OPPI Code of Pharmaceutical Practices 2019

December 2018

OPPI

Organisation of Pharmaceutical Producers of India
Peninsula Chambers, Ground Floor, Peninsula Corporate Park
G.K. Marg, Lower Parel, Mumbai 400 013,
Tel: +91 22 2491 8123, 2491 2486, 66627007
www.indiaoppi.com

Follow us on:

OPPI

Doing Business
The Right Way

OPPI Code of Pharmaceutical Practices

OPPI ETHOS

Members of the Organisation of Pharmaceutical Producers of India (OPPI) are involved in the discovery of new medicines and vaccines for present and future generations and provide the latest scientific and educational content in order to benefit patients and support high-quality patient care. Pharmaceutical companies discover, develop, promote, sell and distribute their products in an ethical manner and in accordance with all the rules and regulations for medicines and healthcare.

The Ethos sets out the foundation to inform the 2019 OPPI Code of Practice which applies to the conduct of OPPI member companies and anyone acting on their behalf. The overarching values of trust, care, fairness, respect and honesty guide their actions. This set of core values and principles helps ensure that their interactions with healthcare professionals and the broader health community are appropriate and in line with ever-changing society's expectations. The Ethos is the baseline from which OPPI members work: It underpins the rules and provides a framework to behave with integrity no matter how testing the circumstances.

TRUST

Act with integrity and honesty to improve patient care and build trust with those we serve and to respect the independence of healthcare providers, patients and other stakeholders.

CARE:

Protect the safety of those who use our products-from the conduct of clinical trials and throughout the product life cycle.

- **INNOVATION:**
  Improve global health through innovative products and services, upholding the highest ethical, scientific, and medical standards.

- **QUALITY:**
  Commit to providing high-quality products that have proven clinical efficacy and have a reliable safety profile.

FAIRNESS:

Support and respect fair trade practices and open competition.

- **INTEGRITY:**
  Act responsibly, ethically and professionally. Do not offer, promise, provide, or accept anything of value in order to inappropriately influence a decision, gain an unfair advantage.

- **ACCOUNTABILITY:**
  Be accountable for our actions and decisions, including the appropriate oversight of external third parties that act on our behalf.

RESPECT:

Respect all people and embrace a culture of diversity and inclusion. Protect the environment . Treat animals under our care responsibly.

- **PRIVACY:**
  Respect privacy rights and appropriately manage and protect personal information.

- **EDUCATION:**
  Support the advancement of the scientific and medical education for the ultimate benefit of patients.

HONESTY:

Ensure truthful and balanced communication with governmental authorities, healthcare professionals, patients and other stakeholders.

- **SPEAKING UP:**
  Foster a culture in our respective organizations where concerns are shared openly and honestly so that we learn from mistakes and continuously improve.

- **TRANSPARENCY:**
  Advance science and patient care by sharing industry-sponsored clinical trial data in a responsible, accurate and appropriate manner.

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 ensure that their interactions with stakeholders 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 IFPMA 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 OPPI 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 OPPI 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 OPPI 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 infringements under relevant codes and comply with the actions initiated and actions taken by OPPI under the applicable national code/s. Companies not in membership with OPPI may notify OPPI in writing to be subject to the OPPI Code and its complaints handling processes.

vi. 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 complaints handling processes and 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 breach 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 in 1988.

viii. Effective 1st January, 2019, the "OPPI Code of Pharmaceutical Practices 2019" replaces the "OPPI Code of Pharmaceutical Marketing Practices 2012".

1. SCOPE & DEFINITIONS:

1.1 Scope:

The OPPI Code covers interactions of OPPI member companies 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. OPPI member companies should, of course, comply with the applicable local laws and regulations.

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 typically a not-for-profit institution that primarily represents the interests and needs of patients, their families and/or caregivers.

- "medical institution" means typically an organization that is comprised of healthcare professionals and/or that provides healthcare or conducts healthcare research.

1.3 Exclusions:

This Code does not seek to regulate the followingactivities:

- 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 regulations and 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.

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.

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;

- Recommended dosage, method of use and where not obvious, method of administration;
- Date of production of the promotional materials; 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 (Objectionable Advertisements) Act, 1954, Drugs and Cosmetics Rules, 1945 and other applicable laws as amended from time to time.

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:

OPPI member companies will comply with the applicable local laws while interacting with the healthcare professionals affiliated to government institutions and hospitals

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 road, 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 must be consistent with the applicable local laws, regulations and/or codes on ethics and promotion. Such promotional information 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:

i. Ensure that healthcare professional's integrity and freedom is not compromised;
ii. Ensure that patients' interest is not compromised in any way;
iii. Ensure that such affiliations are within the law;
iv. 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 to the healthcare professionals by member companies.

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 , except in cases of medical necessity.

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. The compensation arrangement may include reimbursement of reasonable expenses including travel, meals and accommodation.
- Funding for medical research, study etc. received by the healthcare professional is through approved institutions by modalities laid down by law / rules / guidelines adopted by such approved institutions, in a transparent manner and is fully disclosed.

7.5 Cash, Gifts and Promotional Aids:

7.5.1 Prohibition of Gifts:

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

7.5.2 Promotional Aids:

A promotional aid is a non-monetary item given for a promotional purpose (which does not include promotional materials as defined in Articles 5 and 6). Providing or offering them to HCPs in relation to the promotion of prescription-only medicines is prohibited. Promotional aids of minimal value and quantity as permitted under the local laws, codes or guidelines may be provided or offered to HCPs solely for promotion of over the counter medicines, if relevant to the practice of the HCP.

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

Items of medical utility may be offered or provided by member companies if such items are of modest value, do not offset routine business practices and are beneficial to enhancing the provision of

medical services and patient care. They should not be offered on more than an occasional basis, even if each individual item is appropriate. Items of medical utility can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

7.5.4 Informational or Educational Items that enhance Patient Care

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

Informational and educational items provided to HCPs for patient use can include the company name, but must not be product

branded, unless the product's name is essential for the correct use of the item by the patient.

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

7.5.5 Guidance on Values

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

"modest value" for items of medical utility

"reasonable value" for scientific books and journal subscriptions for the Library of hospital / institutions

8. SAMPLES:

8.1 Samples Permitted:

In accordance with local laws, regulations, Guidelines and Code, free samples of a pharmaceutical product may be supplied to healthcare professionals directly or to persons duly authorised by them to or to receive such samples on their behalf 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

OPPI member 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. OPPI members shall not carry out human subject research, including clinical trials and observational studies, as a disguise for brand promotion.

Any study conducted on the efficacy or otherwise of the study drug may be presented to and/or through appropriate scientific bodies or published in appropriate scientific journals.

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.

OPPI member 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" and Appendix 2 -"OPPI Secretariat Standard Operating Procedure".

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 PATIENTS 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, member 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.

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.

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 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 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 the 'Adjudication Group' comprising 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.

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.

1.9 Publication of the Outcome:

When a complaint is upheld and breach of the OPPI Code is determined, or not 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:

The 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: dg@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.

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 cannot be validated because the information provided is inadequate, the complainant must be given an opportunity to provide the additional information needed.
2. If a complaint is not covered by the 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

Composition of the Adjudication and Appeal Groups

The OPPI Secretariat recommends individuals from member associations for the ad hoc groups for adjudication and appeal, respectively for a two-year period. Individuals are chosen based on their expertise. Interested individuals can also volunteer to serve on either group. Individuals with conflict of interest will not form part of the said ad hoc groups for adjudication and appeal. All appointments must be approved by the OPPI Executive Committee.

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 decision of the Adjudication Group. 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 made 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.

APPENDIX 3

OPPI Procedural Requirements

Role of OPPI

OPPI designates a member of its staff to undertake all necessary activities in relation to this operating procedure. OPPI also establishes the OPPI Ethics and Business Integrity Work Group, comprised of individuals experienced in the application of industry codes from member companies. 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 ;
- 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 OPPI complaints procedure as described in 2.5 and 2.6; and
- To stimulate discussions about new challenges related to industry's promotion and marketing practices.

OPPI arranges regular consultations of the Work group. Periodic reports on the operation of the OPPI Code are submitted to the OPPI Executive Committee.

Status Reports

OPPI will regularly issue a Status Report on the OPPI Code, summarizing its operation, related OPPI activities and recent industry developments in the area of self-regulation.