CDSCO

Draft would add four drugs to Schedule H1

Draft G.S.R. 745(E) would add flupentixol, zopiclone, gabapentin and carisoprodol to Schedule H1 of the Drugs Rules, 1945, as serial numbers 53 to 56.

G.S.R. 745(E) IS A NOTIFICATION of the Ministry of Health and Family Welfare (Department of Health and Family Welfare), dated August 19, 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. 679, dated August 19, 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. CDSCO lists the same file as a "Draft notification for inclusion of additional four drugs in Schedule H1".

KEY FACTS

AUTHORITY
CDSCO

PUBLISHED
August 19, 2026

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

DOCUMENT
G.S.R. 745(E), draft rules: the Drugs (..... Amendment) Rules, 2026



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CDSCO · August 19, 2026

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The draft inserts four serial numbers and entries in Schedule H1 of the Drugs Rules, 1945, after serial number 52 and the entries relating to it: "53. Flupentixol", "54. Zopiclone", "55. Gabapentin" and "56. Carisoprodol". It names the drugs only. It gives no strengths, dosage forms or salts, and no exceptions.

The rules are to be called the Drugs (..... Amendment) Rules, 2026, with the number left blank. The English text says they "shall come into force after one eighty days of publication of the final rules in the Official Gazette"; the Hindi text gives one hundred and eighty days. The draft does not restate what Schedule H1 requires, such as labeling or records of sale, and it makes no provision for stock made or labeled before the rules take effect.

The draft rules will be taken into consideration on or after the expiry of thirty days from the date on which copies of the Gazette containing them are made available to the public. The Central Government will consider objections and suggestions received from any person within that period. They 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 draft names no end date. Its e-Gazette ID, CG-DL-E-21082026-275641, and its digital signature date the copy August 21, 2026; thirty days counted from then end on September 20, 2026.

The draft is signed by Harsh Mangla, Joint Secretary, under F. No. X.11014/11/2026-DR. Its note on the principal rules leaves the number and date of their last amendment blank. On October 28, 2026, CDSCO's Gazette notifications list showed no final rule.

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	G.S.R. 745(E), draft rules: the Drugs (..... Amendment) Rules, 2026
Dated	August 19, 2026

Gazette	Extraordinary, Part II, Section 3, Sub-section (i), No. 679, August 19, 2026
Gazette ID	CG-DL-E-21082026-275641; the e-Gazette copy is dated August 21, 2026
Amends	Drugs Rules, 1945: Schedule H1, new serial numbers 53 to 56 after serial number 52
Applies to	Flupentixol, Zopiclone, Gabapentin and Carisoprodol
New entries	"53. Flupentixol"; "54. Zopiclone"; "55. Gabapentin"; "56. Carisoprodol"
Takes effect	"after one eighty days of publication of the final rules in the Official Gazette" (the Hindi text: one hundred and eighty days)
Comment period	Thirty days from the date copies of the Gazette are made available to the public; no end date is given. Counted from August 21, 2026, the date of the e-Gazette copy, thirty days end on September 20, 2026
Send comments to	Under Secretary (Drugs), Ministry of Health and Family Welfare, or drugsdiv-mohfw@gov.in
Status	No final rule on CDSCO's Gazette notifications list on October 28, 2026
Signed by	Harsh Mangla, Jt. Secy.
File number	F. No. X.11014/11/2026-DR

The notification (draft rules) (PDF, 666 KB)

Source: Gazette of India, CG-DL-E-21082026-275641.

Checked against the official copy on October 28, 2026.

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