

September 3, 2026

CDSCO

Draft widens prior intimation for BA and BE studies

Draft G.S.R. 790(E) would amend the New Drugs and Clinical Trials Rules, 2019, omitting "(for export purpose only)" from the proviso to rule 31(2).

THE MINISTRY OF HEALTH and Family Welfare (Department of Health and Family Welfare) has published draft rules, G.S.R. 790(E) dated September 3, 2026, to further amend the New Drugs and Clinical Trials Rules, 2019. The draft appears in the Gazette of India, Extraordinary, Part II, Section 3,

Sub-section (i), No. 722 of September 9, 2026. It is proposed under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940, and the notification states that consultation with the Drugs Technical Advisory Board shall be held as per the provisions.

KEY FACTS

AUTHORITY

CDSCO

PUBLISHED

September 3, 2026

ISSUED BY

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

DOCUMENT

Draft rules, G.S.R. 790(E)



Draft widens prior intimation for BA and BE studies

CDSCO · September 3, 2026

The Ministry of Health and Family Welfare (Department of Health and Family Welfare) has published draft rules, G.S.R. 790(E) dated September 3, 2026, to further amend the New Drugs and Clinical Trials Rules, 2019. The draft appears in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 722 of September 9, 2026. It is proposed under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940, and the notification states that consultation with the Drugs Technical Advisory Board shall be held as per the provisions.

The draft rules would be called the New Drugs and Clinical Trials (.... Amendment) Rules, 2026, with the amendment number left blank in the draft. They would come into force from the date specified by the Government at the time of their final publication in the Official Gazette.

The first change is to rule 31: in sub-rule (2), under the proviso, the words and brackets "(for export purpose only)" would be omitted. In rule 34(1), the words "excluding the cases of prior intimation referred to in the proviso of sub-rule (2) of Rule 31" would be inserted after "Form CT-05". In rule 35, after "rule 34", and in rule 36(1), after "Form CT-07", the draft inserts "or the acknowledgement of prior intimation under the proviso of sub-rule (2) of rule 31 or deemed approval, under the sub-rule (2A) of Rule 34", with "as the case may be" added in rule 35. Clause (xiii) of rule 35 would be deleted.

The draft is published for the information of all persons likely to be affected by it. It will be taken into consideration on or after the expiry of thirty days from the date on which copies of the Gazette of India containing it are made available to the public, and objections and suggestions received from any person within that period will be considered by the Central Government.

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 is signed by Pushpendra Rajput, Joint Secretary, under F. No. X.11014/09/2026-DR. The New Drugs and Clinical Trials Rules, 2019 were published by notification F.No.X.11014/10/2017-DRS-Part (1) dated March 19, 2019.

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	Draft rules, G.S.R. 790(E)
Dated	September 3, 2026

Published	Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 722, September 9, 2026
Proposes to amend	New Drugs and Clinical Trials Rules, 2019: rules 31, 34, 35 and 36
Rule 31(2) proviso	"(for export purpose only)" omitted
Comment period	Thirty days from the date copies of the Gazette are made available to the public
Send comments to	Under Secretary (Drugs), Ministry of Health and Family Welfare, or drugsdiv-mohfw@gov.in
Takes effect	From the date specified by the Government at final publication
Signed by	Pushpendra Rajput, Jt. Secy.

Proposed changes to the New Drugs and Clinical Trials Rules, 2019

Provision	Proposed change
Rule 31(2), proviso	The words and brackets "(for export purpose only)" omitted
Rule 34(1)	After "Form CT-05", insert "excluding the cases of prior intimation referred to in the proviso of sub-rule (2) of Rule 31"
Rule 35	After "rule 34", insert "or the acknowledgement of prior intimation under the proviso of sub-rule (2) of rule 31 or deemed approval, under the sub-rule (2A) of Rule 34, as the case may be"
Rule 35, clause (xiii)	Deleted
Rule 36(1)	After "Form CT-07", insert "or the acknowledgement of prior intimation under the proviso of sub-rule (2) of rule 31 or deemed approval, under the sub-rule (2A) of Rule 34"

[The draft notification](#) (PDF, 681 KB)

Source: [Gazette of India, CG-DL-E-16092026-276269](#).

Checked against the official copy on October 20, 2026.

IndusDesk

hello@indusdesk.com · +91 98917 60000

9th Floor, Hemkunt House, Rajendra Place, New Delhi, Delhi 110008, India

Read online: indusdesk.com/cdsco/insights/draft-widens-prior-intimation-for-ba-and-be-studies/