

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

**RAJYA SABHA
UNSTARRED QUESTION NO.1552
TO BE ANSWERED ON 20th DECEMBER, 2022**

ANOMALIES IN COVAXIN VACCINE TRIALS

1552: SHRI SYED NASIR HUSSAIN:

SMT. RANJEET RANJAN:

DR. AMEE YAJNIK:

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

- (a) whether it is a fact that Government approved, Phase 3 trials for COVAXIN before the results of Phase 2 trials were made available by Bharat Biotech;
- (b) if so, the details of the vaccine efficacy data for COVAXIN used to make this decision;
- (c) if not, when were the Phase 2 trial results for COVAXIN available from Bharat Biotech; and
- (d) when Government approved Phase 3 for COVAXIN?

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

(a) to (d): M/s Bharat Biotech had submitted interim report including safety and immunogenicity data of Phase I/II clinical trial conducted in the country along with its application to Central Drugs Standard Control Organisation (CDSCO) for grant of permission to conduct Phase III clinical trial of COVAXIN vaccine in the country.

CDSCO reviewed the data submitted by M/s Bharat Biotech in consultation with the Subject Expert Committee (SEC) as per the scientific principles and procedures prescribed in the rules.

M/s Bharat Biotech presented their data from Phase I and II clinical trial, and the animal challenge data along with the proposal to conduct Phase III clinical trial in the SEC meeting held on 20.10.2020. Based on the recommendations of the SEC, permission to conduct Phase III clinical trial subject to various conditions was granted on 23.10.2020.
