Rapid Regulatory Framework for COVID-19

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The Department of Biotechnology (DBT), Ministry of Science & Technology has been proactively working on the development of Diagnostics, Therapeutics, Drugs and Vaccines to combat the healthcare challenges posed by COVID-19. DBT has also taken several measures to facilitate research driven and technology based interventions, on a fast-track mode. As a paramount effort to stimulate and facilitate research and development activity towards combating COVID-19, DBT has evolved a set of Rapid Response Regulatory Frameworks.

Rapid Regulatory Framework

- **Rapid response regulatory framework for COVID-19 to deal with applications for development of vaccines, diagnostics, prophylactic and therapeutics for fast track review and approval of applications.**

Review Committee on Genetic Manipulation (RCGM) will approve permission for import/ exchange within 7 days from date of receipt of application.

RCGM will approve permission for initiating research work within 7 days from date of receipt of application.

CDSCO shall make a CORONA unit to address queries on development of diagnostics, prophylactics and therapeutics.

- **Interim guidance document on laboratory biosafety to handle COVID-19 specimens for R&D purpose.**

The guidelines include a whole range of **basic minimal procedures to be followed**, risk assessment and mitigation measures, routine laboratory procedure, specimen and nucleic acid storage, viral isolation, disinfectants and lab waste

management, specimen packaging and shipment procedure.

- **Checklist for application to conduct preclinical toxicity (PCT) studies for recombinant vaccine for COVID-19**

Considering the research collaboration of Indian enterprises with foreign research organizations the **preclinical studies already done outside India may be considered in regulatory submission** and individual application will be examined based on quality of data generated and conduct of limited preclinical study may be asked for after examination, if required.

Data generated outside India will be considered and examined and an abbreviated pathway may be considered for COVID 19 vaccine based on scientific rationale and level of completeness of data in human trials in addition to satisfactory preclinical data. Phase I/II or phase III multicentric study on statistically significant sample size may be considered based on, initial safety studies, proof of concept and dose finding data.