Centre bars over-the-counter sale of drugs with high alcohol content, mandates prescription

The decision follows reports from several state agencies flagging the misuse of medicines listed in the category. According to the Health Ministry, certain drugs that were until now covered under Schedule K exemptions contain high levels of ethyl alcohol and are flagged to be misused for intoxicating purposes.

New Delhi: Continuing its charge of regulating sales of readily available critical medicines, the Union health ministry has reclassified “all oral formulations containing more than 12 per cent ethyl alcohol as Schedule H1 drugs, bringing them under a tighter prescription regime to curb their potential misuse.

In a gazette notification the ministry announced that "oral formulations containing more than 12 per cent ethyl alcohol in quantities exceeding 30 mL" shall no longer be covered under the exemption provided to them under Schedule K and will now be dispensed against a valid prescription of a registered medical practitioner with stricter record-keeping.

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).

Whereas for distributing Schedule H1 classified drugs, drugmakers have to obtain prior approvals from relevant licensing authorities and also requires retailers to maintain detailed sales records, including the details of prescriber and the patient.

The decision follows reports from several state agencies flagging the misuse of medicines listed in the category. According to the ministry, certain Schedule K listed drugs contain high concentrations of ethyl alcohol, in certain cases up to 80–90 per cent in certain cases, making them susceptible to misuse for intoxication.

Ethyl alcohol is used in several cough syrup formulations to dissolve active ingredients and also as a preservative to maintain stability and microbial control.

The amendment, finalised on the recommendation of the Drugs Technical Advisory Board (DTAB), was first proposed in draft form in October last year and adds to a string of reclassification amendments undertaken by the ministry to curb the unchecked sale of alcohol-containing medicines, particularly cough syrups after a spate of deaths linked to an adulterated formulation, Coldrif. During laboratory analysis, the affected batch was found to be contaminated with diethylene glycol (DEG), a toxic solvent at a concentration of "46.8 per cent."

“The initiative is in line with the government's continued efforts to strengthen regulatory oversight for products containing alcohol and will significantly reduce the possibility of diversion and misuse while ensuring their continued availability for legitimate therapeutic use,” the ministry said in a statement.

In February, the Drugs Controller General of India (DCGI), said it had inspected over 90 per cent of the total 1,300 cough syrup manufacturers and taken stringent action against plants found non complaint to the effective cGMP norms —Revised Schedule M— including the issuance of CAPA notices and stop production orders.

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