CDSCO

Cough syrups lose the Schedule K household remedies exemption

G.S.R. 477(E) omits "Syrups," from item (7) of serial 13 of Schedule K, so syrups for cough leave the household remedies sale licence exemption.

THE MINISTRY OF HEALTH and Family Welfare (Department of Health and Family Welfare) issued notification G.S.R. 477(E), dated June 9, 2026. It makes the Drugs (Fifth Amendment) Rules, 2026, and appears in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 427, dated June 15, 2026. The Central Government made the rules under sections 12 and 33 of the Drugs and Cosmetics Act, 1940, after consultation with the Drugs Technical Advisory Board. They came into force on the date of their publication in the Official Gazette. CDSCO lists the notification as the "Removal of Syrup exemption under schedule K", and its copy is the same file as the e-Gazette's.

KEY FACTS

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Notification G.S.R. 477(E), the Drugs (Fifth Amendment) Rules, 2026



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The rules make one change. In Schedule K of the Drugs Rules, 1945, in the column headed Class of Drugs against serial number 13, they omit the word "Syrups," from item number (7). The item read "Syrups, lozenges, pills and tablets for cough." It now lists lozenges, pills and tablets for cough. The draft, G.S.R. 927(E) of December 29, 2025, was made available to the public on December 30, 2025, with thirty days for objections and suggestions. The final notification says the Central Government considered those received. The draft said the word "Syrup," would be omitted; the final rule omits "Syrups,", the word item (7) uses.

The notification does not say what serial number 13 does. In CDSCO's consolidated copy of the Drugs Rules, 1945, as amended up to G.S.R. 360(E) of July 1, 2024, serial number 13 covers "The following household remedies" in 15 items. They include aspirin and paracetamol tablets, analgesic balms, antacid preparations, gripe water for infants, inhalers for cold and nasal congestion, and item (7). It exempts them from "The provisions of Chapter IV of the Act and rules thereunder, which require them to be covered with a sale licence in Form 20A". Form 20A is the restricted licence to sell drugs by retail, for dealers who do not engage the services of a qualified person.

Four conditions apply to the exemption. (a) The drugs are sold only in a village having a population of not more than one thousand persons and where there is no licensed dealer under the Drugs and Cosmetics Act. (b) The drugs do not contain any substance specified in Schedules G, H or X. (c) The drugs are sold in the original unopened containers of the licensed manufacturers. (d) When the drugs are sold under clause (a), condition 3 under "Conditions of licence" of Form 20-B, the wholesale licence, does not apply. That condition says a drug may be sold only if it was bought on a cash or credit memo from a licensed dealer or manufacturer and, with some exceptions, bars sale to a person who does not hold the requisite licence. Syrups for cough are no longer within this exemption.

The notification gives no reason for the change and no transition period for syrups already stocked under the exemption. It leaves the other 14 items and the four conditions as they were, and it mentions no product or brand. Its note says the Drugs Rules, 1945 were last amended before it by G.S.R. 444(E) of June 1, 2026. It is signed by Harsh Mangla, Joint Secretary, under F.

No. X.11014/11/2025-DR. On October 28, 2026, CDSCO's Gazette notifications list showed no other change to serial number 13 since July 2024, before or after this one.

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	Notification G.S.R. 477(E), the Drugs (Fifth Amendment) Rules, 2026
Dated	June 9, 2026
Published	Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 427, June 15, 2026
Gazette ID	CG-DL-E-15062026-273467
Takes effect	On publication in the Official Gazette; the Gazette issue is dated June 15, 2026
Amends	Drugs Rules, 1945: Schedule K, serial number 13, item (7), the word "Syrups," omitted
Applies to	Syrups for cough sold as household remedies under serial number 13 of Schedule K
Item (7) now lists	Lozenges, pills and tablets for cough
Exemption at serial number 13	From the provisions of Chapter IV of the Act and rules thereunder that require a sale licence in Form 20A
Conditions	(a) sold only in a village of not more than one thousand persons with no licensed dealer; (b) no substance specified in Schedules G, H or X; (c) sold in the original unopened containers of the licensed manufacturers; (d) for sales under (a), condition 3 of the conditions of a Form 20-B licence does not apply
Draft	G.S.R. 927(E), December 29, 2025, made available to the public on December 30, 2025 (CG-DL-E-30122025-268923)
Made under	Sections 12 and 33, Drugs and Cosmetics Act, 1940, after consultation with the Drugs Technical Advisory Board
Status	CDSCO's Gazette notifications list, October 28, 2026: no other change to serial number 13 since July 2024
Signed by	Harsh Mangla, Jt. Secy.
File number	F. No. X.11014/11/2025-DR

The notification (final rules amending the Drugs Rules, 1945) (PDF, 1.0 MB)

Source: Gazette of India, CG-DL-E-15062026-273467.

Checked against the official copy on October 28, 2026.

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