

New Pharma code limits number of samples that pharma company can give to a doctor

New Delhi: Pharma companies and Medical Representatives (MRs) can only distribute sample packs that strictly adhere to the prescribed dosage for a maximum of three patients during the requisite treatment period, the recent pharma code issued by the government has stated. Furthermore, no pharma company is permitted to offer more than twelve sample packs per drug to any healthcare practitioner within a single year, the Government notified in its newly introduced Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024.

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The Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, in an endeavor to encourage ethical conduct and transparency within the pharmaceutical industry, has come up with the Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024. The UCPMP 2024, introduced on March 12th 2024, aims to overhaul existing marketing practices by imposing strict guidelines on pharmaceutical companies and healthcare practitioners.

What UCPMP says on Free Samples to Doctors?

Under the new regulations, free samples of drugs are prohibited from being supplied to individuals who are not qualified to prescribe such products. Additionally, stringent conditions have been outlined for the distribution of samples, including limitations on quantity and type of drugs, and the requirement to maintain detailed records of distribution.

The provisions outlined in the Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024, has specified that when samples of pharmaceutical products are distributed by a medical representative, they must be directly handed over to either the qualified healthcare practitioner authorized to prescribe the product or to an authorized representative acting on their behalf. Furthermore, the name and address of the healthcare practitioner receiving the sample must be diligently recorded for documentation purposes.

Additionally, certain conditions must be adhered to when providing samples to qualified practitioners; Firstly, samples are meant solely for the purpose of creating awareness about treatment options and gaining experience with the product. **Secondly, sample packs should be limited to the prescribed dosage for a maximum of three patients over the required course of treatment, with each company restricted to offering no more than twelve sample packs per drug to any healthcare practitioner annually.** Each sample must be clearly labeled as "free medical sample not for sale" or bear a similar disclaimer, ensuring that recipients understand their intended purpose.

Moreover, **sample packs must not exceed the size of the smallest commercially available pack, UCPMP guidelines stated.** Adequate systems for accountability and control must be implemented to monitor the distribution of samples effectively. Additionally, pharmaceutical companies are prohibited from supplying samples of drugs classified as hypnotics, sedatives, or tranquilizers.

UCPMP 2024 has also made it mandatory for each company to maintain comprehensive records detailing the product name, doctor's name, quantity of samples provided, date of distribution, and the monetary value of distributed samples. Importantly, the total value of samples distributed should not exceed two percent of the company's domestic sales per year, ensuring responsible distribution practices and adherence to regulatory standards within the pharmaceutical industry.

In a letter addressed to all pharmaceutical associations, the Joint Secretary (Policy) of the Ministry of Chemicals and Fertilizers, Ravindra Pratap Singh, emphasized the importance of strict compliance with the UCPMP 2024. Associations are urged to establish Ethics Committees for Pharmaceutical Marketing Practices (ECPMP) and set up dedicated UCPMP portals on their websites to facilitate implementation of the code.

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