September 3, 2026

CDSCO

Draft would add levonorgestrel emergency pills to Schedule K

Draft G.S.R. 792(E) would add levonorgestrel tablets 0.75 mg and 1.5 mg to entry 15 of Schedule K of the Drugs Rules, 1945, with four boxed warnings.

G.S.R. 792(E) IS A NOTIFICATION of the Ministry of Health and Family Welfare (Department of Health and Family Welfare), dated September 3, 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. 724, dated September 9, 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 on emergency contraceptives.

KEY FACTS

AUTHORITY

CDSCO

PUBLISHED

September 3, 2026

ISSUED BY

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

DOCUMENT

G.S.R. 792(E), draft rules: the Drugs (..... Amendment) Rules, 2026

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The draft inserts serial number (6), "Levonorgestrel Tablets 0.75mg/1.5mg", after serial number 5 under entry No. 15 of Schedule K. Entry 15 now covers a "Chemical contraceptive having the following composition per tablet", with five compositions listed. Two of them contain levonorgestrel, at 0.15 mg and 0.1 mg, each with "Ethinyloestradiol". It exempts them from "The provisions of Chapter IV of the Act and the rules made thereunder which required them to be covered by a sale licence", and sets no further condition. So the sale licence requirement does not apply to these tablets. Since G.S.R. 135(E) of February 16, 2026, a note to Schedule H also says the class of drugs at serial number 15 of Schedule K is not covered by Schedule H.

After the words "the provisions of Chapter IV of the Act and the rules made thereunder which required them to be covered by a sale license", the draft inserts a condition for Levonorgestrel Tablets 0.75mg/1.5mg only: boxed warnings must also be provided on the packaging and in the package insert. They read: "Emergency contraceptive pill is only to be taken in emergency situations, not to be used as a regular contraceptive." "Frequent use of the emergency contraceptive pill may lead to side effects. Visit the nearest health facility/Registered Medical Practitioner for regular contraception as soon as possible." "It is not an abortion pill." "It does not offer any protection against HIV or any sexually transmitted infections."

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-16092026-276273, and its digital signature date the copy September 16, 2026; thirty days counted from then end on October 16, 2026.

The rules are to be called the Drugs (..... Amendment) Rules, 2026, with the number left blank, and would come into force from a date the Government specifies when it publishes the final rules. The draft does not mention Schedule H, and it sets no size or layout for the boxed warnings. It is signed by Pushpendra Rajput, Joint Secretary, under F. No. X.11014/13/2026-DR. 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. 792(E), draft rules: the Drugs (..... Amendment) Rules, 2026
Dated	September 3, 2026
Gazette	Extraordinary, Part II, Section 3, Sub-section (i), No. 724, September 9, 2026
Gazette ID	CG-DL-E-16092026-276273; the e-Gazette copy is dated September 16, 2026
Amends	Drugs Rules, 1945: Schedule K, entry No. 15, new serial number (6) after serial number 5
Applies to	Levonorgestrel Tablets 0.75mg/1.5mg (emergency contraceptives)
Entry 15 now lists	Chemical contraceptives per tablet: (1) "DL-Norgestrel-0.30 mg. Ethinyloestradiol-0.03 mg."; (2) "Levonorgestrel-0.15 mg. Ethinyloestradiol-0.03 mg."; (3) "Centchroman-30mg."; (4) "Desogestrel -0.150mg. Ethinyloestradiol 0.030mg."; (5) "Levonorgestrel 0.1mg. Ethinyloestradiol 0.02mg"
Exemption under entry 15	"The provisions of Chapter IV of the Act and the rules made thereunder which required them to be covered by a sale licence"
Boxed warnings, on the packaging and in the package insert	(a) "Emergency contraceptive pill is only to be taken in emergency situations, not to be used as a regular contraceptive." (b) "Frequent use of the emergency contraceptive pill may lead to side effects. Visit the nearest health facility/Registered Medical Practitioner for regular contraception as soon as possible." (c) "It is not an abortion pill." (d) "It does not offer any protection against HIV or any sexually transmitted infections."
Comment period	Thirty days from the date copies of the Gazette are made available to the public; no end date is given. Counted from September 16, 2026, the date of the e-Gazette copy, thirty days end on October 16, 2026
Send comments to	Under Secretary (Drugs), Ministry of Health and Family Welfare, or drugsdiv-mohfw@gov.in
Takes effect	From the date the Government specifies at final publication in the Official Gazette
Status	No final rule on CDSCO's Gazette notifications list on October 28, 2026
Signed by	Pushpendra Rajput, Jt. Secy.

File number	F. No. X.11014/13/2026-DR

The notification (draft rules) (PDF, 774 KB)

Source: Gazette of India, CG-DL-E-16092026-276273.

Checked against the official copy on October 28, 2026.

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