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

LOK SABHA
UNSTARRED QUESTION NO. 2054
TO BE ANSWERED ON 12TH FEBRUARY, 2021

AVAILABILITY OF COVID VACCINE

2054.SHRI JASBIR SINGH GILL:

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

(a) the details of the manufacturers of COVID vaccines along with the number of doses of COVID vaccines available in the country; and

(b) whether result/data of 3rd phase trials of these vaccines is available with Government and if so, the details thereof?

ANSWER

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

(a): Two vaccines namely Covishield manufactured by M/s Serum Institute of India and Covaxin manufactured by M/s Bharat Biotech International Limited have been granted permission for restricted use in emergency situation by the National Regulator i.e. Drug Controller General of India [DCG(I)]. So far a total of 410 lakh doses of these two vaccines have been procured for COVID-19 vaccination drive in the country.

(b): M/s Bharat Biotech International Limited, Hyderabad has submitted safety and immunogenicity data of Phase I and II clinical trial carried out in the country along with safety data including Serious Adverse Events (SAE) data of the ongoing Phase III clinical trial in the country. The Subject Expert Committee (SEC) of Central Drugs & Standards Control Organisation (CDSCO) found that the data generated and shared demonstrates a strong immune response (both antibody as well as T cell) and in-vitro viral neutralization. Moreover, firm has presented the safety and efficacy data from Non-human primate challenge study where the vaccine was found to be safe and effective.

M/s Serum Institute of India Pvt., Ltdp. Pune has submitted safety immunogenicity & efficacy data of phase II/III clinical trials of AstraZeneca vaccine carried out in UK & Brazil & South Africa along with the safety & immunogenicity data from the ongoing Phase II/III clinical trial in India. The Subject Expert Committee (SEC) of CDSCO, the National Regulator, noted that the safety & immunogenicity data presented by the firm from the Indian study is comparable with that of the overseas clinical trial data.