Union Health Ministry Notifies Key Amendments to NDCT Rules, 2019 to Reduce Regulatory Burden and Promote Ease of Doing Business

NDCT Amendments to Reduce Timelines and Strengthen Pharmaceutical R&D Ecosystem

Licensing Requirement for Non-Commercial Manufacture of Drugs Replaced with Prior-Intimation Mechanism

Amendments Expected to Reduce Drug Development Timelines by at Least 90 Days; Statutory Processing Period for Test Licences Reduced to 45 Days

Requirement of Prior Permission Waived for Specified Low-Risk BA/BE Studies; Online Intimation Mechanism Instituted

Government Reaffirms Commitment to Trust-Based Regulatory Reforms to Promote Pharmaceutical R&D and Ease of Doing Business

प्रविष्टि तिथि: 28 JAN 2026 9:53AM by PIB Delhi

Union Ministry of Health and Family Welfare has notified key amendments to the New Drugs and Clinical Trials (NDCT) Rules, 2019, in line with the directions of Hon’ble Prime Minister Shri Narendra Modi to reduce regulatory burden and promote Ease of Doing Business.

These amendments are aimed at simplifying regulatory processes, reducing approval timelines, and enabling faster conduct of clinical research and pharmaceutical development in the country.

Under the existing regulatory framework, pharmaceutical companies are required to obtain a test licence from the Central Drugs Standard Control Organization (CDSCO) for the manufacture of small quantities of drugs intended for examination, research, or analysis purposes. Through the notified amendments, this licensing requirement for non-commercial manufacture has been replaced with a prior-intimation mechanism. As a result, the industry will no longer be required to seek a test licence and may proceed with pharmaceutical development upon submitting an online intimation to CDSCO, except in the case of a limited category of high-risk drugs, including cytotoxic drugs, narcotic drugs, and psychotropic substances.

This reform is expected to lead to a minimum saving of 90 days in the drug development life cycle, providing a significant boost to pharmaceutical research and innovation. Furthermore, for categories where test licences continue to be applicable, the statutory processing timeline has been reduced from 90 days to 45 days. Considering that CDSCO processes approximately 30,000 to 35,000 test licence applications annually, the reform is expected to substantially reduce regulatory burden and benefit a large number of stakeholders.

In another important step to expedite clinical research, the requirement of obtaining prior permission for certain categories of low-risk Bioavailability/Bioequivalence (BA/BE) studies has been dispensed with. Such studies may now be initiated on the basis of a simple online intimation to CDSCO, enabling faster commencement of studies, particularly for the generic pharmaceutical industry. CDSCO processes around 4,000 to 4,500 BA/BE study applications every year, and the revised mechanism is expected to significantly reduce procedural delays.

To ensure smooth and seamless implementation of these changes, dedicated online modules will be made available on the National Single Window System (NSWS) and the SUGAM portal, allowing industry to submit intimations in a transparent and hassle-free manner.

Overall, these regulatory reforms are expected to provide substantial benefits to stakeholders while ensuring public health and safety. By significantly reducing timelines for regulatory processing, the amendments will facilitate quicker initiation of BA/BE studies, testing, and examination of drugs for research purposes, and minimise delays across the drug development and approval continuum. The reforms will also enable the Central Drugs Standard Control Organization (CDSCO) to optimise utilisation of its existing manpower, thereby enhancing the efficiency and effectiveness of regulatory oversight.

These measures underscore the Government of India’s commitment to continuous, trust-based regulatory reforms in the pharmaceutical sector, in line with the Jan Vishwas Siddhant and the broader Ease of Doing Business framework. The initiative aims to promote R&D-led growth of the Indian pharmaceutical industry, align domestic regulations with global best practices, and strengthen India’s position as a preferred global destination for pharmaceutical research and development.

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HFW–Union Health Ministry Notifies amendments in Drugs Regulation/28th January 2026/1

(रिलीज़ आईडी: 2219422) आगंतुक पटल : 1014