



सत्यमेव जयते

No. BT/BS/17/635/2015-PID

Dated: 06.08.2020

OFFICE MEMORANDUM

Subject: Streamlining of the Regulation Procedure of Biopharma Drug Development.

Based on the recommendations of the Review Committee on Genetic Manipulation (RCGM), following streamlining of Biopharmaceutical Regulatory processes are hereby notified:

1. Biopharma applicants may decide to come for the presentation only once after completion of pre-clinical studies, however, applicants will be required to submit the pre-clinical studies protocol to RCGM for vetting through IBKP portal. The information regarding vetting of protocols will be communicated to the applicant within 15 days of receipt otherwise the protocol submitted may be considered as approved.
2. The generic PCT protocol developed are being uploaded on IBKP portal for reference. However, in those cases where specific protocols are required, (eg, DNA/RNA based vaccines, GTPs, microsomal based multi-subunit vaccines, etc) RCGM may continue to examine the submitted protocols and recommend suitable protocol on a case by case basis.
3. A minimum of three consistency batch data is required to establish consistency and proper assessment of purity of Drug Substances (DS) and impurities profile of novel vaccines/therapeutic. Batch size should sufficient to provide enough material from a single batch to carry out all CMC and preclinical toxicity studies.
4. The RCGM meetings are being scheduled every 21st day and will be scheduled fortnightly from September, 2020.

(Nitin K. Jain)

Member Secretary, RCGM & Scientist-F

To,

1. All IBSCs (Chairman & DBT Nominee) for information and compliance
2. Member Secretary, GEAC
3. Drug controller General of India, CDSCO for information

Copy to: NIC-DBT for uploading on DBT Website & IBKP Portal