

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

**LOK SABHA  
UNSTARRED QUESTION NO. 922  
TO BE ANSWERED ON 18<sup>th</sup> SEPTEMBER, 2020**

**COVID-19 VACCINE BY ICMR**

**922. PROF. SAUGATA RAY:  
SHRI JAYADEV GALLA:**

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

- (a) whether the Government has issued orders to the officials of ICMR for developing vaccine;
- (b) if so, the details and status of the research programmes announced on 15th August, 2020 to find remedial medicine to check COVID-19;
- (c) the expected date of the availability of such medicine to common man in the country;
- (d) the details of Government institutions and private agencies approved by ICMR that are undertaking such researches and clinical trials for the purpose in the country; and
- (e) whether the Government has ensured financial assistance to such projects and 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): Central Drugs Standard Control Organisation (CDSCO) has informed that in the light of announcements on 15/08/2020 on COVID-19 vaccine, 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 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.

While the Govt. and Industry are trying their best to make available a safe and effective vaccine for COVID-19 at the earliest, it is difficult to comment on the exact timelines in view of various complex pathways involved in vaccine development.

(e): ICMR has so far spent more than Rs.25.00 crore from its intramural budget for undertaking work related to development of vaccine candidate and pre-clinical studies.

The Science and Engineering Research Board (SERB), a statutory body under the Department of Science and Technology, has supported 03 projects under COVID-19 on vaccine research under Intensified Research in High Priority Areas (IRHPA) The sanctioned expenditure is Rs.22,27,579/- and the committed expenditure is Rs.3,20,78,161/-

The Department of Biotechnology is also supporting 08 proposals by Industry and academia for candidate vaccine development and associated research resources at a total cost of Rs. 75 crore.