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Health Ministry to amend New Drugs and Clinical Trials Rules 2019

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In accordance with the directions of Prime Minister Narendra Modi towards reducing the regulatory compliance and towards promoting ease of doing business in the pharmaceutical and clinical research sectors, the Union Health Ministry is set to amend the New Drugs and Clinical Trials (NDCT) Rules, 2019.

The proposed amendments were published in the Gazette of India on 28th August, 2025 seeking public comments. The amendments aim to simplify the requirements and procedures for obtaining test licences and for submitting applications related to Bioavailability/Bioequivalence (BA/BE) studies. Key highlights of the proposed amendments are as under:

1. Test Licence Applications: Under the proposed amendment, the present license system for test licenses has been converted to a notification/intimation system. Through this, the applicants need not wait for test licenses (except a small category of high risk category drugs) but will need to just intimate the Central Licensing Authority. Additionally, the overall statutory processing time for test licence applications will be reduced from 90 days to 45 days.

2. Bioavailability/Bioequivalence (BA/BE) Study Applications: Under the proposed amendment, the existing licence requirement will be dispensed with for certain categories of BA/BE studies, which may instead be initiated upon submission of an intimation or notification to the Central Licensing Authority.

These regulatory reforms are expected to benefit stakeholders by significantly reducing the timelines for processing applications. These proposed amendments will reduce the number of license applications being submitted by approximately 50%. This will facilitate quicker initiation of BA/BE studies, testing and examination of drugs for research, and reduce delays in the drug development and approval processes.

Moreover, the amendments will enable the Central Drugs Standard Control Organization (CDSCO) to optimise the deployment of its human resources, thereby enhancing the efficiency and effectiveness of regulatory oversight.