November 6, 2026

CDSCO

Draft would bring all antimicrobials under the new drug definition

Draft rules of November 6, 2026 would add "antimicrobials," to rule 2(1)(w)(v) of the New Drugs and Clinical Trials Rules, 2019. Comments are open 30 days.

ALL ANTIMICROBIAL DRUGS would come under the definition of new drugs in the New Drugs and Clinical Trials Rules, 2019, under draft rules the Ministry of Health and Family Welfare has published for comment; that is how the e-Gazette and CDSCO list the draft. The draft is notification G.S.R. 983(E), dated November 6, 2026, of the Department of Health and Family Welfare, and would insert the word "antimicrobials," after the words "monoclonal anti-body," in sub-rule (1)(w)(v) of rule 2 of those Rules.

KEY FACTS

AUTHORITY

CDSCO

PUBLISHED

November 6, 2026

ISSUED BY

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

DOCUMENT

G.S.R. 983(E), draft rules: the New Drugs and Clinical Trials (..... Amendment) Rules (the English text says 2025, the Hindi text 2026)



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The draft appears in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 877, dated November 12, 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, after consultation with the Drugs Technical Advisory Board.

The draft has one amending rule, and that one word is the whole change. As printed, its English text differs in two places: the opening paragraph calls it a draft "further to amend the Drugs Rules, 1945", and the short title reads "the New Drugs and Clinical Trials (..... Amendment) Rules, 2025". The Hindi text gives the year as 2026. The rules 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 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 gives no end date for comments. Its e-Gazette ID, CG-DL-E-18112026-278020, and its digital signature date the copy November 18, 2026; thirty days counted from then end on December 18, 2026. It is signed by Pushpendra Rajput, Joint Secretary, under F. No. X.11014/19/2026-DR.

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	G.S.R. 983(E), draft rules: the New Drugs and Clinical Trials (..... Amendment) Rules (the English text says 2025, the Hindi text 2026)
Dated	November 6, 2026
Gazette	Extraordinary, Part II, Section 3, Sub-section (i), No. 877, November 12, 2026

Gazette ID	CG-DL-E-18112026-278020; the e-Gazette copy is dated November 18, 2026
Amends	New Drugs and Clinical Trials Rules, 2019: rule 2, sub-rule (1)(w)(v)
Change	"antimicrobials," inserted after "monoclonal anti-body,"
Made under	Sections 12(1) and 33(1) of the Drugs and Cosmetics Act, 1940, after consultation with the Drugs Technical Advisory Board
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 November 18, 2026, the date of the e-Gazette copy (CG-DL-E-18112026-278020), thirty days end on December 18, 2026
Send comments to	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 drugsdiv-mohfw@gov.in
Signed by	Pushpendra Rajput, Jt. Secy.
File number	F. No. X.11014/19/2026-DR

The notification (draft rules) (PDF, 471 KB)

Source: Gazette of India, CG-DL-E-18112026-278020.

Checked against the official copy on November 21, 2026.

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