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

LOK SABHA
UNSTARRED QUESTION NO.1995
TO BE ANSWERED ON 30TH JULY, 2021

CLINICAL TRAIAL OF COVAXIN

1995. SHRI MANISH TEWARI:

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

(a) whether the Government has taken into cognizance that Covaxin was allowed to be administered before the publishing of the third phase data, if so, the details thereof;

(b) whether the Government is aware that 26 sites in the third phase trial for Covaxin did not follow the New Drug and Clinical Trial Rules 2019, like refusing to provide free medical care to participants in the trial, if so, the details thereof;

(c) whether the members of the Subject Expert Committee of the Drugs Controller General of India (DCGI), changed their minds about Covaxin over the course of meetings on three days between December 30, 2020 to January 2, 2021 and permitted its use in clinical trial mode, if so, the details thereof; and

(d) whether this implies that Covaxin was rolled out for mass inoculation in clinical trial mode and if so, the details thereof?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a) to (d): The approval of COVID-19 vaccine for manufacturing/marketing is based on the submission of adequate data including Chemistry, Manufacturing and Control (CMC), non-clinical (animal studies) data, clinical trial data as per provisions of New Drugs and Clinical Trials (ND & CT) Rules, 2019 and outcomes of evaluation of the same in consultation with Subject Expert Committee (SEC) of the Central Drugs Standard Control Organisation (CDSCO).

CDSCO, in consultation with SEC, has granted permission to manufacture the COVID-19 vaccine of M/s Bharat Biotech International Limited, Hyderabad in light of the urgent need due to COVID pandemic in the country, as per the provisions of New Drugs and Clinical Trials Rules, 2019 (ND & CT Rules 2019) under Drugs and Cosmetics Act, 1940.

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 CDSCO in consultation with SEC comprising domain knowledge experts. The committee noted that this vaccine is “an Inactivated Whole Virion Corona Virus Vaccine”, having potential to also target mutated corona virus strains. The ongoing clinical trial is a large trial on 25800 Indian subjects including subjects with co-morbid conditions as well, which has demonstrated safety till date. Moreover, the firm presented the safety and efficacy data from Non-human primate challenge study also to CDSCO, wherein 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, so as to have more options for vaccinations, especially in case of infection by mutant strains.

Accordingly, based on the recommendations of SEC, CDSCO has granted permission to M/s Bharat Biotech International Limited, Hyderabad to manufacture Covaxin vaccine for restricted use in emergency situation with various conditions/restrictions.

Subsequently, CDSCO in consultation with SEC also approved the implementation protocol for rolling out the Whole Virion Inactivated Corona Virus Vaccine (BBV152) in clinical trial mode along with factsheet, informed consent form and adverse event form. Thereafter, the firm submitted the interim safety and efficacy data of phase III clinical trial of Whole Virion, Inactivated Corona Virus Vaccine (BBV152) to CDSCO which was reviewed in consultation with SEC (COVID-19) meetings held on 08.03.2021 & 10.03.2021 respectively, wherein after detailed deliberation the committee recommended for omission of the condition of the use of the vaccine in clinical trial mode.

Subsequently, Based on the recommendations of SEC, the condition of permission of the vaccine under clinical trial mode has been removed providing that the permission is for restricted use in emergency situation.