

Centre tightens retail norms for cough syrup sale, mandates prescription

The amendment follows a recommendation by the Central Drugs Standard Control Organisation (CDSCO)'s apex advisory body after at least 24 children died in Madhya Pradesh, after consuming an DEG adulterated cough syrup brand, Coldrif.



New Delhi: Amid growing safety concerns over the unchecked use of syrup-based medicines, the Union Health Ministry has restricted their sale to valid prescriptions only, and at licensed pharmacies.

Issuing a gazette notification, the ministry communicated the omission of “Syrup” from the “Class of Drugs” listed under the Schedule K, of the Drugs Rules, 1945.

With this omission, the sale of syrup-based medicines, including cough syrups, will require a valid prescription from a registered medical practitioner and “will be dispensed only through duly licensed pharmacies, in accordance with the provisions of the Drugs and Cosmetics Act, 1940,” the ministry said in a statement.

According to the health ministry “the move is expected to promote responsible distribution and sale of cough syrups while ensuring greater compliance with regulatory standards across the country.”

The amendment follows a recommendation by the Central Drugs Standard Control Organisation (CDSCO)’s apex internal advisory body, the Drugs Consultative Committee (DCC), following the deaths of at least 24 children in Madhya Pradesh, who consumed an DEG adulterated cough syrup brand, Coldrif and the death of a child in Rajasthan who was officially stated to have consumed an “unprescribed” Dextromethorphan Hydrobromide syrup formulation.

The proposal was later examined by the Drugs Technical Advisory Board, which also reached a consensus to enforce the move ahead with the proposal.

In December 2025, the Ministry issued a draft notification seeking public comments on the proposed omission.

Schedule K drugs are medicines which are exempted from the Chapter IV of the Drugs and Cosmetics Act —regulations for manufacturing and distribution—and are allowed to be sold over-the-counter (OTC).

The list includes common household medicines like antiseptics, antacids, contraceptives, which can be dispensed by un-licensed pharmacist or medicine retailers as well.

However, with respect to cough syrups, experts often caution against their unmonitored OTC sales, warning that it may pose health risks to children as several formulations in the category is not intended for pediatric population.

Commenting on the move, AIOCD President J. S. Shinde and General Secretary Rajiv Singhal stated that, "this decision is a positive and significant step towards ensuring responsible distribution of medicines and curbing regulatory loopholes that have been exploited in recent years."

The chemist body representatives also urged the ministry to review and undertake a comprehensive revision of Schedule K, prioritizing patient safety and public health.

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