June 22, 2026

CDSCO

Draft would bar drug imports with under a year of shelf life left

Draft G.S.R. 505(E) would bar drug imports with under a year of residual shelf life; biologicals and radiopharmaceuticals may be allowed 60% of labeled shelf life.

G.S.R. 505(E) IS A NOTIFICATION of the Ministry of Health and Family Welfare (Department of Health and Family Welfare), dated June 22, 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. 454, dated June 22, 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 regarding rationalization of shelf life under Rule 31 of Drugs Rules, 1945".

KEY FACTS

AUTHORITY

CDSCO

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

DOCUMENT

G.S.R. 505(E), draft rules: the Drugs (..... Amendment) Rules, 2026



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The draft substitutes the second proviso to rule 31 of the Drugs Rules, 1945, the rule headed "Standard for certain imported drugs". The new proviso reads: "Provided further that the licensing authority shall not allow the import of any drug having less than one year residual shelf-life period as on the date of import. However, in the case of Biological drugs and Radiopharmaceuticals, 60% of the labelled shelf-life may be allowed." The draft gives no reasons for the change, and it does not quote the proviso it would replace.

CDSCO's compiled copy of the Drugs Rules, 1945 is marked as amended up to G.S.R. 360(E) of July 1, 2024. In that copy, the second proviso provides that "the licensing authority shall not allow the import of any drug having less than sixty per cent, residual shelf-life period as on the date of import". The third proviso, which the draft does not touch, lets the licensing authority, in exceptional cases and for reasons to be recorded in writing, allow the import of a drug with a lesser shelf-life period, but before the date of expiry declared on its container.

The rules are to be called the Drugs (..... Amendment) Rules, 2026, with the number left blank. They would come into force from the date the Government specifies at the time of their final publication in the Official Gazette. The draft 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 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 gives no end date for comments. Its e-Gazette ID, CG-DL-E-25062026-273833, and its digital signature date the copy June 25, 2026; thirty days counted from then end on July 25, 2026. The draft is signed by Harsh Mangla, Joint Secretary, under F. No. X.11014/08/2026-DR, and its note on the principal rules leaves the number and date of their last amendment blank. G.S.R. 951(E), dated October 16, 2026, made the rules final as the Drugs (Thirteenth Amendment) Rules, 2026, in force from their publication in the Gazette of India, Extraordinary, No. 850, dated October 28, 2026; its text runs the biologicals clause into the same sentence.

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	G.S.R. 505(E), draft rules: the Drugs (..... Amendment) Rules, 2026
Dated	June 22, 2026
Gazette	Extraordinary, Part II, Section 3, Sub-section (i), No. 454, June 22, 2026
Gazette ID	CG-DL-E-25062026-273833; the e-Gazette copy is dated June 25, 2026
Amends	Drugs Rules, 1945: rule 31, second proviso (substituted)
Applies to	Imported drugs
Proposed limit	No import of any drug having less than one year residual shelf-life period as on the date of import
Biological drugs and radiopharmaceuticals	60% of the labeled shelf life may be allowed
Second proviso before the final rules	No import of any drug having less than sixty per cent residual shelf-life period as on the date of import (CDSCO's compiled Drugs Rules, as amended up to July 1, 2024)
Takes effect	From the date the Government specifies at the time of final publication in the Official Gazette
Comment period	Thirty days from the date copies of the Gazette are made available to the public; no end date is given. Counted from June 25, 2026, the date of the e-Gazette copy, thirty days end on July 25, 2026
Send comments to	Under Secretary (Drugs), Ministry of Health and Family Welfare, or drugsdiv-mohfw@gov.in
Final rules	G.S.R. 951(E), October 16, 2026, the Drugs (Thirteenth Amendment) Rules, 2026; Gazette of India, Extraordinary, No. 850, October 28, 2026 (CG-DL-E-29102026-277502); in force on publication; the biologicals clause runs into the same sentence
Signed by	Harsh Mangla, Jt. Secy.
File number	F. No. X.11014/08/2026-DR

The notification (draft rules) (PDF, 692 KB)

Source: Gazette of India, CG-DL-E-25062026-273833.

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