

Union Health Ministry Brings Pregabalin Under Schedule H1 to Strengthen Regulation and Prevent Misuse

Measures to Curb Easy Access, Enhance Prescription Monitoring, Strengthen Supply Chain Accountability, and Safeguard Public Health

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The Union Ministry of Health and Family Welfare has notified the inclusion of the drug “Pregabalin” under Schedule H1 of the Drugs Rules, 1945 vide Gazette Notification G.S.R. 377(E) dated 13th May 2026, published in the Gazette of India Extraordinary on 20th May 2026.

The decision has been taken in view of reports received from certain States regarding the misuse and abuse of Pregabalin, particularly among youth. The drug, which is prescribed for the treatment of chronic pain, neuropathies, fibromyalgia, and certain neurological conditions, has reportedly been misused for its sedative, euphoric, and dissociative effects. Recent seizures of illegally stocked and unauthorisedly sold Pregabalin have also been reported from some parts of the country.

With this notification, Pregabalin will now be regulated under the stricter provisions of Schedule H1, instead of the existing Schedule H, under the Drugs and Cosmetics Rules, 1945.

Schedule H1 Prescription Drug-CAUTION:

- It is dangerous to take this preparation except in accordance with the medical advice.
- Not to be sold by retail without the prescription of a Registered Medical Practitioner.

The revised classification mandates that:

Pregabalin can be sold only against a valid prescription issued by a Registered Medical Practitioner (RMP);

Retailers must maintain a separate register recording details of prescriptions and sales;

Manufacturers shall prominently display the prescribed “Schedule H1 Drug Warning” label on product packaging;

Violations and non-compliance will attract penal action under the Drugs and Cosmetics Act, 1940 and Rules thereunder.

The measure is aimed at strengthening accountability across the supply chain, preventing unauthorised access, enhancing prescription monitoring, curbing illegal trafficking, and safeguarding public health from drug misuse and abuse.

All stakeholders, including manufacturers, distributors, wholesalers, retailers, and pharmacists, are advised to ensure strict compliance with the provisions of the notification.

The e-Gazette can be accessed through the following link - [https://egazette.gov.in/\(S\(rqa3ekkjb0kpe5pwg0vwdyg4\)\)/ViewPDF.aspx](https://egazette.gov.in/(S(rqa3ekkjb0kpe5pwg0vwdyg4))/ViewPDF.aspx)

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