DISCUSSION

A comparison of codes of pharmaceutical marketing practices

AMITAVA GUHA

Federation of Medical Representatives Associations of India, 372/21 Russa Road East, Kolkata 700033, India. e-mail: amitava45@vsnl.net

The promotion of any irrational drug combination is bound to be unethical. It is also unethical to promote an irrational claim. The need of determining an ethical code of promotion of medicine is important. The following codes were available for study:

- IFPMA code of Pharmaceutical Marketing Practices—updated in 1994
- Criteria for medicinal drug promotion—prepared by WHO in 1988
- Guidelines on IFPMA Code of Pharmaceutical Marketing Practices—prepared by OPPI, downloaded from their web page in August 2003
- International Code on Pharmaceuticals—prepared by Health Action International (HAI)

This is an attempt to compare different codes towards developing a suitable code for India.

Objectives of the codes

The IFPMA code says, 'The international pharmaceutical industry is committed to the improvement of the health of the mankind through research and development of new medicines and production and marketing of pharmaceutical products of reliable quality, in accordance with internationally defined standards of good practice.'

What is a new medicine? Many new drugs do not have any significant advantage over existing drugs. Many are produced with mere molecular manipulation to overcome a competitive edge and medicines with the same effect are sold at higher prices.

The WHO code states: 'The main objective of ethical criteria for medicinal drug promotion is to support and encourage the improvement of health care through the rational use of medicinal drugs.' The ethical criteria start from the validity of the drug itself: is the drug or combination of drugs rational?

Today another important question is that of the price of medicines. In this context, the HAI code is explicit: 'The aim of this code is to enable consumers, particularly those from the developing countries, to procure safe and effective pharmaceuticals essential to their real health needs, at a cost they can afford.'

Another question arising from IFPMA's code is that of 'internationally defined standards of good practice'. Is it possible to have such a standard when so many codes exist, all for voluntary implementation?

Applicability of the codes

While IFPMA confines the applicability of its code to its member organisations and affiliates in the industry, WHO expanded its scope to people in all walks of life: governments; the pharmaceutical industry (manufacturers and distributors); the promotion industry (advertising agencies, market research organisations and the like); health personnel involved in the prescription, dispensing, supply and distribution of drugs; universities and other teaching institutions; professional associations; patients and consumer groups; and the professional and general media (including publishers and editors of medical journals and related publications). This definition of applicability is widest of all the codes. However, as things stand, it is a futile statement and does not enable corrective measures for violation of the code.

Scope of the codes

The IFPMA code states that promotional activities within the scope of the code include direct to-consumer advertising, where this is permitted under local laws. In many Third World countries, no regulatory law for promotion of medicines exists. What will be the responsibility of the industry and who will monitor them?

The HAI code defines the scope in different sectors such as drug registration; registration of new drugs; pre-registration clinical trials of new drugs; provision of information; labelling; package inserts and promotional materials; sales promotion of pharmaceutical products; pricing; sales and distribution; pharmaceutical technology; and research and development. The HAI code also explains and defines each of these sectors. In the absence of such definitions, the scope of the Code become futile—a problem evident in several clauses of the IFPMA code.

Definition of promotion in the codes

The definition of 'promotion' is vital. WHO has stated, 'In this context, promotion refers to all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.'

For some reason the IFPMA code did not feel the need to provide such a definition. It states: 'Promotional materials for pharmaceutical products should be accurate, fair and objective and presented in such a way as to conform not only to legal requirements but also to high ethical standards and to be in good taste.' This statement is vague.

OPPI guideline have been more specific regarding promotion, defining it as: 'Promotional material on pharmaceutical products: printed literature (package inserts, data sheets, detail/visual aids, flip-charts, leave-behinds, mailings and advertisements); audio–visuals; sponsored symposia/conferences/guest lectures; gift items; information through medical representative training.'

However, OPPI has ignored advertising through the electronic media, gifts, literature or display materials given to wholesalers and chemists, the sponsoring of individuals to attend meetings/conferences, etc.

WHO has also defined 11 specific criteria for advertisements. OPPI mentions some four criteria and the IFPMA code mentions three. IFPMA categorises advertisements as 'all advertisements' and 'full advertisements'. Its code states that contraindications, side-effects and precautions must be mentioned only in 'full advertisements'. The HAI code defines advertisements as: 'Any representation conveyed by any means whatever for the purpose of promoting, directly or indirectly, the distribution or sale of any drug.'

Medical representatives

The IFPMA code mentions that medical representatives must be trained with sufficient medical and technical knowledge. They should also collect information from professionals about the use of a product.

The WHO criteria state that training must include updated and continuing training. The training should also include ethical conduct including training on codes. Also, medical representatives should not offer inducements to prescribers and dispensers, and prescribers and dispensers should not solicit such inducements.

The OPPI guidelines in this respect are:

- Adequate training should include information on basic medical sciences such as anatomy, physiology, microbiology and pharmacology.
- Sufficient medical knowledge should be given regarding aetiopathology and clinical aspects of the disease for which the product is used.
- The representatives should be properly trained to impart information in an accurate and scientific manner.

There is no reference to the appropriate conduct of a medical representative (MR). The company may refuse to take responsibility for the claims or quality of the campaign made by an MR.

The HAI code adds an important element by stating that the number of MRs 'must not exceed one representative per promoted pharmaceutical product per 500 registered physicians or other prescribers.' With the large product ranges of companies in India, this number would become outrageous. The number of MRs in each company must be restricted but so should the frequency of visits. The IFPMA only states that 'the frequency of printed material to healthcare professionals should be reasonable.'

Distribution of free samples

The OPPI remains quiet in this respect. The IFPMA states that 'samples may be given to prescribing professionals to familiarise them with the products, enable them to gain experience with the products in their practice, or on request.' WHO guidelines are more lenient, considering that free samples may be used by the weaker sections of society. However, in India, samples of old drugs are regularly distributed in large quantities. In some instances sale packs are also used as samples and these packs do not even contain the words 'free sample'. There is no regulation on the giving of samples. Some companies use the strategy of providing samples proportionate to the product's sales. This may lead to violation of ethics since samples should not be considered saleable.

Symposia and scientific meetings

The WHO code acknowledges the need for such meetings to be sponsored by manufacturers and distributors, and permits the giving of gifts or hospitality but they should be 'secondary'. The code states that 'any support to individual participants should not be conditional upon any obligation to promote any medical product.' This is absurd because obligation is implicit in such a relationship. Why else should a company sponsor individuals?

The IFPMA code states: 'payment of reasonable honoraria and reimbursement of out-of-pocket expenses, including travel, for speakers/prescribers are customary and proper,' but 'companies should not pay travel costs of persons accompanying invited members of the medical and allied professionals.'

In India, virtually no professional meetings are possible without the sponsorship of drug companies. In most of

these meetings the main events are sparsely attended but the funfair sponsored by drug companies are always crowded. There is no limit to the money spent here and no sign of modesty. Companies compete with each other to sponsor in more and more exotic ways.

Gifts

Gifts found in professionals' offices vary from trifles to expensive items, and most are unrelated to their work. Quoting the IFPMA code, OPPI states: 'Promotional items of insignificant value, provided free of charge, are permissible as long as they are related to the healthcare provider's work and/or entail a benefit to patients.' Gift items should bear the brand names of the product and the generic name, only if possible. The value of the gift should not be so high as to oblige doctors to prescribe.

Though simple gifts may not directly influence prescription practices, they would not be distributed unless they had some related impact. It has been pointed out that a policy of limiting gift size is unlikely to eliminate bias, because 'even small gifts can subtly bias how arguments are evaluated, they can be surprisingly influential.'

Other issues

The IFPMA code does not provide guidelines on pre-registration of a drug which is left to the regulation of the respective countries. Similarly, there is no mention of the procedure to be followed in post-marketing surveillance. However, WHO discusses both these issues.

As the WHO code dates back to 1988, it has not addressed problems related to advertising in the electronic media. The IFPMA code deals with both the electronic media and advertisements on the Internet, but is vague and has nothing to say on web pages created by drug companies.

The IFPMA has many details on complaints regarding the code's violation but global experience shows that few complaints have been entertained and there is almost no redressal.

Regulations in India

The less said about this the better. We have a Magic Remedies (Objectionable Advertisement) Act, 1954. It has only one relevant clause, Clause 4, on misleading advertisements which: directly or indirectly gives false impression regarding the true character of the drug; makes a false claim for the drug, or is otherwise false or misleading in any particular material. After almost 50 years, surely it is time to develop a code on pharmaceutical promotional practices that is suitable for India, and the appropriate legislation to enforce it.