Government Simplifies Procedure for Import of Drugs for Examination, Test or Analysis under Drugs Rules, 1945

Draft amendment to Drugs Rules, 1945 to introduce acknowledgement-based system for import of drugs for analytical and non-clinical testing

प्रविष्टि तिथि: 26 JUN 2026 3:31PM by PIB Delhi

In a significant step towards promoting research and innovation and enhancing ease of doing business in the pharmaceutical sector, the Union Ministry of Health and Family Welfare has proposed amendments to the Drugs Rules, 1945 to simplify the procedure for obtaining permission for import of drugs for examination, test or analysis. This is commonly known as Form 11.

The amendment introduces an acknowledgement-based system for import of all drugs in small quantities for analytical and non-clinical testing purposes. Under the revised provisions, applicants intending to import such drugs will be required to submit a prior intimation form and may import the drug based on the acknowledgement generated upon submission of such intimation.

The simplified procedure shall be applicable for import of drugs for analytical and non-clinical testing, except for certain drugs belonging to the categories of sex hormones, cytotoxic drugs, beta lactam drugs, biologics containing live microorganisms, and narcotic and psychotropic substances, which shall continue to require prior licensing.

It may be recalled that the Ministry of Health and Family Welfare had already carried out amendments to the New Drugs and Clinical Trials Rules, 2019 in January 2026 introducing a similar notification system for domestic test licences. The present proposed amendment expands it to imports also.

The amendment is expected to significantly reduce the compliance burden on applicants by eliminating licensing requirements for importing small quantities of drugs for testing or R&D purposes. This will play a substantial role in deregulating the R&D sector in pharmaceuticals and enable start-ups and industries to quickly initiate testing or analysis. The online intimation system will offer a seamless and instant gateway for the stakeholders.

The initiative is expected to provide a major boost to research and innovation in the country while facilitating more efficient and streamlined regulatory process. It also aligns with the Government's continued efforts to improve the regulatory ecosystem, promote ease of doing business and foster innovation in the pharmaceutical sector.

The draft notification has been placed in the public domain for stakeholder consultation. Objections and suggestions, if any, may be submitted 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 may be emailed to drugsdiv-mohfw[at]gov[dot]in.

The draft Gazette Notification is available at: https://egazette.gov.in/WriteReadData/2026/273857.pdf

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HFW/ Draft amendment to Drugs Rules, 1945 /26 June 2026/4

(रिलीज़ आईडी: 2278200) आगंतुक पटल : 1225
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