Union Ministry of Health Proposes Separate Licensing Framework for Wholesale of Bulk Drugs

Proposed Amendments to Drugs Rules, 1945, to Enhance Accountability and Control in Bulk Drug Distribution; strengthen Supply Chain Oversight

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The Union Ministry of Health and Family Welfare has proposed amendments to the Drugs Rules, 1945, vide Draft Gazette Notification G.S.R. No. 987 (E) dated 2nd November, 2026, to introduce a separate application form (Form 19-BC) and licence form (Form 20-BC) for the sale of bulk drugs (active or inactive bulk substances), distinct from the existing licensing provisions for formulations.

At present, a common licence covers the wholesale sale of both formulations and bulk drugs. The proposed amendment seeks to establish a dedicated licensing framework for bulk drugs, enabling more focused regulatory oversight of their wholesale sale and greater accountability in the pharmaceutical supply chain. The proposal was agreed upon by the Drugs Consultative Committee (DCC) in its 67th meeting held on 17 November 2025, and by the Drugs Technical Advisory Board (DTAB) in its 93rd meeting held on 16 February 2026.

Under the proposed framework, the licence will capture the categories of bulk drugs handled by wholesalers, including drugs covered under the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985. The sale of bulk drugs will be carried out under the personal supervision of a competent person, thereby strengthening accountability in their distribution and handling.

Upon implementation, the proposed amendment will:

- Give better control over the sale of bulk drugs by way of wholesale.
- Strengthen enforcement control in relation to antimicrobial resistance and the movement of NDPS drugs.
- Require wholesalers of bulk drugs to obtain a separate licence for sale.

To facilitate the transition to the revised licensing requirements, existing licensees will be provided adequate time to comply with the new provisions. The requirements will become applicable to them upon expiry of their current retention period or 12 months after the

final publication of the amendment, whichever is later.

Stakeholders and members of the public are invited to submit their objections and suggestions, if any, 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 via email at drugsdiv-mohfw[at]gov[dot]in, within 30 days from the date on which copies of the Gazette containing the draft rules are made available to the public.

The e-Gazette can be accessed through the following link: **https://egazette.gov.in/WriteReadData/2026/278030.pdf**

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