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

LOK SABHA
UNSTARRED QUESTION NO. 899
TO BE ANSWERED ON 5TH FEBRUARY, 2021

DEVELOPMENT OF VACCINE FOR CORONAVIRUS

899. SHRI OMPRAKASH BHUPALSINH ALIAS PAWAN RAJENIMBALKAR:
SHRI RAHUL RAMESH SHEWALE:

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

(a) whether any deviation has been reported in research and development of vaccine for Coronavirus from the standard established procedure;

(b) if so, the details thereof and the reasons therefor along with the standard established procedure for research and development of a vaccine for any virus/ bacteria in the country;

(c) whether the Institutes/Companies developing vaccine for Coronavirus have shared the outcome of human trials conducted by them with the Government;

(d) if so, the details thereof along with the number of cases of adverse reactions reported in such trials; and

(e) the time by which vaccine for Coronavirus is likely to be provided to all citizens in the country?

ANSWER

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

(a) to (d): 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.

Furthermore, CDSCO has granted permission to conduct clinical trials of COVID-19 vaccines either manufactured in the country/outside the country.

Common adverse events which have been reported from COVID -19 vaccines which are approved for restricted use in emergency situation includes headache, rash, chills, myalgia, fatigue, fever, dizziness, inflammation and pain, swelling or redness at the site of injection, vaccination site, erythema, pruritus etc. So far as Serious Adverse Events (SAE) are concerned, 51 SAEs have been received by CDSCO from various clinical trials of COVID-19 vaccine.

(e): The priority groups for vaccination have been recommended by the National Experts Group on Vaccine Administration for Covid-19 (NEGVAC). The recommendations of NEGVAC in this regard have been accepted by the Central Government. The vaccine administration across the country is being done following the recommendations of NEGVAC.