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Health Ministry proposes amendment to Drugs Rules, 1945

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To strengthen regulatory oversight on Schedule H, H1 and X drugs



The Ministry of Health and Family Welfare, Government of India has proposed to amend the Drugs Rules, 1945 to strengthen regulatory oversight on Schedule H, H1 and X drugs. The proposal was issued in the draft gazette notification GSR issued on 8th September 2026. Submitted via 791(e).

Schedule H, H1, and X drugs are prescription-only medicines in India, with H1 and X subject to stricter controls due to higher risk of misuse or adverse effects.

The proposed amendment aims to address concerns related to unauthorised access and sale of Schedule H, H1 and X drugs. It has recommended mandatory CCTV surveillance at medical stores as an additional regulatory safeguard.

The proposal was initially considered by the Drug Advisory Committee (DCC). It was then circulated among the members of the Drugs Technical Advisory Board (DTAB) for discussion. After considering the proposal, DTAB recommended its approval.

Once implemented, the proposed amendment is expected to strengthen monitoring of sale and distribution of Schedule H, H1 and X drugs and prevent their unauthorised access and sale without a valid prescription.

The proposed CCTV surveillance system will also increase transparency and accountability in the drug supply chain, thereby further strengthening public health protection.