# CDSCO constitutes eight-member subcommittee to look into OTC classification

The Central Drugs Standard Control Organisation (CDSCO) has constituted a sub-committee to examine matters regarding amendment of the Drugs Rules to incorporate necessary provisions for drugs to be declared as over-the-counter (OTC), in line with a recommendation of the Drugs Technical Advisory Board (DTAB) meeting.

The Department of Health and Family Welfare has issued a draft notification on May 25, 2022 for amendment of the Schedule K of the Drugs Rules, 1945, to incorporate necessary provisions for drugs to be sold OTC for providing exemptions from requirements of prescription from Registered Medical Practitioners (RMPs) for sales. The sub-committee will look into the proposal for amendment, said Drugs Controller General (India) Dr Rajeev Singh Raghuvanshi in an office memorandum.

The eight-member sub-committee will be headed by Dr Anupam Prakash, Director and Professor of Medicine, Lady Hardinge Medical College, Delhi, with Dr Umesh D Suranagi, Associate Professor of Medicine, Director General of Health Services (DGHS); Dr Ratan Kumar Gupta, Department of Paediatrics, Vardhman Mahavir Medical College & Safdarjung Hospital, Delhi, Dr Bikash Medhi, Professor, Department of Pharmacology, Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh; Dr Abhishek Agarwal, Professor, Department of Medicine, SMS Medical College, Jaipur; one representative from Indian Council of Medical Research (ICMR), and Drugs Controllers of Jharkhand and Karnataka, as members.

The sub-committee is expected to submit its report within a timeframe of three months and they may co-opt subject experts as and when required.

All the members of the sub-committee shall follow the principle of confidentiality and the experts nominated as a member of the sub-committee shall not have any conflict of interest, said the drug regulator. Different committees of clinicians have been constituted by the DGHS on the OTC matter, which will give inputs to the sub-committee for its consideration, it added.

The DCGI said that the development follows representation from some companies for certain drugs formulations to be sold OTC, including diclofenac diethylamine transdermal patch 200 mg, acetylsalicylic acid effervescent 500 tablets, dextromethorphan HBr lozenges 50 mg and mometasone furoate nasal spray 50 mcg, among others.

As reported earlier, the proposal was placed in the DTAB's 90th meeting held on January 25, 2024, and the committee recommended to form a sub-committee to examine the matter with reference to various conditions based on which status of a drug as an OTC is decided and a detailed mechanism is to be developed for the drugs to be considered as OTC.

The Board also recommended a comprehensive revisit of the draft notification for which international guidelines may also be considered.

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