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

LOK SABHA
UNSTARRED QUESTION NO. 912
TO BE ANSWERED ON 5TH FEBRUARY, 2021

COVISHIELD AND COVAXIN

912. SHRI MANISH TEWARI:

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

(a) the details of the regulatory approval that has been given to both Covishield and Covaxin;

(b) whether Phase 3 trials of these vaccines have been completed, if so, the details thereof and if not, the reasons for using these vaccines for mass immunization programme;

(c) whether approval of these vaccines certified for restricted use in emergency situation qualify for mass immunization, if so, the details thereof;

(d) whether a large number of people in Bhopal were made to participate in the trials of Covaxin without taking their informed consent, if so, the details thereof; and

(e) whether many of them have reported adverse effects after participating in the Covaxin trials, and this was taken into account by the Subjects' Experts Committee and other concerned bodies before recommending Covisheild and Covaxin for the immunisation drive, if so, the details thereof?

ANSWER

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

(a) to (c): Central Drugs Standards Control Organization (CDSCO) has granted permission to manufacture both Covishield and Covaxin as per 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 Central Drugs Standard Control Organisation (CDSCO) in consultation with Subject Expert Committee (SEC) comprising domain knowledge experts. 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 M/s Bharat Biotech International Limited, Hyderabad to manufacture Covaxin vaccine for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode with various conditions/restrictions.

M/s Serum Institute of India Pvt., Ltd. Pune has submitted safety immunogenicity & efficacy data of phase II/III clinical trials of AstraZeneca vaccine carried out in UK, Brazil and South Africa along with the safety & immunogenicity data from the ongoing Phase II/III clinical trial in the country. The Subject Expert Committee (SEC) of CDSCO reviewed the proposal of restricted emergency use along with above details and the data received. The Medicines and Healthcare products Regulatory Agency (MHRA) approval for AstraZeneca vaccine on 30.12.2020 along with its conditions/restrictions was also reviewed by the committee.

The committee noted that the safety & immunogenicity data presented by the firm from the Indian study is comparable with that of the overseas clinical trial data.

Based on the recommendations of SEC, CDSCO granted permission to Serum Institute of India to manufacture COVISHIELD vaccine for restricted use in emergency situation with various conditions/restrictions.

(d) & (e): As per the provisions under New Drugs and Clinical Trials Rules, 2019, in all trials, a freely given, informed, written consent is required to be obtained from subjects of each study before their inclusion in clinical trial. As per available information, none of the participants in the Covaxin clinical trial have been enrolled without taking an informed consent.

Common adverse events which have been reported from COVID-19 vaccines approved for restricted use in emergency situation include headache, rash, chills, myalgia, fatigue, fever, dizziness, inflammation and pain, swelling or redness at the site of injection, erythema, pruritus etc. The data from phase 1 safety trials of Covaxin have been recently published in The Lancet Infectious Diseases.