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# Public Health at a Crossroads: Legal and Regulatory Dimensions of the Proposed Drugs Rules Amendment, 2026

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On 9th March 2026, the Ministry of Health and Family Welfare, Government of India, published a significant draft amendment to the Drugs Rules, 1945, by way of Gazette Notification G.S.R. 164(E). Issued in exercise of powers conferred under sub-section (1) of Section 12 and sub-section (1) of Section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), and following consultation with the Drugs Technical Advisory Board (DTAB), it proposes that, in the Drugs Rules, 1945, under Schedule F, Part XII C, Para G, the words “The final products shall be tested for freedom from HIV I and HIV II antibodies, Hepatitis B surface antigen and Hepatitis C virus antibody.” shall be omitted. This means the express mandatory requirement for such testing of final products covered by Part XII C is proposed to be deleted from the Schedule text.

## Nature and Scope of the Proposed Amendment

The draft amendment proposes the deletion of a specific provision under Schedule F, Part XII C, Para G of the Drugs Rules, 1945. In its current form, the said provision mandates that final products be tested for freedom from HIV I and HIV II antibodies, Hepatitis B surface antigen and Hepatitis C virus antibody. If the amendment is finalised, this statutory testing obligation shall stand wholly omitted from the regulatory framework. The amendment is yet to attain legal force and shall come into effect only upon final publication in the Official Gazette on a date to be specified by the Central Government.

## Procedural Framework and Public Consultation

In accordance with the rule-making procedure prescribed under the Drugs and Cosmetics Act, 1940, the draft rules have been published to afford all persons likely to be affected thereby a period of thirty days from the date of publication to submit objections and suggestions. Such representations may be addressed in writing to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Kartavya Bhawan-1, New Delhi – 110001, or transmitted electronically to drugsdiv-mohfw@gov.in. The Central Government is statutorily obligated to take into consideration all objections and suggestions received within the stipulated period prior to finalising the rules.

## Regulatory Rationale: A Case for Reform?

From a regulatory standpoint, the proposed omission may be viewed as an alignment of India’s pharmaceutical standards with contemporary international practice. Global regulatory authorities, including the World Health Organization and the European Medicines Agency, have progressively transitioned from prescriptive end-product testing mandates toward a process-validation model. Under such a paradigm, validated pathogen inactivation and elimination steps undertaken during the manufacturing process are considered sufficiently reliable indicators of product safety, rendering duplicative end-product serological testing redundant. The DTAB’s endorsement of this amendment suggests that India’s regulatory architecture may be moving in a similar direction.

## Legal and Public Health Concerns

Notwithstanding the foregoing, the proposed amendment raises legitimate legal and public health concerns that warrant careful scrutiny. The draft notification does not specify the category of biological products to which Schedule F, Part XII C, Para G presently applies, nor does it articulate any replacement safeguard, alternative testing protocol, or compensatory regulatory mechanism. The absence of such transitional provisions creates a discernible lacuna in the statutory framework. Legal practitioners and public health stakeholders would be justified in questioning whether the deletion of a mandatory testing floor, without the concurrent introduction of equivalent process-based standards, comports with the overarching object and purpose of the Drugs and Cosmetics Act, 1940, namely the regulation of drugs to ensure public safety.

## Current Status and Implications for Industry

As of the date of this publication, the amendment remains at the draft stage and has not yet acquired the force of law. Pharmaceutical manufacturers, biologics producers, and other regulated entities operating under Schedule F, Part XII C are accordingly advised that the existing testing obligations remain fully operative and must continue to be observed without exception. Compliance teams and regulatory affairs professionals within the life sciences industry would do well to monitor this development closely, participate in the public consultation process where appropriate, and assess the downstream impact of this

amendment on their existing quality management and release-testing protocols.

## Conclusion

The proposed amendment to the Drugs Rules, 1945 represents a potentially significant recalibration of India's pharmaceutical regulatory framework. Whether it constitutes a rational modernisation of outdated testing requirements or an inadvertent dilution of critical public health safeguards will ultimately depend on the robustness of the process-based controls expected to underpin it. Stakeholders with a legal or commercial interest in the outcome are strongly encouraged to engage with the consultation process before the expiry of the thirty-day window.

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