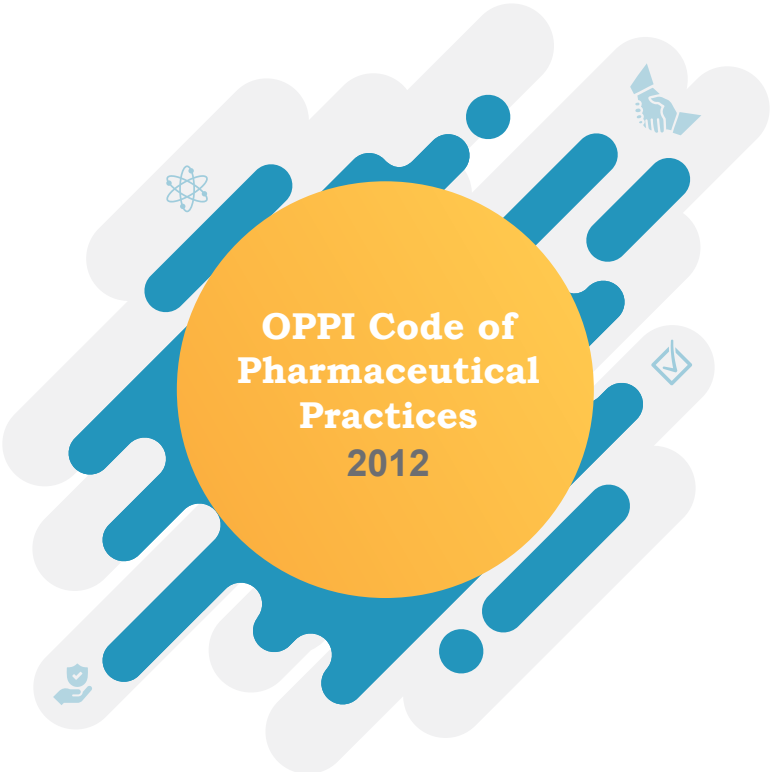
OPPI

Organisation of Pharmaceutical Producers of India



OPPI Code of Pharmaceutical Practices 2012

About OPPI

- Organisation of Pharmaceutical Producers of India (OPPI) established in 1965, is a premier association of research and innovation driven pharmaceutical companies in India and is also a scientific and professional body. It caters to the needs of Research based Pharmaceutical Industry thereby creating and sustaining an environment conducive to innovation and growth, simultaneously, facilitating industry and stakeholders partnership through various advisory and consultative processes to achieve the Healthcare objectives of the Nation.

- OPPI Members Follow:
  - Good Manufacturing Practices (GMP)
  - Code of Pharmaceutical Marketing Practices
  - OPPI's position on Intellectual Property Rights (IPR)

- OPPI Members Follow:
  - Continuous dialogue with the stakeholders
  - Actively engage in knowledge creation & knowledge sharing with value addition
  - Engage in "Corporate Academia Interaction"

- OPPI identifies itself with the country's national healthcare objectives and encourages its members to make substantial contributions to social concerns and actively promotes Corporate Social Responsibility (CSR)

- OPPI is an active member of International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Geneva

OPPI Code of Pharmaceutical Practices 2012

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OPPI VISION

OPPI is an organisation of research and innovation driven pharmaceutical companies committed to address India's healthcare needs through:

- Facilitating greater access to quality healthcare solutions
- Encouraging research and innovation
- Disseminating knowledge and sharing best practices
- Contributing meaningfully in policy dialogues

Introduction

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

IFPMA Guiding Principles on Ethical Conduct and Promotion

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

The healthcare and well-being of patients are the first priority for pharmaceutical companies.

1. Pharmaceutical companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities.

2. Pharmaceutical companies' interactions with stakeholders must at all times be ethical, appropriate and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence.

3. Pharmaceutical companies are responsible for providing accurate, balanced and scientifically valid data on products.

4. Promotion must be ethical, accurate, balanced and must not be misleading. Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use.

5. Pharmaceutical companies will respect the privacy and personal information of patients.

6. All clinical trials and scientific research sponsored or supported by companies will be conducted with the intent to develop knowledge that will benefit patients and advance science and medicine. Pharmaceutical companies are committed to the transparency of industry sponsored clinical trials in patients.

7. Pharmaceutical companies should adhere to both the spirit and the letter of applicable industry codes. To achieve this, pharmaceutical companies will ensure that all relevant personnel are appropriately trained. 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.

Preamble

i. The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of improving patient outcomes by discovering, developing and promoting new medicines. Ethical promotion helps to ensure that healthcare professionals globally have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.

ii. Organisation of Pharmaceutical Producers of India (OPPI) established in 1965, is a premier association of research and innovation driven pharmaceutical companies in India and is also a scientific and professional body. OPPI Member Companies are committed to the ethical standards set out in this Code.

iii. The OPPI Code includes standards for the ethical promotion of pharmaceutical products to healthcare professionals and helps ensure that member companies' interactions with healthcare professionals and other stakeholders, such as medical institutions and patient organizations, are appropriate and perceived as such.

iv. OPPI member companies must comply directly with applicable national codes as and when they come into existence.

v. OPPI member companies are accountable for addressing and correcting infringements under relevant codes. Companies not in membership with OPPI may notify OPPI in writing to be subject to the OPPI Code and its complaints handling processes.

vi. The OPPI is open to receiving complaints in writing or by email from any source on any aspect of the OPPI Code, in accordance with its operating procedures. However, no anonymous complaints will be considered. Where it is determined that there has been a breach of the OPPI Code, the objective is to correct the matter as rapidly as possible.

vii. OPPI acknowledges the role of relevant codes of ethics developed by IFPMA, the World Medical Association, the International Council of Nurses and the International Federation of Pharmacists. OPPI also recognizes the role of Ethical Criteria for Medicinal Drug Promotion provided by the World Health Organization in1988.

viii. Effective 31st December, 2012 the "OPPI Code of Pharmaceutical Practices 2012" replaces the "OPPI Code of Pharmaceutical Marketing Practices 2010".

1. SCOPE & DEFINITIONS:

1.1 Scope: The OPPI Code covers interactions with healthcare professionals, organizations /associations of healthcare professionals, medical institutions and patient organizations, and the promotion of pharmaceutical products. Where direct promotion to the public is allowed, this is covered by local laws, regulations and/or relevant codes of practice. Member companies should, of course, comply with these local laws, regulations and/or codes.

1.2 Definitions: 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, or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, or administer a pharmaceutical product.

- "company" means any pharma company that is a member of OPPI that agrees to abide by this Code.

- "patient organization" means typially 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 healthcare professionals and/or that provides healthcare or conducts healthcare research.

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 legitimate consultancy or other legitimate 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. BASIS OF INTERACTIONS:

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 **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 36)

2.3 **Independence of Healthcare Professionals:** No financial benefit or benefit-in-kind 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.

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

2.5 **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.

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. Q & A 8 (see Page 36)

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.

4.2 **Substantiation:** Promotion should be capable of substantiation either by reference to the approved labeling or by scientific evidence. Such evidence should be made available on request to healthcare professionals. Companies should deal objectively with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry. Q & A 9 – 10 (see Page 40-41)

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. Q&A 11 (See Page 41)

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 and Meetings

7.1.1 Scientific and Educational Objectives: The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an "Event") for healthcare professionals organised or sponsored by a company should be to inform healthcare professionals about products/therapy and/or to provide scientific or educational information.

7.1.2 Travel Facilities: Member companies or their representatives shall not give any travel facility inside the country or outside, including rail, air, ship, cruise tickets, paid vacations, etc. to healthcare professionals for self and family members for vacation or for

attending conferences, seminars, workshops, CME programme, etc. as a delegate.

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.) 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.

7.1.4 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.

7.1.5 Affiliation: Member companies may engage a medical practitioner in advisory capacities, as consultants, as researchers, as treating doctors or in any other professional capacity. In doing so, a member company shall always:

- Ensure that healthcare professional's integrity and freedom is not compromised;
- Ensure that patients' interest is not compromised in any way;
- Ensure that such affiliations are within the law;
- Ensure that such affiliations/employments are fully transparent and disclosed, wherever required under law.

7.1.6 Hospitality: Member companies shall not provide any hospitality like hotel accommodation to healthcare professionals and family members under any pretext with the exception of as elaborated under clauses 7.1.5 and 7.4.

7.1.7 Entertainment: No entertainment or other leisure or social activities should be provided or paid for by member companies. Q&A 12 (see page 42)

7.2 Sponsorships: Member Companies may sponsor healthcare professionals who are affiliated consultants to attend events by signing appropriate agreements in accordance with the clause 7.1.5 and clause 7.4. The

event should comply with the requirements of the Code as described in clause 7.1

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

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

- a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services;
- a legitimate need for the services must be clearly identified and documented in advance;
- the criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service;
- the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;
- the hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine; and

the compensation for the services must be reasonable and reflect the fair market value of the services provided. Q & A 13 (see Page 42)

7.5 Cash, Gifts and Promotional Aids:

7.5.1 Cash: Member Companies shall not provide to a medical practitioner any cash or monetary grant for individual purpose in individual capacity under any pretext.

7.5.2 Gifts: Member Companies or their sales people or representatives shall not provide any gift to a medical practitioner.

7.5.3 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. Q & A 14 (see Page 38)

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 or to persons duly authorised by them who are qualified to prescribe such products 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. CLINICAL RESEARCH AND TRANSPARENCY

9.1 Transparency: Companies are committed to the transparency of clinical trials which they sponsor. It is recognized that there are important public health benefits associated with making clinical trial information more publicly available to healthcare practitioners, patients, and others. Such disclosure, however, must maintain protection for individual privacy, intellectual property and contract rights, as well as conform to legislation and current national practices in patent law.

Companies disclose clinical trial information as set out in the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (2009) and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (2010) issued by the IFPMA, the European Federation of Pharmaceutical Industries and Associations(EFPIA), the Japanese Pharmaceutical Manufacturers Association (JPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA).

9.2 Distinction from Promotion: All human subject research must have a legitimate scientific purpose. Human subject research, including clinical trials and observational studies, must not be carried out as a disguise for brand promotion.

10. SUPPORT FOR CONTINUING MEDICAL EDUCATION

Continuing Medical Education (CME) helps ensure that healthcare professionals obtain the latest and most accurate information and insights on therapeutic areas and related interventions that are critical to the improvement of patient care and overall enhancement of the healthcare system.

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 OPPI Code where applicable.

11. COMPANY PROCEDURES AND RESPONSIBILITIES:

11.1 Procedures: Companies should establish and maintain appropriate procedures to ensure compliance with relevant codes and applicable laws and to review and monitor all of their activities and materials in that regard.

11.2 Training: Each member company shall provide to its employees and in particular the sales and marketing employees the training on this Code to ensure that they understand the procedure and their responsibilities and follow the guidance under this code while representing their employer company. The member companies shall maintain with them the record of such training provided to their respective employees.

11.3 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.

12. INFRINGEMENT, COMPLAINTS AND ENFORCEMENT:

12.1 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 1 - "OPPI Code of Pharmaceutical Practices Operating Procedure" and Appendix 2 - "OPPI Secretariat Standard Operating Procedures".

12.2 Measures to Ensure and Enforce Compliance: OPPI strongly encourages its members to adopt procedures to assure adherence to the Code.

13. INTERACTIONS WITH PATIENT ORGANIZATIONS

13.1 Scope: This covers all the interactions the Member companies will have with any patient organizations duly registered and or recognized under the Indian laws or the institutes/bodies representing the welfare of the patients in general.

13.2 Declaration of Involvement: When working with patient organizations, companies must ensure that the involvement of the company and the nature of that involvement are 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 15 (see Page 43)

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

13.4 Events: Companies may provide financial support for patient organisation meetings provided that the primary purpose of the meeting is professional, educational and scientific in nature, or otherwise supports the mission of the patient organization. When companies hold meetings for patient organizations, companies must ensure that the venue and location is appropriate and conducive to informational

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

Appendix 1

OPPI Code of Pharmaceutical Practices Operating Procedure

1. THE PROCEDURE FOR CODE COMPLAINTS :

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

1.2 Process :

(A) 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 promotional material / 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.

(B) Invalid Complaint: Complaints not received in writing or by email and anonymous complaints will be considered invalid. 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.

(C) Processing a Valid Complaint

Inform: 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.

Time Limits: In an accompanying letter OPPI must state the time within which a response must be received. This will normally be 30 calendar days from the company's receipt of the documentation. In exceptional cases the OPPI Secretariat can grant an extension to the time allowed. If the complaint is from outside the pharmaceutical industry the OPPI Secretariat may suggest the sections of the Code to be addressed in the response.

1.3 **Non-OPPI Member Companies:** When a case refers to a company that is not subjected to Code, the case cannot be processed formallY.

1.4 **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.

1.5 **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.

1.6 **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.

1.7 **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 member from Medical, Regulatory, Biotechnology, Diagnostics and Vaccines Committee, Ethics, Marketing Code & Compliance Committee and Legal & IP Committee.

Appeal Group consists of 2 members from Medical, Regulatory, Biotechnology, Diagnostics & Vaccines Committee, and one each from Executive Committee, Ethics, Marketing code & Compliance Committee and Legal & IP Committee.

In case of conflict of interest, the Director General or his nominee will induct alternate members from uninvolved companies in Adjudication and Appeal Groups on a case to case basis.

1.8 **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, media person or holder of a public office, 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
Organisation of Pharmaceutical Producers of India
Peninsula Corporate Park
Peninsula Chambers, Ground Floor
Ganpatrao Kadam Marg, Lower Parel
Mumbai 400 013.
Telephone: +91 22 2491 8123 / 2491 2486
Email: kanchana.tk@indiaoppi.com

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

2.4 Status Reports

OPPI will regularly issue a Status Report on the OPPI Code, summarizing its operation, related OPPI activities and recent industry development in the area of self-regulation. The report is published and given wide circulation to Government health departments, World Health Organisation (WHO), the technical press and leading medical journals, and to member companies of OPPI.

Appendix 2

OPPI Secretariat Standard Operating Procedures

Action List for the Processing of Complaints by OPPI

A) Validation of a Complaint

- **Consideration by OPPI Secretariat**

1) Unless there is a 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) Is the Company alleged to be in breach a Member of OPPI?

5) 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?

6) 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 OPPI Secretariat**

1) If a complaint is not covered by the OPPI Operating Procedure, the OPPI must refer it to the company concerned. In addition, a copy must be sent to the relevant member company.

2) If a complaint is not covered by the OPPI Operating Procedure, the OPPI must refer it to the company concerned. In addition, a copy must be sent to the relevant member company.

3) Except as dealt with above, if a complaint cannot be validated it must not be processed and where possible the complainant must be notified accordingly (the complainant would normally be advised). In appropriate cases, OPPI can refer the complainant or forward the complaint to an appropriate member company.

C) Processing a Valid Complaint

- **Procedure for OPPI Secretariat**

1) The complaint and support evidence must be sent to the senior management of the company alleged to be in breach at its headquarters and at the local level within 5 working days of its receipt by OPPI.

2) In an accompanying letter OPPI must state the time within which a response must be received. This will normally be 30 calendar days from the company's receipt of the documentation. In exceptional cases OPPI Secretariat can grant an extension to the time allowed. If the complaint is from outside the pharmaceutical industry the OPPI Secretariat may suggest the sections of the Code to be addressed in the response.

3) The respondent company must be asked for full details

if it rejects the allegation, the reasons must be clearly stated and, where appropriate supporting data must be provided.

4) The respondent company must be informed that if it acknowledges that it has breached the OPPI Code, it must indicate what action has been taken or will be taken to remedy the matter.

D) Adjudication

- **Procedure for OPPI Secretariat**

1) The case must normally be decided within 30 working days from the receipt of the company's response. Following a request from one of the adjudication bodies, the OPPI 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 OPPI Secretariat must refer the complaint to an ad hoc group of 3 individuals experienced in the application of Codes and selected from member companies. Decisions are made by a simple majority without participation by any members of OPPI Staff. The Adjudication Group can ask the OPPI Secretariat to obtain expert advice.

3) The Adjudication Group must decide whether consideration of the complaint can proceed. If the complaint is under investigation then the Adjudication Group cannot consider the case and it must also inform the OPPI Secretariat so that the case can be suspended. In such circumstances the OPPI Secretariat informs the complainant that the case is being considered elsewhere.

4) The Adjudication Group will provide the OPPI Secretariat with its decision and reasons for it. The OPPI Secretariat will contact the parties with details of the decisions and inform the parties of the process for accepting the decision including the provision of a Compliance Statement where required or the process for appealing the first decision.

E) Appeals

- **Procedure for OPPI Secretariat**

1) The complainant or a company ruled in breach may, within 30 calendar days appeal against the ruling. If new facts or arguments are put forward, the other party has 30 days in which to comment on them.

2) OPPI Secretariat must refer the matter to an ad hoc Group of 5 individuals experienced in the application of national codes and selected from member companies (other than the individuals participating in the first instance ruling).

3) Decisions are taken by simple majority without the participation by any member of OPPI staff. The Appeal Group can ask the OPPI Secretariat to obtain expert advice.

4) The Appeal Group will provide the OPPI Secretariat 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 OPPI Secretariat**

1) Where a breach is ruled, a summary of the case must be made public immediately on the OPPI website. The information to be disclosed is the identity of the

complainant, the identity of the company in breach of the OPPI Code, the names of the product or products where relevant, the country in which the breach took place and summary of the key facts.

2) Where no breach is ruled, a summary of the case must be made immediately on the OPPI website. The information to be disclosed is the country in which the activity took place and a brief summary of the key facts. The respondent company, the product and the complainant are not named.

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

4) A copy of the material to be published is provided to the respondent company for information only.

QUESTIONS & ANSWERS

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

1 Communications with the Public

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

A: No. The OPPI Code covers interactions with healthcare professionals and other stakeholders, such as medical institutions and patient organizations, and the promotion of pharmaceutical products. Where direct promotion to the public is allowed, this is covered by local laws, regulations and/ or relevant codes of practice. Member companies should of course, comply with these local laws, regulations and/or codes.

2 Code Application

Q: To whom does the OPPI Code apply?

A: The OPPI Code applies to OPPI's member companies. Pharmaceutical companies that are not members of OPPI fall outside the reach of the OPPI Code. OPPI encourages such companies and other organizations marketing healthcare products or services to healthcare professionals, or those having interactions with healthcare professionals, medical institutions and patient organizations to follow ethical standards for promotion and interactions, similar to those set forth in the OPPI Code.

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

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

- Promotion of prescription only pharmaceutical products directly to the general public (i.e. Direct To Consumer advertising);
- Promotion of self-medication products that are provided “over-the-counter”(OTC) directly to consumers without prescription;
- Pricing or other trade terms for the supply of pharmaceutical products, including promotion and marketing of pharmaceutical products to commercial customers;
- Certain types of non-promotional information or activities (Refer Part 6 of Q&A); and
- Promotion of medical devices

3 Disease Awareness Campaigns

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

A: The OPPI Code covers interactions with healthcare professionals, medical institutions and patient organizations, and the promotion of pharmaceutical products. A public disease awareness campaign targeted at the public must not promote specific pharmaceutical products. Whilst not covered by the OPPI 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?

A: Promotion of self-medication for the scheduled drug (Schedule H and X) as indicated in the Drugs and Cosmetics Act, 1940 (DCA), the Drugs and Cosmetics Rules, 1945 (DCR) is not permitted in India. However, promotion of OTC products to consumers, not belonging to schedule H and X, falls outside the scope of this Code.

5 Pricing and Terms of Trade

Q: Does the OPPI Code prohibit member companies from giving its customers discounts or other favourable trade terms for the supply of pharmaceutical products?

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

Q: Does the OPPI Code apply to the promotion and marketing of pharmaceutical products to commercial customers who are also practising healthcare professionals operating his/her own practice.

A: The OPPI Code does apply to the promotion and marketing of pharmaceutical products to such a customer. However, the OPPI 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 comply with the requirements of the OPPI Code.

Q: Does the OPPI 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 OPPI 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 OPPI 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 OPPI 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 OPPI complaints procedure applies.

6 Non-Promotional Information

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

A: Correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product is not covered by the Code.

Non-promotional, general information about companies (such as information directed to investors or to current/ prospective employees), including financial data, descriptions of research and development program, and discussion of regulatory developments affecting the company and its products is also not covered by the Code.

7 Disguised Promotion

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

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

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

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

8 Consistency of Information

Q: What level of detail is required to be included on 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.

9 Use of Comparisons

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

A: Yes. Any comparison made between different pharmaceutical products should be based on relevant and comparable aspects of the products and be capable of substantiation. Comparative advertising should not be misleading.

10 Use of Quotations

Q: Does the OPPI Code allow for quotations to be included in promotional materials?

A: Yes. Quotations from medical and scientific literature or from personal communications should be faithfully reproduced (except where adaptation or modification is required in order to comply with any applicable codes, in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified. Quotations should not change or distort the intended meaning of the author or the significance of the underlying work or study.

11 Reprints

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

A: No. Reprints of scientific and medical articles, when used as stand-alone documents, are not developed by pharmaceutical companies and as such cannot be considered as promotional materials. If, however, they are proactively presented to a healthcare professional together, with other, company originated documents, they then become promotional materials. In all cases, where promotion refers to, includes, or is presented together with scientific or medical articles or studies, clear references should be provided. Any reprint of artwork (including graphs, illustrations, photographs or tables) taken from articles or studies and included or presented with promotional materials should clearly indicate the source of the artwork and be faithfully reproduced.

12 Entertainment

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

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

13 Engagement of Services from Healthcare Professionals

Q: When a health professional is employed by a company to speak at a meeting can that company

reimburse out of pocket expenses including travel and accommodation?

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

14 Promotional Aids

Q: What can be given as a promotional aid?

A: A promotional aid is a non-monetary item given for a promotional purpose. Promotional aids can only be given to healthcare professionals as defined in Article 1.2. Promotional aids must be related to the work of the recipient healthcare professionals and should be of minimal value and quantity. Possible examples include inexpensive pens and notepads. Promotional items intended for the personal benefit of the healthcare professional, such as music CDs, paintings or food baskets are not acceptable. Promotional literature such as detail aids, leave-behind pieces, booklets, etc. are not considered to be promotional aids as meant in Article 7.1.3

15 Interactions with Patient Organisations

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

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

OPPI Mission

To make continuing contribution towards achieving healthcare objectives of the nation while professionally addressing the collective interests of its members and encouraging innovation for inclusive growth.

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