Union Health Ministry Proposes Amendment to Drugs Rules, 1945 to Provide Regulatory Flexibility for Medicinal Gases, Empty Gelatin Capsules and Disinfectant Fluids

Proposed amendment seeks to continue exemptions available under the pre-revised Schedule M

Posted On: 19 NOV 2026 1:01PM by PIB Delhi

Union Ministry of Health and Family Welfare has proposed an amendment to the Drugs Rules, 1945, through a draft Gazette Notification G.S.R. 985 (E) dated 6th November, published in the Gazette of India to provide regulatory flexibility under the revised Schedule M for certain categories of drugs, namely medicinal gases, empty gelatin capsules and disinfectant fluids.

The proposed amendment follows representations received from stakeholders regarding the applicability of certain provisions of the revised Schedule M, notified vide G.S.R. 922(E) dated 28 December 2023, to these categories of products.

The matter was deliberated in detail by the Drugs Technical Advisory Board (DTAB) during its 93rd meeting held on 16 February 2026. The Board observed that certain requirements under the revised Schedule M may not be relevant to the manufacturing processes of medicinal gases, empty gelatin capsules and disinfectant fluids. Accordingly, it recommended the continuation of exemptions that were available to these categories under Schedule M prior to its revision.

The proposed amendment seeks to ensure that regulatory requirements are appropriately aligned with the nature and manufacturing processes of specific categories of drugs, while maintaining effective regulatory oversight. It also provides for Licensing Authorities to take product-specific decisions based on relevant scientific and practical considerations.

The proposal does not dilute the applicable standards of quality, safety or regulatory oversight. Rather, it aims to provide a pragmatic and product-specific regulatory framework while ensuring continued compliance with the applicable quality requirements.

Stakeholders and members of the public are invited to submit their objections and suggestions, if any, within the prescribed period from the date of publication of the draft notification in the Official Gazette. The comments may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Kartavya Bhawan-1, New Delhi – 110011, or sent via email to drugsdiv-mohfw[at]gov[dot]in.

The draft Gazette Notification can be accessed at: https://egazette.gov.in/WriteReadData/2026/278031.pdf.aspx

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