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Govt enhances regulatory control over cough medicines

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Exemption on sale of cough medicines in small villages withdrawn



The Ministry of Health and Family Welfare, Government of India, has notified amendments to the Drugs Rules, 1945 vide Gazette Notification GSR 927 (E) dated 29th December 2025. It was published in the Gazette of India Extraordinary on the date of December 30, 2025, wherein the word "syrup" under the head "class of drugs" under Schedule K, No. 13, Entry 7 is omitted.

Schedule 'K' of the Drugs Rules, 1945 exempts certain types of drugs from certain provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. Prior to this amendment, Entry No. 13 of Schedule 'K' allowed sale of cough medicines in villages with population less than 1,000 for which certain provisions relating to retail sale license were not required.

Due to omission of the word "syrup" from the said entry, this exemption shall not apply to syrups for cough medicines. Consequently, the sale and distribution of cough syrups in small villages shall now be mandatorily done only through pharmacies duly licensed in accordance with the Drugs and Cosmetics Act, 1940 and Rules framed thereunder.

The amendment has been made to strengthen regulatory oversight on syrup formulation process and to align the draft exemption with contemporary public health and safety requirements. It is expected that this measure will promote responsible distribution and sale of cough medicines, as well as ensure better compliance with regulatory standards across the country.

Manufacturers, distributors and retailers of cough medicines are advised to ensure strict compliance of licensing and regulatory requirements applicable under the Drugs and Cosmetics Act, 1940 and Drugs Rules, 1945.