

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH RESEARCH**

**LOK SABHA
UNSTARRED QUESTION NO. 1063
TO BE ANSWERED ON 18TH SEPTEMBER, 2020**

DISTRUBUTION OF VACCINES FOR COVID-19

**1063. SHRI RAHUL GANDHI:
SHRI TALARI RANGAIAH:**

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether the Government has formulated a vaccine strategy to facilitate the development, manufacture and distribution of vaccines for COVID-19 in India, if so, the details thereof ;
- (b) the details of the COVID-19 vaccine candidates currently being developed or manufactured in India;
- (c) whether India has joined international efforts to ensure equitable and fair access to vaccines for COVID- 19, if so, the details thereof;
- (d) whether India is planning to enter into advance purchase agreement(s) with vaccine manufacturers, if so, the details thereof?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)**

(a) to (d) Government of India has formed a National Expert Group on Vaccine Administration for Covid-19 chaired by Member(health), Niti Aayog.

They Expert Group has deliberated on broad parameters guiding the selection of Covid-19 vaccine candidates for the country and working in close coordination with Standing Technical Sub-Committee of National Technical Advisory Group on Immunization (NTAGI). It is also creating strategy on the procurement mechanisms for COVID-19 vaccine, including both indigenous and international manufacturing along with guiding principles for prioritization of population groups for vaccination.

Central Drugs Standard Control Organisation (CDSCO) 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

Indian Council of Medical Research (ICMR) 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. Phase I clinical trials along with parallel studies in hamsters and rhesus macaques have been completed & have 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. 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 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.

Department of Biotechnology (DBT)/Department of Science and Technology (DST) are also supporting more than 30 vaccine candidates which are in different stages of development.

The Government of India conveyed its intent to be part of the Vaccine Pillar of the Access to COVID-19 Tools (ACT) Accelerator, which may be beneficial in providing access to the global vaccine candidates in advanced stages, for their further utilization in the country. Under this pillar, COVAX facility has been created which is led by GAVI and WHO, for fair and equitable distribution of Covid-19 vaccine across the world.

The Department of Biotechnology through the IND-CEPI Mission is involved in key partnerships with 'Coalition for Epidemic Preparedness Innovations (CEPI)' for supporting Indian researchers for development of clinical immune assays to advance vaccine research.

No advance purchase agreement with any vaccine manufacturers have been entered into.