Ministry Invites Public Comments on Draft Amendment to the Drugs Rules, 1945 to Update Testing Norms for Blood Products

Proposed Amendment to Drugs Rules Seeks to Remove Duplicate Viral Testing of Blood Products and Align with Global Pharmacopoeial Standards

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The Ministry of Health and Family Welfare (MoHFW), Government of India, has issued a draft Gazette Notification GSR 164(E) dated 9th March 2026, inviting public comments on a proposal to amend Para G (Testing of Blood Products), Part XII C, Schedule F of the Drugs Rules 1945.

The proposed amendment seeks to align regulatory requirements for testing of blood products with internationally accepted pharmacopoeial standards and to remove additional testing requirements on products that are not warranted under global best practices.

As per the official monographs of Human Plasma for Fractionation in the Indian Pharmacopoeia (IP), British Pharmacopoeia (BP), United States Pharmacopeia (USP), and European Pharmacopoeia (EP), stringent testing protocols are prescribed for pooled human plasma.

Under these harmonized standards:

- The first homogeneous pool of plasma is mandatorily tested for Hepatitis B surface antigen (HBsAg), Hepatitis C virus RNA and antibodies to HIV.
- The pooled plasma must test negative for these viral markers before it is permitted for fractionation.
- Only plasma pools that meet these safety requirements are used for manufacturing plasma-derived medicinal products.

Despite this, under the current regulatory framework, the final products manufactured from already tested and qualified plasma pools are again tested.

This results in duplication of testing for the same viral markers at both the pooled plasma stage and the finished product stage. Such double testing is not aligned with international regulatory practices.

The proposed amendment is a progressive step towards regulatory harmonization, scientific rationalization of testing requirements, and reduction of avoidable compliance burden while continuing to uphold the highest standards of patient safety.

Stakeholders are encouraged to review the draft notification and submit their comments and suggestions within the prescribed timeline.

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