

File No. ECR/Misc./16/Validity-Notice/2019

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road
New Delhi-110002, India

Dated: 18/01/2019

NOTICE

Ethics Committees involved in review and according approval of clinical trials and BA BE study protocols for new drugs are required to be registered as per the New Drugs and Clinical Trials Rules, 2019, notified by Government of India on 19.03.2019.

Before 19.03.2019, the registration of Ethics Committees was regulated as per the provisions of Part XA and Schedule Y of the Drugs and Cosmetics Rules, 1945.

As per the provisions of Drugs and Cosmetics Rules, prevalent before 19.03.2019, registration granted by CDSCO was valid for a period of three years from the date of issue, provided that if the application for re-registration is received by the Licensing Authority within three months before the expiry, the registration was continued to be in force until orders are passed by the said authority

According to provisions of the New Drugs and Clinical Trials Rules, 2019, the registration granted by CDSCO is valid for a period of five years from the date of its issue; provided that if the application for renewal of registration is received by the Central Licencing Authority ninety days prior to the date of expiry, the registration shall continue to be in force until an order is passed by the said authority on such application.

In accordance with the above provisions of the rules, it is brought to the notice of all concerned that registration of those Ethics Committees which have submitted their application to CDSCO for re-registration/renewal of the registration following the above mentioned timelines and the same are under process, shall remain valid until an order is passed by CDSCO on their applications otherwise.



(Dr. V.G Somani)

Drugs Controller General (I)

To:

All Concerned through CDSCO website.