

UNIFORM CODE OF MARKETING PRACTICES FOR THE INDIAN PHARMACEUTICAL INDUSTRY

INTRODUCTION

The Department of Pharmaceuticals in India issued the Uniform Code of Marketing Practices (the “**Uniform Code**”) as a voluntary code on 2nd June 2011. Its implementation will be reviewed after a period of six (6) months and if it is found that it has not been voluntarily and effectively implemented by Pharmaceutical Associations / Companies, the Government will consider making it a statutory or binding regulation. The Uniform Code is applicable to pharmaceutical companies / associations who are manufacturing and marketing medicinal products.

As and by way of background, the Medical Council of India passed the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 on 11th March 2002 (the “**IMC Regulations**”). While the Uniform Code lays down a policy that is recommended to be adhered to by pharmaceutical companies while marketing their medicinal products, the IMC Regulations prescribe, as a matter of law, the ethics and duties of physicians practicing the medical profession. In other words, while the IMC Regulations are binding and have to be complied with, the Uniform Code is not yet binding on pharmaceutical companies.

FEATURES OF THE UNIFORM CODE

The Uniform Code has laid down, in detail, points that Pharmaceutical Associations / Companies have to bear in mind while marketing their medicinal products. Important aspects of the Uniform Code are briefly summarized below:

1. Promotion of the medicinal product:

A medicinal product cannot be promoted prior to the receipt of the product authorization which authorizes its sale or supply. When product authorization has been obtained, promotion of such product has to be consistent with the terms of the product authorization.

2. Information supplied about the medicinal product:

Information supplied about the medicinal product must be accurate, balanced, fair, objective, up-to-date, verifiable, must accurately reflect current knowledge or responsible opinion and should not be misleading. Information so supplied must also be capable of substantiation, without delay, as and when requested by members of the medical and pharmacy professions.

3. Claims and Comparisons:

Claims of the usefulness of a medicinal product must be based on an up-to-date evaluation. Further, certain restrictions have been placed on the use of the words “safe” and “new”.

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.

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 twelve (12) months.

With respect to product comparisons, they must be factual, fair and capable of substantiation and should not be misleading. Further, brand names of products of other companies must not be used in comparison unless the prior consent of the companies concerned has been obtained.

4. Textual and Audio-Visual Promotional Material:

All promotional material issued by a product authorization holder must be consistent with the requirements of the Uniform Code. Certain details such as the active ingredients used in the medicinal product, recommended dosage, methods of use and administration, adverse reaction, warnings and precautions for use, to name a few, have to be mentioned clearly and legibly and must be an integral part of the advertisement. The IMC Regulations incorporates similar provisions that drugs prescribed by a physician or brought from the market for a patient should explicitly state the proprietary formulae as well as the generic name of the drug.

5. Medical Representatives:

The Uniform Code has defined the term “medical representatives” to mean 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.

The Uniform Code has laid down that medical representatives have to adhere to the Uniform Code while promoting medicinal products. Medical representatives have to, at all times, maintain a high standard of ethical conduct in the discharge of their duties. They must not employ any inducement or subterfuge to gain an interview and must not pay, under any guise, for access to a healthcare professional.

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 Uniform Code. Further, the Uniform Code states that 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 Uniform Code, must have a good working knowledge of the Uniform Code.

6. Samples:

The Uniform Code states that free samples of medicinal products cannot be supplied to any person who is not qualified to prescribe such product. The Uniform Code also lays down certain conditions that have to be observed while samples are being provided. Further, supply of samples of a medicinal product which is an anti-depressant, hypnotic, sedative or tranquillizer is not allowed.

7. Gifts:

The Uniform Code states that pharmaceutical companies / associations shall not offer or promise to offer, gifts, pecuniary advantages or benefits in kind to persons qualified to prescribe or supply medicinal products. Gifts for the personal benefit of healthcare professionals (such as tickets to entertainment events) should not be offered or provided.

While the Uniform Code lays down certain obligations on pharmaceutical companies, the IMC Regulations lay down reciprocal obligations for doctors and professional association of doctors with respect to gifts. The IMC Regulations prescribe that medical practitioners should not receive any gifts from any pharmaceutical or allied health care industry and their sales people or representatives.

8. Hospitality, Sponsorship and Meetings:

The Uniform Code lays down certain guidelines that need to be followed by pharmaceutical companies with respect to the hosting and the sponsorship of educational events in relation to the pharmaceutical industry. Pharmaceutical companies may legitimately provide assistance that is directly related to the *bona fide* continuing education of healthcare professionals and which genuinely facilitates attendance of such healthcare professionals for the duration of the educational aspect of the event held in India. Further, the Uniform Code makes it explicitly clear that such meetings should not coincide with sporting, entertainment or other leisure events or activities.

Likewise, the IMC Regulations provide that medical practitioners shall not accept any travel facility inside the country or outside, including rail, air, ship, cruise tickets, paid vacations from any pharmaceutical or allied healthcare industry or their representatives for self and family members for vacation or for attending conferences, seminars, workshops, continuing medical education programme as a delegate. A medical practitioner should not accept individually any hospitality, like hotel accommodation for himself and family members, and shall not receive any cash or monetary grants from any pharmaceutical and allied healthcare industry for individual purpose in individual capacity, under any pretext.

9. Mode of Operation:

All Indian Pharmaceutical Manufacture associations have to upload the Uniform Code, and a detailed procedure for lodging complaints, on their website.

10. Complaints / Breach:

The Uniform Code lays down in detail how complaints received by pharmaceutical companies should be handled. It states that a complaint handling committee named “Committee for Pharma Marketing Practices” has to be present in all pharmaceutical companies / associations. Further, the procedure of lodging a complaint and the method of responding to complaints has also been provided in the Uniform Code. The committee has to consist of a panel of five (5) member companies, represented by the Executive head of such companies or a nominee not below the rank of Director in such company.

The Uniform Code also provides for a Review Committee which will consist of a panel of seven (7) member companies of the association. Based on the company involved, the Secretary General or the Chairman or the President of the Association, as the case may be, will nominate five (5) members to the review committee, which must include three (3) complaint committee members who dealt with the complaint in the first instance.

In case there has been a breach of the Uniform Code, which breach has been established, the Committee can:

- (i) suspend or expel the company from the association;
- (ii) reprimand the company and publish details of the reprimand; or
- (iii) 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.

A pharmaceutical company which has been held by the committee to be in the breach of the Uniform Code, has the option to request for a review against such ruling of the committee within ten (10) working days of the notification of the ruling of the committee.

Pharmaceutical companies and companies manufacturing and marketing medicinal products would do well to consider implementing strategies within their respective organizations addressing the requirements of the Uniform Code. Even though Uniform Code is a voluntary code currently, it is likely that its requirements will be mandatory in the near future; in any event, these requirements capture good corporate procedures and governance, and it is always advisable to follow such stipulations. Companies therefore need to analyze and evaluate measures to incorporate the Uniform Code into their various internal systems, including, employees’ and representatives’ codes of conduct and, indeed, their employment or consultancy agreements.

Legal Advice Disclaimer: Please note that the contents of this note are not meant to be a substitute for obtaining legal advice. The note is only an introduction and we urge you to consult your lawyer for specific advice.