

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

**LOK SABHA
UNSTARRED QUESTION NO. 842
TO BE ANSWERED ON 5TH FEBRUARY, 2021**

MANDATORY PROTOCOLS FOR VACCINE APPROVAL

**842. SHRI BALUBHAU ALIAS SURESH NARAYAN DHANORKAR:
DR. MOHAMMAD JAWED:
DR. A. CHALLAKUMAR:**

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

- (a) whether the government was aware that the data for approving the vaccine candidate of Bharat Biotech, phase 3 trials had not yet been concluded?
- (b) if so, the reasons for the approval of vaccine candidates without following mandatory protocols, including verification of data on safety and efficacy;
- (c) whether the government intends to review the data on safety and efficacy of the approved vaccine candidates; and
- (d) if so, details thereof and if not, reasons therefor?

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) 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.

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.

(c) & (d): 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 for further review.