



No. BT/03/27/2020-PID

Dated 20.3.2020

OFFICE MEMORANDUM

Subject: Rapid Response Regulatory Framework for COVID-19 to deal with applications for development of vaccines, diagnostics, prophylactics and therapeutics - reg.

Taking into account the rapid spread of COVID-19 in various countries and the need for immediate research and product development, it has been decided to fast track the regulatory approval process in consultation with DCGI to deal with the applications for development of vaccines, diagnostics, prophylactics and therapeutics for COVID-19 as per following:

- i. Permission for Import/ exchange: Review Committee on Genetic Manipulation (RCGM) will approve the application fulfilling all essential criteria within 7 days from the date of receipt of application along with IBSC recommendation on IBKP Portal.
- ii. Permission for initiating research work- RCGM will approve the application fulfilling all essential criteria within 7 days from the date of receipt of application along with IBSC recommendation on IBKP Portal.
- iii. Examination of physico chemical & molecular characterisation data and approval of the Animal Toxicity Protocol- 10 days after submission of all essential data, PCT protocol and IBSC recommendations on IBKP portal.
- iv. Recommendation of RCGM for appropriate phase of clinical trial – 10 days after submission of all essential Preclinical Toxicity Data.
- v. Approval of Form 29 / test licence/NOC to manufacturer by CDSCO within 10 days from the receipt of application.
- vi. CDSCO shall make a CORONA unit to address queries on development of diagnostics, prophylactics and therapeutics for COVID- 19 and will also provide a link at CDSCO portal in this regard.

2. For this purpose, an Empowered Committee of RCGM and CDSCO has been constituted to examine the applications and to recommend the applications for approvals as per the agreed timeframe.

This issues with the approval of the Secretary, Department of Biotechnology

(Nitin K. Jain)
Scientist F & Member Secretary, RCGM

To
NIC-Department of Biotechnology and CDSCO for uploading on websites