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

LOK SABHA
UNSTARRED QUESTION NO. 4089
TO BE ANSWERED ON 19TH MARCH, 2021

REGULATORY PROCESS FOR CLEARING VACCINES

4089. SHRI MANISH TEWARI:

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

(a) the regulatory processes/steps involved in clearing a vaccine for mass inoculation;

(b) whether the regulatory processes were followed while granting approvals to both Covishield and Covaxin respectively, if so, the details thereof;

(c) the details of the recommendation of the Subjects Experts Committee on Covaxin;

(d) whether the SEC did a U turn on it's recommendations with regard to Covaxin between December 30th 2020 and January 2nd 2021, if so, the details thereof; and

(e) whether the approvals to Covaxin were granted without completion of Phase - 3 Trials and overlooking the unfavourable trial results and if so, the details thereof?

ANSWER

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

(a) to (e): 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).

As per New Drugs and Clinical Trials Rules, 2019 (ND & CT Rules 2019) under Drugs and Cosmetics Act, 1940 and in light of urgent need due to COVID pandemic in the country, Central Drugs Standard Control Organisation (CDSCO) in consultation with Subject Expert Committee (SEC) has granted permission to manufacture the following COVID-19 vaccines:

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 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, 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.

Subsequently, CDSCO in consultation with Subject Expert Committee (SEC) had 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. However, the vaccine should be continued to be used under restricted use in emergency situation condition.

Further, the ongoing phase III clinical trial should be continued as per the approved protocol. The firm should update the prescribing information and factsheet accordingly (under restricted use in emergency situation condition). All other conditions of the marketing authorisation shall continue to remain the same. 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.

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.