CDSCO

Draft would replace some drug test licences with prior intimation

Draft G.S.R. 509(E) would let drugs imported for analytical and non-clinical testing come in on an acknowledged prior intimation in Form 12, not a Form 11 licence.

THE MINISTRY OF HEALTH and Family Welfare (Department of Health and Family Welfare) has published draft rules, G.S.R. 509(E) dated June 23, 2026, to further amend the Drugs Rules, 1945. They appear in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 458 of June 23, 2026. The Central Government proposes to make them under section 12(1) of the Drugs and Cosmetics Act, 1940, after consultation with the Drugs Technical Advisory Board. CDSCO lists the same file as a draft notification "regarding simplification of the process for obtaining test licences for import of drugs under Form 11 of the Drugs Rules, 1945". The rules would be called the Drugs (..... Amendment) Rules, 2026, and would come into force from the date the Government specifies at final publication.

KEY FACTS

AUTHORITY

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

DOCUMENT

G.S.R. 509(E), draft rules: the Drugs (..... Amendment) Rules, 2026

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CDSCO · June 23, 2026

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Rule 33 lets small quantities of drugs, whose import is otherwise prohibited under section 10 of the Act, be imported for examination, test or analysis. In CDSCO's compiled text of the Drugs Rules (amended to July 1, 2024), clause (a) allows this only under a licence in Form 11. Rule 34(1) says the application is made in Form 12. The draft adds a proviso to rule 34(1) for "import of drug for analytical and non-clinical testing". For it, "an online application in Form 12 to the Central Licencing Authority shall be submitted as prior intimation and the applicant may import such drug based on the acknowledgment of such intimation". The proviso leaves out "drugs of category of sex hormones, cytotoxic, beta lactam, biologics with live microorganisms and narcotics and psychotropic drugs". Form 12's heading and opening paragraph would read "licence or prior intimation".

The draft keeps the Form 11 licence. Rule 33(a) would allow import under "Form 11 or the acknowledgement of prior intimation under the proviso of sub-rule (1) of rule 34 as the case may be". So the licence still covers the excluded categories and any import outside the proviso. In rule 33(b) to (e), the holder of an acknowledgement would take on the licensee's conditions. In the compiled text, the drugs may be used only for examination, test or analysis, at the place the licence names or another place the licensing authority allows. An authorized Inspector may enter, inspect and take samples. The holder keeps a record of the drugs imported, with quantities, date of import and manufacturer, and reports it to the licensing authority. Later rules may add requirements, with at least a month's notice. Under rule 35, an acknowledgement could be cancelled for breach of its conditions, as a licence can. The holder could appeal to the Central Government within three months of the order.

The draft sets no quantity limit for the new route. Rule 33's "small quantities" stays, and Form 12 lists each drug with the quantity to be imported. The draft does not define analytical and non-clinical testing. It does not say how soon the authority acknowledges an intimation or how long an acknowledgement lasts; a Form 11 licence is in force for three years. It does not say whether the rule 34(3) fee on every application in Form 12 applies to an intimation. In the compiled text,

that fee is five thousand rupees for a single drug and two thousand rupees for each additional drug. The draft amends only the Drugs Rules, 1945.

The draft will be taken into consideration on or after thirty days from the date copies of the Gazette containing it are made available to the public. 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 draft names no end date. Its e-Gazette ID, CG-DL-E-26062026-273857, and its digital signature date the copy June 26, 2026; thirty days counted from then end on July 26, 2026. It is signed by Harsh Mangla, Joint Secretary, under F. No. DC-DT-11011(11)/5/2026-eoffice. 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. 509(E), draft rules: the Drugs (..... Amendment) Rules, 2026
Dated	June 23, 2026
Gazette	Extraordinary, Part II, Section 3, Sub-section (i), No. 458, June 23, 2026
Gazette ID	CG-DL-E-26062026-273857; the e-Gazette copy is dated June 26, 2026
Proposes to amend	Drugs Rules, 1945: rules 33, 34 and 35, and Form 12 in Schedule A
Applies to	Import of drugs for analytical and non-clinical testing, outside the excluded categories
New route	An online application in Form 12 to the "Central Licencing Authority" as prior intimation; import on its acknowledgment
Excluded	"sex hormones, cytotoxic, beta lactam, biologics with live microorganisms and narcotics and psychotropic drugs"
Form 11 licence	Kept: rule 33(a) would read "Form 11 or the acknowledgement of prior intimation"
Takes effect	From the date specified by the Government at final publication
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 26, 2026, the date of the e-Gazette copy, thirty days end on July 26, 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, Joint Secretary
File number	F. No. DC-DT-11011(11)/5/2026-eoffice

Proposed changes to the Drugs Rules, 1945

Provision	Proposed change
Rule 33(a)	For "Form 11", substitute "Form 11 or the acknowledgement of prior intimation under the proviso of sub-rule (1) of rule 34 as the case may be"
Rule 33(b), (c) and (d)	"licensee" becomes "licensee or the holder of the acknowledgement of prior intimation under the proviso of sub-rule (1) of rule 34 as the case may be"; in (b) and (d), "licence" becomes "licence or the acknowledgement of prior intimation under the proviso of sub-rule (1) of rule 34 as the case may be"
Rule 33(e)	"licensee" as in (b); "holders of licenses" becomes "holders of licences or the acknowledgements of prior intimation under the proviso of sub-rule (1) of rule 34 as the case may be"
Rule 34, marginal heading	"licence" becomes "licence or prior intimation"
Rule 34(1), new proviso	"Provided that in case of import of drug for analytical and non-clinical testing (excluding drugs of category of sex hormones, cytotoxic, beta lactam, biologics with live microorganisms and narcotics and psychotropic drugs) an online application in Form 12 to the Central Licencing Authority shall be submitted as prior intimation and the applicant may import such drug based on the acknowledgment of such intimation."
Rule 35, marginal heading	"licence" becomes "licence or acknowledgment of prior intimation"
Rule 35(1)	"licence", wherever it occurs, becomes "licence or the acknowledgement of prior intimation under the proviso of sub-rule (1) of rule 34 as the case may be"
Rule 35(2), substituted	"A licensee or the holder of the acknowledgement of prior intimation under the proviso of sub-rule (1) of rule 34 as the case may be, whose licence or acknowledgement of prior intimation has been cancelled, may appeal to Central Government within three months of the date of the order."
Form 12, heading	"LICENCE" becomes "LICENCE OR PRIOR INTIMATION"
Form 12, opening paragraph	"licence" becomes "licence or prior intimation"

The notification (draft rules) (PDF, 1.2 MB)

Source: Gazette of India, CG-DL-E-26062026-273857.

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