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DoP's new Uniform Code for Pharmaceutical Marketing Practices, 2024

A new Uniform Code for Pharmaceutical Marketing Practices, 2024 ("**New Code**") has been notified by the Department of Pharmaceuticals ("**DoP**") on March 12, 2024 as a replacement to the Uniform Code for Pharmaceutical Marketing Practices, 2014 ("**Earlier Code**") bringing changes to the regulatory framework on pharmaceutical marketing practices.

Key Changes

The following are the key changes brought about in the New Code:

1. **Definition of Promotion**

   There was no definition for the term 'promotion' in the Earlier Code. However, it has been defined in the New Code as referring 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 medical drugs.*"

2. **Brand reminders**

   Brand Reminders are anything used by pharma companies to market the brand. This is usually done by providing information about the drug through e-journals, books, dummy device models etc.

   The New Code permits the use of Brand Reminders on the basis of the following 2 (two) categories, viz., (a) Informational and education items and (b) Free samples provided by the companies to medical professionals.

   Informational and education items include books, calendars, diaries, journals including e-journals, dummy device model and clinical treatment guidelines, with value of such items capped at INR 1,000 (Indian Rupees one thousand) per item. It is also mentioned that these items must not have any independent commercial value for the healthcare professionals.

   With respect to free samples, the New Code has added the following:

   a) in addition to the name and address of the medical representative distributing the sample, the companies must take note of the name and address of the healthcare practitioner to whom the samples of products are distributed;

   b) samples will be provided only for the purpose of creating awareness about treatment options and for acquiring experience in dealing with the product;

   c) in addition to the condition that the sample packs be limited to prescribed dosage for not more than 3 (three) patients, there is a mandate for the Company to not offer more than 12 (twelve) sample packs per drug to a healthcare practitioner in a year;

   d) the monetary value of samples distributed should not exceed 2% of the domestic sales of the company per year;

   e) the requirement of procuring a signed and dated request for supply of sample packs has now been removed;

It is also clarified that receipt of brand reminders from pharma companies by healthcare practitioners may not be construed as endorsement activity if it does not amount to recommendation or issuance of a statement by a healthcare professional with respect to use of the respective brand.

3. **Continuing medical education**

   Continuing medical education will only be through a well-defined, transparent, and verifiable set of guidelines. A framework has been established for operation of activities and events for continuing medical education and professional development.

   This framework prohibits conduct of events in foreign locations and allows for the events to be conducted in places such as medical colleges, universities, hospitals, professional associations, certain laboratories, colleges/other academic and research institutions, pharma companies etc.

   The pharma companies are required to share details of the events conducted, including the expenditures incurred thereupon, on their website, and may be subject to independent, random, or risk-based audit for this purpose.

   The organisers must provide comprehensive details of procedure followed in selection of participants and speakers, display a statement of their funding sources and expenditures on their website, and may be subject to special audit for this purpose.

4. **Enhanced authority for the Ethics Committee**

   The New Code provides enhanced authority to the overseeing Ethics Committee, empowering it to forward its recommendations to relevant government agencies through the DoP. The impact of this being possible of scrutiny by statutory bodies and contravening companies being accountable under relevant legislations, such as the Drugs and Cosmetics Act, 1940, and associated rules and regulations.

5. **Change from being voluntary in nature**

   The Earlier Code, in its introductory paragraph states that, "*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 issue. If it is found that it has not been implemented effectively by the pharma associations/ companies, the Government may consider making it a statutory code.*"

   The Earlier Code was widely criticised for lacking teeth since the obligations imposed were voluntary in nature. The DoP in its annual report in FY 2018 stated that after having consulted with the stakeholders including the non-governmental organisations / civil societies, it was desirable that the code be made mandatory in order for it to be implemented effectively.

   The New Code has chosen to forego the term 'voluntary' and instead urges the pharma companies to set up an Ethics Committee for taking steps to implement the New Code. The language of the New Code brings in increased accountability for the pharma companies. The authority of the Ethics Committee has been enhanced by providing the power to forward their recommendations to relevant government agencies through the DoP.

Conclusion

The New Code represents a step towards a more robust framework for pharma stakeholders today. Its emphasis on strict compliance and the power given to pharma companies to send recommendations to statutory authorities takes strides towards its objective of curbing unethical practices in the pharma industry. It remains to be seen however, whether the Ethics Committee appointed under the pharma code will be effective in its implementation of the New Code.

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