint is upheld and breach of the Code is determined, or non disputed by the company, information identifying the company (and product, where relevant) concerned, the complainant, and providing a summary of the key facts of the case, is immediately made public by display on the OPPI's website. Likewise, information may be made public in cases where the company fails to respond within the specified time limit.

2. **Use Of The Complaint Procedure:**

The 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 Code.

- 2.1 **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 Association secretariat.

- **Company:**

For each case, the identity of the company which is alleged to be in breach of the 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 Code.

- **Summary**

For each case, a brief description of the complaint with, if possible, a specific reference to the part of the Code under which the complaint is being made (section and paragraph number.)

All correspondence should be marked '**Confidential**' and addressed to Director General / Secretary General of the Association:

2.2 **Sanctions:**

[A] Sanctions against a member of OPPI where breach of the Code of Practice has been established may consist of one or more of the following.

- The requirement that the Member gives an undertaking, in writing, to discontinue any practice which has been determined to constitute a breach of the Code on or before a date to be determined by the Adjudication / Appeal Group.
- The issuing of retraction statements by the member, the format, size, wording, mode of publication and method of distribution of such a statement shall be subject to the approval of the Adjudication / Appeal Group prior to release and will in general conform with the original statement. The Group will ensure that such a statement is made.
- Any other action including expulsion of the company from the membership can be decided by the Executive Committee of OPPI depending upon the nature and circumstances of the breach.

[B] OPPI will publish details of a complaint in their websites, such as the name of the company, product(s) involved, nature of complaints, etc., if the complaint is upheld and a breach of the Code is determined by the adjudicators, or if the complaint is not disputed by the company concerned.

2.3 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 1.6 and 1.7 (only experts from associations); and
- To stimulate discussions about new challenges related to industry's promotion and marketing practices.

IFPMA arranges an annual consultation of the Code Compliance Network.