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

LOK SABHA
UNSTARRED QUESTION NO. 953
TO BE ANSWERED ON 18th SEPTEMBER, 2020

MUTATION IN SPIKE PROTEIN OF SARS-COV2

953. SHRI BALAK NATH:
SHRI SUMEDHANAND SARASWATI:

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

(a) whether the future of the COVID-19 vaccine is uncertain because of the mutation in spike protein of SARS-CoV2, which hinders the development of COVID- 19 vaccine;

(b) if so, the facts in this regard;

(c) the present status of research of COVID-19 vaccine in India; and

(d) the timeline by which it is likely to be available in the market as per World Health Organisation estimates?

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

(a) & (b): The Indian Council of Medical Research (ICMR), an autonomous organisation of the Department of Health Research, has informed that all the vaccines for COVID-19 are under various stages of development. It is difficult as well as premature to comment on their effectiveness and correlation with virus mutations. This data will be available once full clinical development of vaccine(s) is completed and after correlation with the virus strain sequence available at that particular time point.

(c): 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 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-clincial 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.

(d): 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.