October 16, 2026

CDSCO

Final rule bars drug imports with under a year of shelf life left

G.S.R. 951(E) bars drug imports with under a year of residual shelf life; biological drugs and radiopharmaceuticals may be allowed 60% of labeled shelf life.

THE MINISTRY OF HEALTH and Family Welfare (Department of Health and Family Welfare) issued notification G.S.R. 951(E), dated October 16, 2026, making the Drugs (Thirteenth Amendment) Rules, 2026. It was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 850, dated October 28, 2026. The e-Gazette copy, Gazette ID CG-DL-E-29102026-277502, is digitally signed October 29, 2026. The rules come into force on the date of their publication in the Official Gazette. CDSCO lists the notification as "2026.10.28 G.S.R. 951(E)", a "Notification regarding rationalization of shelf life under Rule 31 of Drugs Rules, 1945", and its copy, uploaded October 30, 2026, is the same file.

KEY FACTS

AUTHORITY

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Notification G.S.R. 951(E), the Drugs (Thirteenth Amendment) Rules, 2026



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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. The recitals say the draft was published as G.S.R. 505(E), dated June 22, 2026, inviting objections and suggestions within thirty days from the date copies of the Gazette were made available to the public. Copies were made available on June 25, 2026, and the Central Government considered the objections and suggestions received. The notification does not summarize them.

The rules substitute the second proviso to rule 31 of the Drugs Rules, 1945. 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 and in case of biological drugs and Radiopharmaceuticals, Sixty percent of the labelled shelf-life may be allowed:". The notification does not quote the proviso it replaces. 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 says 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 limits are the draft's: one year, and sixty percent of the labeled shelf life for biological drugs and radiopharmaceuticals. The wording differs. The draft put the second limit in a sentence of its own: "However, in the case of Biological drugs and Radiopharmaceuticals, 60% of the labelled shelf-life may be allowed." The final text joins it to the first with "and in case of", writes "Sixty percent" for "60%", and ends with a colon. The notification does not comment on the change.

The rules change only the second proviso and leave the third as it is. In CDSCO's compiled copy, the third proviso 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 notification sets no transition period and says nothing about consignments shipped before it came into force. It gives no reasons and does not define biological drugs or radiopharmaceuticals. It is signed by Pushpendra Rajput, Joint Secretary, under F. No. X.11014/08/2026-DR. Its note says the Drugs Rules, 1945 were last amended by G.S.R. 713(E), dated August 6, 2026.

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	Notification G.S.R. 951(E), the Drugs (Thirteenth Amendment) Rules, 2026
Dated	October 16, 2026
Published	Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 850, October 28, 2026
Gazette ID	CG-DL-E-29102026-277502; the e-Gazette copy is digitally signed October 29, 2026
Applies to	Imported drugs
Takes effect	On the date of publication in the Official Gazette; the Gazette is dated October 28, 2026
Amends	Drugs Rules, 1945: rule 31, second proviso (substituted)
Before	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)
Now	No import of any drug having less than one year residual shelf-life period as on the date of import; for biological drugs and radiopharmaceuticals, sixty percent of the labeled shelf life may be allowed
Third proviso (exceptional cases)	Not changed
Transition	None stated
Draft	G.S.R. 505(E), June 22, 2026; Gazette copies made available to the public on June 25, 2026
Signed by	Pushpendra Rajput, Joint Secretary
File number	F. No. X.11014/08/2026-DR

The notification (PDF, 572 KB)

Source: Gazette of India, CG-DL-E-29102026-277502.

Checked against the official copy on November 1, 2026.

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