Health ministry amends NDCT Rules to enable faster commencement of BA/BE studies

In an effort to enable faster commencement of Bioavailability/Bioequivalence (BA/BE) studies, particularly for the generic pharmaceutical industry in certain low-risk categories, the Union health ministry has amended the New Drugs and Clinical Trials (NDCT) Rules, 2019.

The amendment would allow the industry to conduct studies after submission of an online application as prior intimation and obtaining an acknowledgement from the Central Licensing Authority (CLA), subject to certain conditions.

Through the amendment, the government inserted a proviso to the sub-rule (2) of the Rule 31, that in case of single-dose, two-period, two-sequence, two-treatment, BA/BE studies in normal health adult volunteers (for export purpose only), of oral dosage form of a drug - other than drugs of cytotoxic, hormone, narcotic and psychotropic substances categories and not a drug of Narrow Index Therapeutic Index or a drug having highly variable pharmacokinetics - already approved in the country or any one of USA, European Union, Japan, Australia, Canada and UK, "the studies may be conducted after submission of an online application as prior intimation in Form CT-05 and its acknowledgement by the Central Licensing Authority," subject to certain conditions.

The application of the prior intimation shall be accompanied with approval of the Ethics Committee registered with the Central Licensing Authority under Rule 8. The Ethics Committee shall maintain the record of review and approval of such BE/BE studies being conducted under the proposed notification process separately and it shall be reviewed by the CLA at the time of renewal of the registration of the ethics committee. The sample size shall be more than or equal to eighteen.

"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," said the Health Ministry in a statement announcing the notification of amendment.

Besides, in the sub-rule (1) of the Rule 33, which deals with the procedures for applying for permission to conduct the BA/BE study, regarding the export only products mentioned in the newly proposed proviso in Rule 31, an online application in Form CT-05 may be submitted as notification with the CLA.

It also proposes to substitute the sub-rule (2) of the Rule 33, to mandate that a fee should be remitted as specified in the Sixth Schedule along with other information and documents as specified in the Table 2 of the Fourth Schedule.

However, no fee shall be payable for conducting a bioavailability or bioequivalence study by an institution or organisation owned or funded wholly and partially by the Central government or a state government.

Amendments has also been made in Rule 35 to 38 in tune with these changes.

The Ministry, on August 27, issued the draft notification for these amendments in August 27, 2025, and in November, issued corrections reducing the sample size from the initially proposed 48 to "more than or equal to 18".

It may be noted that the Ministry has also notified amendment to the NDCT Rules, replacing the licensing requirement for non-commercial manufacture with a prior-intimation mechanism.

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," said the Ministry.

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.

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

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.

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