Health ministry brings changes to sample size requirement in draft amendment of NDCT Rules

The Union health ministry has brought in changes to the draft amendment it issued in August, related to the BA/BE study of new drug or investigational new drug and the process of its application, to reframe the requirement of the sample size for the studies.

The Ministry, on August 27, issued a draft notification to amend the New Drugs and Clinical Trials Rules (NDCTR), 2019, to mandate that the industry should submit online application and get approval from the Central Licensing Authority (CLA) to conduct bioavailability (BA) of Bioequivalence (BE) studies of oral dosage forms for export purpose only.The conditions to conduct the study, according to the draft amendment, included that the application for the notification must be accompanied with approval of the ethics committee registered with CLA under Rule 8 of the Act, and the sample size should not be more than 48.

In a new notification dated October 31, the Ministry said that the condition for sample size should not be more than 48 shall be substituted as "The sample size should be more than or equal to 18."

Objections and suggestions received from any person within 15 days of the publication of the corrigendum will be considered by the Central Government, it added.

The Ministry has, in August, issued a draft notification to amend the Rules 31 and 33, which are related to the BA/BE study of new drug or investigational new drug and the process of its application.

Through the draft amendment, the government proposes to amend the sub-rule (2) of the Rule 31, to insert a proviso 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.

In such cases, the studies may be conducted after submission of an online application as notification and its acknowledgement by the CLA, subject to certain conditions.

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.

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.

The draft has been prepared after consultation with the Drugs Technical Advisory Board and published for information of all persons likely to be affected. The Ministry said that the draft rules shall be taken into consideration on or after the expiry of a period of 30 days from the date on which the copies of the Gazette of India containing the draft are made available to the public. Objections and suggestions shall be addressed to the Under Secretary (Drugs), under the Ministry.

News Source:

https://www.pharmabiz.com/NewsDetails.aspx?aid=182251&sid=1