Code of Marketing Practice for Indian Pharmaceutical Industry

This is a voluntary code of Marketing Practices for Indian Pharmaceutical Industry , for the present and its implementation will be reviewed after a period of six months from the date of its coming into force and if it is found that it has not been implemented effectively by the Pharma Associations/Companies , the Government would consider making it a statutory code.

1. General Points

1.1 A medicinal product must not be promoted prior to receipt of the product authorization , authorizing its sale or supply.

1.2 The promotion of a medicinal product must be consistent with the terms of the product authorization.

1.3 Information about medicinal products must be up-to-date, verifiable and accurately reflect current knowledge or responsible opinion.

1.4 Information about medicinal products must be accurate, balanced, fair, objective, and must not mislead either directly or by implication.

1.5 Information must be capable of substantiation.

1.6 Substantiation that is requested pursuant to para 1.5 above must be provided without delay at the request of members of the medical and pharmacy professions including the members of those professions employed in the pharmaceutical industry.

2. Claims & Comparisons

2.1 Claims for the usefulness of a medicinal product must be based on an up-to-date evaluation of all the evidence .

2.2 The word “safe” must not be used without qualification and it must not be stated categorically that a medicine has no side effects, toxic hazards or risk of addiction

2.3 The word “new” must not be used to describe any medicinal product which has been generally available, or therapeutic indication which has been generally promoted, in India for more than 12 months.

2.4 Comparisons of medicinal products must be factual, fair and capable of substantiation. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by undue emphasis, omission or in any other way.

2.5 Brand names of products of other companies must not be used in comparison unless the prior consent of the companies concerned has been obtained.

2.6 Other companies, their products, services or promotions must not be disparaged either directly or by implication.

2.7 The clinical and/or scientific opinions of members of healthcare professionals must not be disparaged either directly or by implication.

3. Textual and Audio-Visual Promotional Material

3.1 All promotional material issued by a product authorisation holder or with his authority, must be consistent with the requirements of this Code.

3.2 Where the purpose of promotional material is to provide persons qualified to prescribe or supply with sufficient information upon which to reach a decision for prescribing or for use, then the following minimum information, must be given clearly and legibly and must be an integral part of the advertisement:

(i) The relevant product authorisation number and the name and address of the holder of the authorisation or the business name and address of the part of the business responsible for placing the medicinal product on the market;

(ii) The name of the product, and a list of the active ingredients, using the common name, placed immediately adjacent to the most prominent display of the name of the product;

(iii) Recommended dosage, method of use and, where not obvious, method of administration;

(iv) Adverse reactions, warnings and precautions for use and relevant contraindications of the product;

(v) A statement that additional information is available on request;

(vi) The date on which the above particulars were generated or last updated.

3.3 Promotional material such as mailings and journal advertisements must not be designed to disguise their real nature. Where a pharmaceutical company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble editorial matter.

3.4 All promotional materials appearing in journals, the publication of which is paid for or secured or arranged by a company and referring by brand name to any product of that company, must comply with Clause3.3 of this Code as appropriate, irrespective of the editorial control of the material published.

3.5 Promotional material must conform, both in text and illustration, to canons of good taste and must be expressed so as to recognize the professional standing of the recipients and not be likely to cause offence.

3.6 The names or photographs of healthcare professionals must not be used in promotional material .

3.7 Promotional material must not imitate the devices, copy, slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.

3.8 Where appropriate (for example, in technical and other informative material), the date of printing or of the last review of promotional material must be stated.

3.9 Extremes of format, size or cost of promotional material must be avoided.

3.10 Postcards, other exposed mailings, envelopes or wrappers must not carry matter which might be regarded as advertising to the lay public or which could be considered unsuitable for public view.

3.11 Audio-visual material must be accompanied by all appropriate printed material so that all relevant requirements of the Code are complied with.

4. MEDICAL REPRESENTATIVES

4.1 The term “medical representative” means sales representatives, including personnel retained by way of contract with third parties, and any other company representatives who call on healthcare professionals, pharmacies, hospitals or other healthcare facilities in connection with the promotion of medicinal products.

4.2 Medical representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties. They must comply with all relevant requirements of the Code.

4.3 Medical representatives must not employ any inducement or subterfuge to gain an interview. They must not pay, under any guise, for access to a healthcare professional.

4.4 Companies are responsible for the activities of all their employees and must ensure that employees who are concerned in any way with the drafting or approval of promotional material (including employees of third parties contracted on behalf of the company) are fully conversant and compliant with the requirements of the Code.

4.5 Other third parties working for or on behalf of pharmaceutical companies, (including advertising companies executives, business consultants and market research companies), and those that do not act on behalf of companies (such as joint ventures and licensees) commissioned to engage in activities covered by the Code should also have a good working knowledge of the Code.

5. Samples

5.1 Free samples of medicinal products shall not be supplied to any person who is not qualified to prescribe such product.

5.2 Where samples of products are distributed by a medical representative, the sample must be handed directly to a person qualified to prescribe such product or to a person authorised to receive the sample on their behalf.

5.3 The following conditions shall be observed in the provision of samples to a person qualified to prescribe such product:

(i) Such samples are provided on an exceptional basis only (see (ii) to (vii) below) and for the purpose of acquiring experience in dealing with such a product;

(ii) Such sample packs shall be limited to prescribed dosages for three patients ;

(iii) Any supply of such samples must be in response to a signed and dated request from the recipient;

(iv) An adequate system of control and accountability must be maintained in respect of the supply of such samples;

(v) Each sample pack shall not be larger than the smallest pack presented in the market;

(vi) Each sample shall be marked “free medical sample – not for sale” or bear another legend of analogous meaning;

(vii) Each sample shall be accompanied by a copy of the most up-to-date version of the Product Characteristics relating to that product.

5.4 A person shall not supply a sample of a medicinal product which is an anti-depressant, hypnotic, sedative or tranquillizer.

5.5 The companies will maintain a detail record of free samples distributed to Healthcare practitioners.

6. GIFTS

6.1 No gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply by a pharmaceutical company .

6.2 Gifts for the personal benefit of healthcare professionals (such as tickets to entertainment events) also are not be offered or provided.

7. Hospitality, Sponsorship & Meetings

7.1 Companies may legitimately provide assistance that is directly related to the bona fide continuing education of the healthcare professionals and which genuinely facilitates attendance of the healthcare professional for the duration of the educational aspect of the event held in India . Such support and assistance must however, always be such as to leave healthcare professionals' independence of judgment .

7.2 Where appropriate and depending on the time, location and length of the meeting, support to healthcare professionals may cover actual travel expenses, meals, refreshments, accommodation and registration fees. The events have to be organized in India only and all expenses mentioned above, must be incurred only for the events held in India.

7.3 Companies must not organise meetings to coincide with sporting, entertainment or other leisure events or activities. Venues that are renowned for their entertainment or leisure facilities or are extravagant must not be used.

7.4 Any hospitality offered to healthcare professionals must:

(i) Be reasonable in level and be likely to appear to independent third parties, to be reasonable;

(ii) Be secondary and strictly limited to the main purpose of the event at which it is offered;

(iii) Not exceed the level that recipients would normally be prepared to pay for themselves;

(iv) Not be extended to spouses or other accompanying persons, unless they are healthcare professionals who qualify as participants in their own right. Travel expenses are not to be paid for spouses or other accompanying persons, unless they are healthcare professionals who qualify as participants in their own right;

(v) Not include sponsoring, securing, organising directly or indirectly any entertainment, sporting or leisure events.

7.5 Funding of healthcare professionals to compensate them for the time spent in attending the event is not permitted.

7.6 All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, for example, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) (each, an "event") organized or sponsored by or on behalf of a company must be held at an appropriate venue in the country that is conducive to the main purpose of the event.

7.7 The companies must maintain a detail record of expenditure incurred on these events.

8. Mode of Operation

8.1 All the Indian Pharmaceutical Manufacturer associations will have UCMP uploaded on their website.

8.2 All the associations will upload the detail procedure (as stated in Para 10) of lodging complaints.

8.3 All the associations will have a detail of complaints received i.e. the nature of complaint, the company against whom the complaint has been made, the action

taken by the association including the present status in the complaint , uploaded on their web site for three years. Whenever proceedings in a complaint are completed, a copy of proceedings and decisions will be sent by the concerned Association to the Department of Pharmaceuticals, on following address:

Under Secretary(PI),
Room No-347, A-wing, Shastri Bhawan
New Delhi 110001

8.4 If a complaint received in a particular association is not concerned to its member, the receiving associations will input the details of the complaint but in the column of action taken, it will mention that the complaint has been transferred to such and such association as the respondent company is not its member.

9. Committee for complaint Handling:

9.1 There will be a complaint handling committee named “Committee for Pharma Marketing Practices ” in all the associations.

9.2 The committee will have a panel of 5 member companies, represented by the Executive head of the companies or a nominee from the Executive Head , but not below the rank of Director in the Board of Company.

9.3 Based on the complaint, specially, the company involved (either as complainant or as respondent), the Secretary General/Chairman/President (to be decided by the Executive Body of the Association) of the association will decide three members from the panel of 5 for handling the complaint.

9.4 There will be a review committee for which there will be a panel of seven member companies of the association and based on the company involved, Secretary General/Chairman/President of the Association will nominate five members for review committee including the three members of the complaint committee , who dealt with the complaint.

10. Procedure of Lodging a complaint:

10.1 All correspondences should be addressed to the “Committee for Code of Pharma Marketing” , Secretary General/Chairman/President, “Name of Association”.

10.2 All complaints about any one activity should to the extent practicable be made at one time.

10.3 Complaints must be in writing and for each case **THE COMPLAINANT** should:

i) identify himself (whether a company or an individual) with a full mailing address (fax number, if possible, mobile telephone nos.). When the complaint is from a pharmaceutical company, the complaint must be signed or authorized in writing by the company’s managing director or chief executive or equivalent and must state those clauses of the Code which are alleged to have been breached.

ii) identify the company which is alleged to be in breach of the Code, and the name of any company personnel, product or products which are specifically involved.

iii) give the details of the activity which is alleged to be in breach of the Code.

iv) give the date of the alleged breach of the Code which must have occurred during the last two months of the date of making the complaint.

v) provide supporting evidence of the alleged breach(es).

10.4 A non-refundable charge of Rs.1,000/- by any complainant. **The associations will elaborate how this payment is to be made.**

10.5 The name of the complainant has to be kept confidential by the association.

10.6 When it appears from media reports (other than letters to the editor of a publication) that a company may have breached the Code, the matter will be treated as a complaint. The author of the article, or the editor where no author is named, will be treated as the complainant not the person who has brought this

report in the notice of the committee. If the editor or author declines involvement, this is stated in the case report.

10.7 A published letter from which it appears that a company may have breached the Code will be dealt with as a complaint with the author being treated as the complainant. The procedure set out in Paragraph (10.6) above shall be followed.

10.8 Any complaint received by the Department of Pharmaceuticals will also be forwarded to the concerned Association for necessary action. In such cases , the concerned association will further take up the matter with the complainant directly.

11. Procedure of handling of complaint

11.1 Once lodged a complaint, the complainant cannot withdraw it and it has to be dealt with by the committee.

11.2 The complaints will be received by the Secretary General/Chairman/President of the concerned associations.

11.3 The Secretary General/Chairman/President will mark the complaint to the senior most (by designation) member of the panel as Chairman , also indicate the names of other two members of the committee.

11.4 The decision will be made by majority.

11.5 When the committee receives information from which it appears that a company may have contravened the Code, the managing director or chief executive or equivalent of the company concerned will be requested to provide a complete response to the matters of complaint.

11.6 To assist companies in ensuring that a complete response is submitted the committee may suggest relevant supporting material to be supplied. It is the responsibility of the respondent to ensure that a full response is submitted.

11.7 The company against which the complaint is made should provide supporting evidence if it thinks that the Code has not been breached.

11.8 Upon receipt of information from the committee, the respondent company has ten working days in which to submit its comments and supporting documents to the committee.

11.9 The Committee shall render a decision within 30 days of receipt of the complaint with supporting documentation and shall promptly notify the parties of its decision, and the reasons therefore, in writing and by registered mail.

11.10 Where the committee rules no breach of the Code because it considers the matter of complaint is not within the scope of the Code the complainant will be so advised in writing. .

11.11 Where the committee rules that there is a breach of the Code, the complainant and the respondent company are so advised in writing and are given the reasons for the decision.

11.12 If a party to the complaint is dissatisfied with the decision of the Committee, it may request for review its decision. Any party requesting a review of a decision of the Committee shall notify the Secretary General/Chairman/President of the Association as per the guidelines for review given in clause 12.

11.13 If no request for a review of the Committee's decision is made within the period specified, the decision of the Committee shall be final and binding, and adherence to the decision shall be a condition of continued membership of the Association.

11.14 Once it is established that a breach of code has been made by a company, the committee can take one of the following decisions against the alleged company:

(i) To suspend or expel the company from the Association.

(ii) To reprimand the company and publish details of that reprimand.

(iii) To require the company to issue a corrective statement; details of the proposed content and mode and timing of dissemination of the corrective statement must be provided to the committee for approval and the same shall be put on the website of the Association.

(iv) To ask the company to take steps to recover items given in connection with the promotion of a medicine provided to health professionals and members of the public and the like; details of the action taken must be provided in writing to the Committee which will be uploaded on the website of the Association.

12. Review of Decisions of the Complaints:

12.1 The complainant or the respondent company may go for review against a ruling of the committee.

12.2 Once asked for a review, the complainant/respondent cannot ask for the withdrawal

12.3 A review by the complainant must be lodged within ten working days of notification of the ruling of the Committee.

12.4 Where the respondent company appeals, it must give notice of appeal within five working days of notification of the ruling of the committee and must lodge the review within ten working days of notification of the ruling of the Committee.

12.5 If a complaint concerns a matter closely similar to one which has been the subject of a previous adjudication, it may be allowed to proceed at the discretion of the committee if new evidence is adduced by the complainant or if the passage of time or a change in circumstances raises doubts as to whether the same decision would be made in respect of the current complaint. If a complainant does not accept a decision of the committee ,he may ask for the matter to be referred to the review committee and the decision of the review committee will be final.

12.6 If, in the view of the committee, a complaint does not show that there may have been a breach of the Code, the complainant shall be so advised. If the complainant does not accept that view, he may ask for review .

12.7 Where review is asked by the complainant, the respondent company has five working days to comment on the reasons given by the complainant for the review

and these comments will be circulated to the members of the review committee. The complainant has five working days to comment on the respondent company's comments upon the reasons.

12.8 Where review is asked by the respondent company, the complainant has five working days to comment on the reasons given by the respondent company for the review and these comments will be circulated to the respondent company and the review committee. The respondent company has five working days to comment on the complainant comments upon the reasons.

12.9 If the promotional material or activity at issue is considered by the committee to be likely to prejudice public health and/or patient safety, and/or it represents a serious breach of the Code, the committee must decide whether, if there is subsequently review by the respondent company , the use of the promotional material or the activity would continue during the period of review. If suspension of the promotional material or the activity during the period of review would be required, the company must be so notified when it is advised of the committee's ruling of a breach of the Code.

12.10 In case the respondent company accepts the breach of code , it has five working days to provide a written undertaking that the promotional activity or use of the material in question and any similar material (if not already discontinued or no longer in use) will cease forthwith and that all possible steps will be taken to avoid a similar breach of the Code in the future. This undertaking must be signed by the managing director or chief executive or equivalent of the company or with his authority and must be accompanied by details of the actions taken by the company to implement the undertaking, including the date on which the promotional material was finally used or appeared and/ or the last date on which the promotional activity took place.