

Pharma & Healthcare Update

August 29, 2011

PRODUCT PROMOTIONS - PHARMA COMPANIES UNDER RESTRICTIONS

INTRODUCTION:

In view of the recent uproar regarding incentives being given to the doctors by various pharmaceutical companies to make sure they prescribe their medicines, the Department of Pharmaceuticals in India ("DOP") released a Code of Marketing Practice for the Indian Pharmaceutical Industry ("DOP Code") in June, 2011. The DOP Code has put various restrictions on the practices adopted by companies while marketing medicines to doctors including banning all kinds of gifts to doctors.

At present, the DOP Code is voluntary. However, the Government will review the implementation by companies after a period of six months and then the Government may consider making it a statutory code if not implemented effectively.

Specific provisions relating to restrictions on benefits to be procured by doctors have also been incorporated in the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (MCI Code). Registered medical practitioners in India are required to adhere to the MCI Code, issued by the Medical Council of India, under the provisions of section 20A read with section 33(m) of the Indian Medical Council Act, 1956. In a recent amendment, the MCI Code has put restrictions on doctors in their dealings with the pharmaceutical and allied health sector industry.

Moreover, the Organization of Pharmaceutical Producers of India had issued a Code of Pharmaceutical Marketing Practices 2010 (the "OPPI Code"). The OPPI Code has set out specific standards for the promotion of pharmaceutical products ethically to the doctors. It is based on the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code that has been in practice for the last two decades. However, the OPPI Code is a matter of self regulation and self discipline on part of the member companies.

In this update, we have examined the combined effect of the DOP Code and the amendments to the MCI Code.

In India, advertisements of prescription drugs is not permitted. Hence, pharmaceutical companies promote medicines to doctors to convince them to prescribe their medicines with a view to increase the companies' sales. The sales representative of a pharmaceutical company, popularly known as a medical representative (MR) plays a vital role in this process. MRs hold meetings with doctors and explain the benefits of the drug along with the safety and the side effects of the drugs.

IMPORTANT FEATURES OF THE DOP CODE:

1. Timing of promotion

The promotion can be carried out only after product authorization by the office of the Drug Controller General of India (DCGI). The promotion should be consistent with the terms of product authorization. E.g. if the product authorization is only for one indication, the drug cannot be promoted for any other indication.

2. INFORMATION SUPPLIED

The information supplied must be accurate, fair, objective, verifiable and must not be misleading. In case of a request for additional substantiation by medical or pharmacy professionals, the same has to be provided without delay.

3. CLAIMS

The DOP has expressed concern over the use of the words "safe" and "new" by the companies or their MRs. The DOP Code mentions that "safe" should 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. If medicines are generally available in India for more than 12 months, then the term "new" should not be used.

4. PRODUCT COMPARISONS

As far as product comparisons are concerned, the DOP Code prescribes as follows:

- The comparisons of medicinal products must be factual, fair and capable of substantiation;
- Due care must be taken to ensure that comparison does not mislead by distortion, by undue emphasis, omission or in any other way;
- Brand names of the products of other companies should not be used without obtaining prior consent;
- Companies, their products, services or promotions as well as clinical and/or scientific opinions of members of

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healthcare professionals should not be disparaged, either directly or by implication.

5. PRODUCT PROMOTIONAL MATERIAL

The DOP Code prescribes certain do's and don'ts in relation to promotional material ("PM") and also prescribes the contents to be incorporated in such material. An illustrative list of the do's and don'ts is provided below:

| Do's | Don'ts |
|---|---|
| · PM to be consistent with the DOP Code | · The paid or secured PM in journals not to resemble the editorial matter |
| · Date of printing or of the last review of PM to be mentioned | · Photographs or names of healthcare professionals should not be used |
| · Audio-visual material to be accompanied by printed material in compliance with the DOP Code | |

6. GIFTS

Companies should not give any kind of gifts or promise, offer or supply any kind of pecuniary advantage or benefits to doctors including gifts for personal benefits such as tickets to entertainment events etc.

7. SAMPLES

The free samples that are provided by the companies must be supplied only to the qualified professionals and that too in response to a signed and dated request from the recipient. Detailed records of samples provided are required to be maintained. Such samples can be supplied only on an exceptional basis and for the purpose of acquiring experience in dealing with such a product. The sample pack should be limited to prescribed dosage for 3 patients and each sample pack shall not be larger than the smallest pack presented in the market. The DOP Code prohibits supply of samples of an antidepressant, hypnotic, sedative or tranquillizer.

8. HOSPITALITY, SPONSORSHIPS AND MEETINGS

As per the DOP Code, the companies are permitted to provide assistance to doctors for continuing education facilitating doctors' genuine attendance in such events. This assistance could cover actual travel expenses, meals, refreshments, accommodation and registration fees to attend such an event. The DOP Code has, however, laid down certain conditions: (i) events for which assistance will be provided must be held in India at an appropriate venue that is conducive to the main purpose of the event; and (ii) such events should not coincide with sporting, entertainment or other leisure events or activities or organized at venues that are renowned for their entertainment or leisure facilities or are extravagant. This assistance cannot be provided to a doctor's spouse unless the spouse is a doctor too and qualifies to attend such an event. The hospitality offered should be reasonable and strictly limited to the main purpose of the event. The funding provided should not be for the time spent in attending the event.

9. MEDICAL REPRESENTATIVES

MRs employed by the company or on contract with third parties are required to maintain a high standard of ethical conduct in the discharge of their duties and comply with all relevant requirements of the DOP Code. They are restricted from employing any inducement or subterfuge to gain an interview and paying, under any guise, for access to the doctor. It is important to note that the companies are made responsible for activities of its employees including MRs to ensure that the DOP Code has been complied with.

10. COMPLAINT HANDLING

The DOP Code has stipulated that each association of pharmaceutical companies shall form a "committee for pharma marketing practices" that will handle all the complaints received by them. The associations will also be required to form a review committee that will review the complaints, in case the review of the decision is sought. The DOP Code has also included the methodology for lodging and handling of complaints. The associations will be required to submit a copy of the proceedings and the decisions once the proceedings in a complaint are completed, to the DOP.

MCI CODE:

The Medical Council of India has amended the MCI Code to include specific restrictive provisions for doctors and professional associations of doctors in their relationship with the pharmaceutical and the allied health sector industry. The MCI Code has imposed the following restrictions on the doctors:

- A medical practitioner shall not receive any gift from any pharmaceutical or allied health care industry and their sales people or representatives;
- A medical practitioner shall not accept any travel facility inside the country or outside, including rail, air, ship, cruise tickets, paid vacations etc. from any pharmaceutical or allied healthcare industry or their representatives for self and family members for vacation or for attending conferences, seminars, workshops, CME programme etc as a delegate;
- A medical practitioner shall not accept individually any hospitality like hotel accommodation for self and family members under any pretext;
- A medical practitioner shall not receive any cash or monetary grants from any pharmaceutical and allied healthcare industry for individual purposes in individual capacity under any pretext. Funding for medical research, study etc. can only be received through approved institutions by modalities laid down by law / rules / guidelines adopted by such approved institutions, in a transparent manner. It shall always be fully disclosed;
- A medical practitioner may carry out, participate in or work on research projects funded by pharmaceutical and allied healthcare industries, after taking necessary clearances and fulfilling certain conditions;
- A medical practitioner shall not endorse any drug or product of the industry publicly.

In case of violation of these provisions by the medical practitioners, the MCI Code provides for disciplinary action.

In the recent past, in view of the restrictions imposed, a practice of entering into consultancy arrangements with pharmaceutical companies has developed. Under the MCI Code, a medical practitioner may work for pharmaceutical and allied healthcare industries in advisory capacities, as consultants, as researchers, as treating doctors or in any other professional capacity.

GLOBAL PRACTICES:

European Federation of Pharmaceutical Industries and Associations ("EFPIA"):

The EFPIA has prescribed a code of practice that covers the promotion of medicine to doctors. The said code has put restrictions on activities like events and hospitality organized by companies. However, the code does not specifically prohibit offering gifts to doctors, but it does state that the companies may offer inexpensive gifts that provide value to the practice of medicine or pharmacy.

Pharmaceutical Research and Manufacturers of America ("PhRMA") USA:

PhRMA has issued a set of voluntary guidelines for the members of the group regarding promotion of medicines to the doctors since 2002 and updated them in January 2009. The PhRMA code prohibits providing entertainment and recreation facilities including gifts that are non-educational to the doctors. However, it permits conducting CME and consulting arrangement with the doctors.

The office of the Inspector General for the U.S. Department of Health and Human Services has also issued guidelines similar to PhRMA code but with stricter penalties.

Singapore Association of Pharmaceutical Industries ("SAPI") code of marketing practices:

The SAPI Code has stipulated that no inappropriate financial or material benefits, including inappropriate hospitality, should be offered to doctors. It permits items of insignificant value of no more than \$20 provided free of charge but prohibits offering gifts and funds or cash that are inappropriate.

IMPLICATIONS:

The pharmaceutical companies will certainly be required to change their strategy to market the medicines to doctors and be more creative and innovative. Since MRs are actively involved in the promotion of prescription drugs, companies will be required to conduct intensive training so that even inadvertently the code is not violated.

At present, the DOP Code is voluntary, but the MCI Code is mandatory. After six months, if the DOP Code is incorporated as a statutory code, then pharma companies are likely to face prosecution or penalties in case of violation.

A review of the global practices seems to indicate that in some respects, the DOP Code and the MCI Code may be more restrictive than the codes / regulations in other jurisdictions. However, there are certain other aspects that are covered in other jurisdictions that are still not covered in the Indian codes. Further, some of the provisions under the MCI Code are more onerous than that of the DOP Code. E.g., while the DOP Code permits companies to provide assistance for travel and events within India, the MCI Code prohibits doctors from accepting the same. Hence, the government should, once again, take a look at both the codes, and re-align the same for more cohesive implementation.

- Dr. Milind Antani & Gowree Gokhale

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