



Ministry of Health and Family Welfare

Procedure for Research on Vaccine

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The Central Drugs Standard Control Organisation (CDSCO) has informed that the requirements and guidelines to conduct clinical trial or grant of permission for marketing of new drugs including vaccines are prescribed under New Drugs and Clinical Trials Rules, 2019.

Further, the Indian Council of Medical Research (ICMR), an autonomous organisation of the Department of Health Research, has informed that the stages of vaccine development include the following steps:

- i. Identification and development of an appropriate vaccine strain which may be safe and immunogenic.
- ii. Full characterization of the vaccine strain by in-vitro experiments.
- iii. Pre-clinical studies in small animals like rats, mice, rabbits, guinea pigs, hamsters etc. These are safety and dose determination studies.
- iv. Preclinical studies in large animals (depending upon feasibility and availability) to determine safety, protective efficacy and potential dose and formulation.
- v. Phase I human clinical trials which establish the safety of the product. The numbers are usually < 100.
- vi. Phase II human clinical trials to determine the immunogenicity or immune protection. The numbers are usually < 1000.
- vii. Phase III human clinical trials to determine the efficacy. The numbers range in several thousands. After successful completion of phase III studies, regulatory approval is accorded.
- viii. Phase IV or post marketing surveillance studies.

CDSCO has informed that it has not received any report regarding such deviation from the standard procedures in research and development of vaccine for Coronavirus.

Central Drugs Standard Control Organisation (CDSCO) has informed that it has granted test license permission for manufacture of COVID-19 Vaccine for preclinical test, examination and analysis to the following manufacturers in India:

1. M/s Serum Institute of India Pvt., Ltd., Pune
2. Ms. Cadila Healthcare Ltd., Ahmadabad
3. M/s Bharat Biotech International Ltd., Hyderabad
4. Biological E Ltd., Hyderabad



5. M/s Reliance Life Sciences Pvt Ltd., Mumbai
6. M/s Aurbindo Pharma Limited, Hyderabad
7. M/s Gennova Biopharmaceuticals Limited, Pune

The Indian Council of Medical Research (ICMR), an autonomous organisation under the Department of Health Research, has informed that it is facilitating the following studies related to COVID-19 vaccines:

(i) An inactivated whole virion candidate vaccine (BBV152) for SARS-CoV-2 has been developed by Bharat Biotech International Ltd (BBIL) using the virus isolate (NIV-2020-770) provided by ICMR-National Institute of Virology (NIV), Pune. Characterization of the vaccine candidate has been undertaken at ICMR-NIV followed by safety and tolerability studies in small animals like rats, mice and rabbits. Status of clinical trials is as follows:

- Phase I clinical trials along with parallel studies in hamsters and rhesus macaques have been completed. The trial has revealed excellent safety of the candidate vaccine. Immunogenicity testing is in progress.
- Phase II clinical trials are ongoing.

(ii) A DNA vaccine (ZyCov-D) has been developed by Cadila Healthcare Ltd. Pre-clinical toxicity studies were conducted in small animals: mice, rats, rabbits and guinea pigs. The vaccine has been found to be safe and immunogenic. Cadila has partnered with ICMR for conduct of parallel pre-clinical studies in rhesus macaques. Status of clinical trials is as follows:

- Phase I clinical trials have been completed. The trial has revealed excellent safety of the candidate vaccine. Immunogenicity testing is in progress.
- Phase II clinical trials are ongoing.

(iii) Serum Institute of India (SII) and ICMR have partnered for clinical development of two global vaccine candidates:

- ChAdOx1-S, which is a non-replicating viral vector vaccine developed by University of Oxford/AstraZeneca. This vaccine is undergoing phase III clinical trials in Brazil. Phase II/III bridging studies have been initiated by ICMR at 14 clinical trial sites. ICMR-National Institute for Research in Tuberculosis (NIRT), Chennai is the lead institution.
- ICMR and SII have also partnered for clinical development of a glycoprotein subunit nanoparticle adjuvanted vaccine developed by Novavax from USA. The trial will be initiated in second half of October after the vaccine is manufactured by SII. The trial is led by ICMR-National AIDS Research Institute (NARI), Pune.

As per details provided by Department of Biotechnology (DBT)/Department of Science and Technology (DST), more than 30 vaccine candidates have been supported which are in different stages of development.

The Minister of State (Health and Family Welfare), Sh Ashwini Kumar Choubey stated this in a written reply in the Lok Sabha here today.



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