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Health Ministry to reduce regulatory burden and promote ease of doing pharma business

29 January 2026 | News

Amendments are expected to reduce drug development timelines by at least 90 days



In line with Prime Minister Narendra Modi's directions to reduce regulatory burden and promote ease of doing business, the Union Ministry of Health and Family Welfare has notified significant amendments to the New Drugs and Clinical Trials Rules, 2019.

These amendments aim to simplify regulatory processes, reduce approval timelines, and expedite clinical research and drug development in the country.

Under the existing regulatory framework, pharmaceutical companies were required to obtain a test license from the Central Drugs Standard Control Organisation (CDSCO) for manufacture of limited quantities of drugs for the purposes of testing, research or analysis.

Through the notified amendments, this licensing requirement for non-commercial construction has been replaced by the Early Notice System. As a result, the industry will no longer be required to obtain a test license and drug development work can be pursued by submitting information online to CDSCO, except in the case of a limited category of high-risk drugs, including cytotoxic drugs, narcotic drugs, and psychotropic substances.

This improvement is likely to save at least 90 days in the life cycle of drug development, providing a significant boost to pharmaceutical research and innovation. Also, for categories that still require a test license, the statutory process time limit has been reduced from 90 days to 45 days. Since CDSCO processes about 30,000 to 35,000 test license applications every year, this reform can be helpful in reducing the regulatory burden and providing benefits to a large number of stakeholders.

In an effort to expedite clinical research, the requirement of prior approval for certain low-risk bioavailability and bioequivalence (BA/BE) studies has been done away with. Now such studies can be initiated only by giving a simple online information to CDSCO, which will speed up and facilitate the process of these studies, especially in the area of generic medicines.

It may be noted that CDSCO processes around 4,000 to 4,500 BA/BE study applications every year, and the time taken in the processes is likely to be significantly reduced under this new mechanism.

To ensure smooth and seamless implementation of these changes, dedicated online modules will be made available on the National Single Window System and Sugam Portal which will enable the industry to submit information in a transparent and hassle-free manner.