

# Union Ministry of Health and Family Welfare Amends Drugs Rules, 1945; Exemption for Sale of Cough Syrups in Small Villages Withdrawn

## Key Amendment to Drugs Rules to Enhance Regulatory Control Over Cough Syrups notified

प्रविष्टि तिथि: 16 JUN 2026 11:41AM by PIB Delhi

The Ministry of Health and Family Welfare has notified an amendment to the Drugs Rules, 1945, vide Gazette Notification G.S.R. 927 (E) dated 29<sup>th</sup> December 2025, published in the Gazette of India Extraordinary on , Part II, section 3, sub-section (i), dated the 30<sup>th</sup> December, 2025, omitting the word “Syrup” from Schedule K, Serial No. 13, Entry 7 under the heading “Class of Drugs”.

Schedule K of the Drugs Rules, 1945 provides exemptions from certain provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder for specified classes of drugs. Prior to this amendment, Entry No. 13 of Schedule K permitted the sale of cough syrups in villages with a population of less than 1,000 without requiring compliance with certain retail sale licensing provisions.

With the omission of the word “Syrup” from the said entry, this exemption will no longer be available for cough syrups. Consequently, the sale and dispensing of cough syrups in smaller villages will now be required to take place only through duly licensed pharmacies in accordance with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules framed thereunder.

The amendment has been undertaken to strengthen regulatory oversight of syrup formulations and to align the exemption framework with contemporary public health and safety requirements. The measure is expected to promote responsible distribution and sale of cough syrups while ensuring greater compliance with regulatory standards across the country.

Manufacturers, distributors and retailers dealing with cough syrups are advised to ensure strict adherence to the applicable licensing and regulatory requirements under the Drugs and Cosmetics Act, 1940 and the Drugs Rules, 1945.

The e-Gazette notification can be accessed at <https://egazette.gov.in/WriteReadData/2026/273467.pdf>

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