

Vaccines Being Developed to Combat Coronavirus

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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 Genova 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 alongwith 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.

CDSCO has informed that it has granted permission to conduct clinical trials in various clinical trial sites such as New Delhi, Chennai, Chandigarh, Jaipur, Kanpur, Surat, Hyderabad, Pune, Mumbai, Ahmadabad, Bhubaneswar, Patna, Gorakhpur etc. and the trials are on going.

Presently, under Universal Immunization Program (UIP) vaccine distribution is based on Electronic Vaccine Intelligence Network (eVIN) system. eVIN is an internet based digital system to track routine immunization, vaccine stocks, storage temperature in about 25,000 dedicated cold chain storage points across the country as well as movement of vaccine. The vaccine is distributed to health facilities and outreach station sites, so as to reach in all areas. even system is regularly monitored by health authorities at state and district level. eVIN system is being enhanced to address the needs for distribution and tracking of COVID 19 vaccine, when it becomes available.

Further, a National Expert Group on COVID 19 vaccine has been constituted to guide the Government on:-

- Prioritization of population groups for vaccination.
- Selection of COVID 19 vaccine candidates.
- Inventory management and delivery mechanism of the vaccine including making of vaccination process.
- Selection of delivery platforms.
- Cold chain and associated infrastructure for roll-out of COVID 19 vaccination etc.

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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