

September 28, 2026

CDSCO

Draft rule would require sanction for Schedule H drug ads

Draft G.S.R. 861(E) proposes a new sub-rule (22) in rule 65 of the Drugs Rules, 1945 barring ads for Schedule H, H1 and X drugs without central sanction.

G. S.R. 861(E) IS A notification of the Ministry of Health and Family Welfare (Department of Health and Family Welfare), dated September 28, 2026, publishing draft rules further to amend the Drugs Rules, 1945. It appears in the Gazette of India, Extraordinary, Part

II, Section 3, Sub-section (i), No. 790, dated October 5, 2026. The Central Government proposes to make the rules under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board.

KEY FACTS

AUTHORITY

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Ministry of Health and Family Welfare
(Department of Health and Family Welfare)

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G.S.R. 861(E), draft rules



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The draft inserts a new sub-rule (22) in rule 65 of the Drugs Rules, 1945, after sub-rule (21). It reads: "No advertisement of the drugs specified in Schedule H, Schedule H1 or Schedule X shall be made except with the previous sanction of the Central Government." The rules are to be called the Drugs (..... Amendment) Rules, 2026, with the amendment number left blank in the draft, and they would come into force on the date of their final publication in the Official Gazette.

The draft is published for the information of all persons likely to be affected by it. It will be taken into consideration on or after the expiry of thirty days from the date on which copies of the Gazette containing it are made available to the public, and objections and suggestions received from any person within that period will be considered by the Central Government. The notification does not state the date on which those copies were made available.

Objections and suggestions may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, U-6, Work Hall- C Wing, first floor, Kartavya Bhawan-1, New Delhi, 110001, or emailed to drugsdiv-mohfw@gov.in. The notification is signed by Pushpendra Rajput, Joint Secretary, under F. No. X.11014/05/2026-DR.

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	G.S.R. 861(E), draft rules
Dated	September 28, 2026
Gazette	Extraordinary, Part II, Section 3, Sub-section (i), No. 790, October 5, 2026
Amends	Drugs Rules, 1945: new sub-rule (22) in rule 65
Proposed rule	No advertisement of drugs in Schedule H, Schedule H1 or Schedule X except with the previous sanction of the Central Government
Comment period	Thirty days from the date copies of the Gazette are made available to the public

Send comments to	Under Secretary (Drugs), Ministry of Health and Family Welfare, or drugsdiv-mohfw@gov.in
Takes effect	On final publication in the Official Gazette
Signed by	Pushpendra Rajput, Jt. Secy.

[The notification \(draft rules\)](#) (PDF, 756 KB)

Source: [Gazette of India, CG-DL-E-08102026-276941](#).

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