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

RAJYA SABHA
UNSTARRED QUESTION NO.115
TO BE ANSWERED ON 2ND FEBRUARY, 2021

RUSH IN APPROVAL OF COVAXIN VACCINE

115 SHRI SYED NASIR HUSSAIN:
SHRI MALLIKARJUN KHARGE:
SHRI SANJAY SINGH:

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

(a) whether it is a fact that Phase-3 trial results of Covaxin vaccine that has been approved recently for emergency uses, have not been made available;

(b) if so, the basis on which Government gave the approval;

(c) the authority responsible in case of any adverse side-effects which come to light post administration of the vaccine, and

(d) the reason for such rush in giving approval?

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

(a) & (b): Covaxin vaccine is being manufactured by M/s Bharat Biotech International Limited. The firm had submitted interim safety and immunogenicity data of Phase I and II clinical trials carried out in the country along with safety data including Serious Adverse Event (SAE) data of the ongoing Phase III clinical trial in the country. The data was reviewed by Central Drugs Standard Control Organisation (CDSCO) in consultation with Subject Expert Committee (SEC). The committee noted that this vaccine is Inactivated Whole Virion Corona Virus Vaccine having potential to target mutated corona virus strains. The data demonstrated a strong immune response (both antibody as well as T cell) and in-vitro viral neutralization. The ongoing clinical trial is a large trial on 25800 Indian subjects in which all 25800 subjects have already been enrolled. Moreover, the firm presented the safety and efficacy data from Non-human primate challenge study also to CDSCO, where the vaccine has been found to be safe and effective.

After detailed deliberations, the SEC recommended grant of permission for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode, to have more options for vaccinations, especially in case of infection by mutant strains.

Based on the recommendations of SEC, CDSCO has granted permission to manufacture COVID-19 vaccine to M/s Bharat Biotech International Limited, Hyderabad for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode with various conditions/restrictions.

(c): As a part of the above permission granted by CDSCO, M/s Bharat Biotech International Limited is required to submit safety data on Adverse Events Following Immunization (AEFI) and Adverse Events of Special Interest (AESI) with due analysis every 15 days for first two months and monthly thereafter to CDSCO.

CDSCO, in consultation with Subject Expert Committee, has approved the protocol for rolling out the Whole Virion Inactivated Corona Virus Vaccine (BBV152) in clinical trial mode alongwith factsheet, informed consent form and adverse event form. As per the approval “In case of any serious adverse events, Vaccine recipients will be provided medically recognized standard of care in the government designated and authorized centres/hospitals. The compensation for serious adverse event will be paid by sponsor (BBIL) if the SAE is proven to be causally related to the vaccine. If any Vaccine recipient develops symptoms of COVID-19, Vaccine recipient will be provided medically recognized standard of care in the government designated and authorized centers/hospitals”.

(d): The approval in question has been given by the National Regulator based on the recommendations of the Subject Expert Committee.