November 2, 2026

CDSCO

Draft adds a wholesale licence for bulk drugs, Form 20BC

Draft rules of November 2, 2026 would add Form 19BC (fee Rs 1,500) and a perpetual Form 20BC licence for selling or distributing bulk drugs by wholesale.

A BUSINESS THAT WANTS to sell, stock or distribute bulk drugs, active or inactive, would apply on a new form, Form 19BC, with a fee of Rs 1,500, and would get a new licence, Form 20BC, under draft rules the Ministry of Health and Family Welfare has published for comment. The draft is notification G.S.R. 987(E), dated November 2, 2026, of the Department of Health and Family Welfare, amending rule 59 and related rules of the Drugs Rules, 1945: the application "shall be made in Form 19BC accompanied by a fee of rupees one thousand and five hundred", and the licence "shall be issued in Form 20BC". It appears in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 881, dated November 12, 2026.

KEY FACTS

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G.S.R. 987(E), draft rules: the Drugs (..... Amendment) Rules, 2026

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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 new licence covers bulk drugs "falling under Schedules C & C(1), Other than Schedules C& C(1), Schedule X and Inactive bulk drug substance, as the case may be". The draft adds a second proviso to rule 59(2) for the application and a new sub-rule (4) to rule 61 for the licence, and adds Form 20BC to rules 63(1), 64 and 65.

For Form 20BC, the sale is to be in the charge of a competent person who is a Registered Pharmacist, or holds a degree in Science with two years' experience in dealing of such bulk drugs by wholesale. Form 19-BC asks for the categories applied for, a list of bulk drugs falling under the NDPS Act, 1985, and particulars of special storage accommodation where products need it.

The licence in Form 20-BC, "unless sooner suspended or cancelled, shall remain valid perpetually". Compliance with its conditions and with the Act and Rules "shall be assessed not less than once in three years or as needed as per risk based approach". Its conditions include that bulk drugs "should be sold in the same intact container as supplied by the manufacturer", that no bulk drug is sold unless it was purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer, and that no bulk drug intended to be used in drug formulation is sold to a person not holding the requisite manufacturing licence. That last condition does not apply to sales to an officer or authority buying for the Government, an educational or research institution for research, or a maker of hydrogenated vegetable oils, beverages, confectionery biscuits and other non-medicinal products that needs the drug for processing. The licensee shall inform the Licensing Authority in writing of any change in the constitution of the firm, and the current licence is then "deemed to be valid for a maximum period of three months" from the date of the change unless, in the meantime, a fresh licence has been taken.

The rules, to be called the Drugs (..... Amendment) Rules, 2026, would come into force from the date of their final publication in the Official Gazette, in two ways. They would apply to a new applicant for a wholesale licence from the date of publication in the Official Gazette, and to

existing licensees holding licences in Form 20B, 21B or 20G "upon expiry of the current retention period or after 12 months from the date of publication in the Official Gazette, whichever is later".

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, Kartavya Bhawan-1, New Delhi - 110011, or emailed to drugsdiv-mohfw@gov.in.

The draft gives no end date for comments. Its e-Gazette ID, CG-DL-E-18112026-278030, 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.11014/18/2026-DR.

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Document	G.S.R. 987(E), draft rules: the Drugs (..... Amendment) Rules, 2026
Dated	November 2, 2026
Gazette	Extraordinary, Part II, Section 3, Sub-section (i), No. 881, November 12, 2026
Gazette ID	CG-DL-E-18112026-278030; the e-Gazette copy is dated November 18, 2026
Amends	Drugs Rules, 1945: rules 59(2), 61, 63(1), 64 and 65, and Schedule A (Forms 19-BC and 20-BC added)
Application	Form 19BC, with a fee of rupees one thousand and five hundred
Licence	Form 20BC, valid perpetually unless sooner suspended or cancelled; compliance assessed not less than once in three years or as needed as per risk based approach
Categories	Schedules C & C(1); other than Schedules C & C(1); Schedule X; inactive bulk drug substance
Competent person	A Registered Pharmacist, or a degree in Science with two years' experience in dealing of such bulk drugs by wholesale
New applicants	From the date of publication in the Official Gazette
Existing licensees (Forms 20B, 21B, 20G)	Upon expiry of the current retention period or after 12 months from the date of publication in the Official Gazette, whichever is later

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-18112026-278030), thirty days end on December 18, 2026
Send comments to	Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Kartavya Bhawan-1, New Delhi - 110011, or drugsdiv-mohfw@gov.in
Signed by	Pushpendra Rajput, Jt. Secy.
File number	F. No. X.11014/18/2026-DR

The notification (draft rules) (PDF, 497 KB)

Source: Gazette of India, CG-DL-E-18112026-278030.

Checked against the official copy on November 21, 2026.

IndusDesk

hello@indusdesk.com · +91 11 4141 3939

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

Read online: indusdesk.com/cdsco/insights/draft-adds-a-wholesale-licence-for-bulk-drugs-form-20bc/