

F. No.12-22/2019-DC (Pt-Misc-SND)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Subsequent New Drugs Division)

Dated: 10 APR 2019

NOTICE

Subject: Uploading of applications through SUGAM Portal in accordance with New Drugs and Clinical Trials Rules, 2019- Reg.

The New Drugs and Clinical Trials Rules, 2019 have been published with effect from 19.03.2019 for regulation of New Drugs, Investigational New Drugs for human use, Clinical trials, bioequivalence study, bioavailability study and Ethics Committee.

The rules provide various Forms for submission of applications & grant of approvals of various categories of new drugs and clinical trials.

Earlier the applications for approval of New Drugs, Investigational New Drugs for human use, Clinical trials, bioequivalence study, bioavailability study and Ethics Committee were required to be submitted as per the provisions prevalent in the Drugs and Cosmetic Rules, 1945. Applications for various categories of new drug are submitted and processed online through SUGAM portal.

In light of the New Drugs and Clinical Trials Rules, 2019, it is brought to the notice of applicants that they should submit their application as per the relevant checklist provided in the SUGAM portal.

The application Form for specific purpose should be prepared offline in the relevant Form as per the New Drugs and Clinical Trials Rules, 2019 and a scan copy of the same should be uploaded in the respective item provided in the checklist. The Gazette notification containing the New Drugs and Clinical Trials Rules, 2019 including the Forms is available at www.cdsc.gov.in. Necessary provisions in this regard has already been made in the SUGAM portal for the online submission of the applications.

Similarly the applicants are also required to submit fees as per the Sixth Schedule of New Drugs and Clinical Trials Rules, 2019 for which they are required to upload copy of T.R. Challan or receipt of Bharat Kosh in the respective item provided in the check-list.

For further clarification, if any, required by any stakeholders in this regard, they may contact the IT Cell of CDSCO at email it-helpdesk@cdsco.nic.in.