Recent amendments to the Drugs Rules, 1945

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Why in News?

The Union Health Ministry has proposed amendments to the Drugs Rules, 1945, to simplify the procedure for obtaining permission for the import of drugs for examination, testing, or analysis.

- **The Mechanism -** Importers are ***no longer required to obtain*** a prior, time-consuming physical license.
- Instead, they must submit an online prior intimation form.
- The digital system instantly generates an acknowledgement, which serves as the valid legal clearance to execute the import.
- **Domestic Alignment –** The government already amends *New Drugs and Clinical Trials Rules, 2019* in January 2026 for domestic manufacturing test licenses.
- The new draft extends this swift protocol to international imports.
- **Critical Safety Exclusions -** To prevent the misuse of hazardous substances under the guise of research, it explicitly excludes the following sensitive categories.
    - Sex Hormones
    - Cytotoxic Drugs (anti-cancer formulations)
    - Beta-Lactam Drugs (specific antibiotic classes like penicillin)
    - Biologics containing live microorganisms
    - Narcotic and Psychotropic substances
- **The Shift -** The Ministry has simultaneously proposed an amendment to Rule 31 of the Drugs Rules, 1945.
- The existing framework mandates that any imported drug must possess a minimum residual shelf life of more than ***60%*** of its original lifetime upon arrival in India.
- The amendment proposes to change this to a flat, predictable minimum residual shelf life of ***12 months*** at the time of import.

- **The Safeguard -** An absolute shelf life of 1 year guarantees that the domestic supply chain has an adequate operational buffer to distribute, stock, and consume the medicines safely before their expiration dates.
- **Specialized Structural Exemptions -** To preserve public health safety, the strict, original requirement of more than 60% residual shelf life will remain mandatory for certain categories:
    - Biological Products (vaccines, blood products, gene therapies)
    - Radiopharmaceuticals (radioactive agents used in nuclear medicine and cancer diagnostics)
    - Institutional and Supply Chain Impact
- **Reduction in Inventory Wastage -** The rigid 60% rule frequently resulted in the rejection of perfectly viable batches of imported medicines if transit delays caused the remaining lifespan to slip marginally below the percentage threshold.
- Transitioning to a flat 12-month window reduces avoidable destruction of inventory.
- **Optimized Cost Management -** Relaxing the percentage barrier lowers operational losses for importers.
- **Unyielding Quality Standards-** The Ministry clarified that this modification solely alters the timeline threshold at port entry.
- It does not relax, amend, or compromise any statutory quality, safety, or efficacy standards laid out under the parent Drugs and Cosmetics Act, 1940.
- **Strategic Impact-** By replacing rigid licensing hurdles with an instant online gateway, the amendment strips away compliance blockages.
- This allows pharmaceutical start-ups and deep-tech research laboratories to rapidly procure small quantities of chemical entities to initiate R&D testing without administrative delays.

Reference

[The Hindu | Amendment to Drugs Rules, 1945]

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