

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

**LOK SABHA
UNSTARRED QUESTION NO.412
TO BE ANSWERED ON 03RD FEBRUARY, 2023**

COVAXIN VACCINE

412: DR. AMAR SINGH:

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

- (a) whether the results of Phase 2 trials of COVAXIN have been made available by Bharat Biotech International Limited;
- (b) if not, the reasons therefor and the time by which it is likely to be made available;
- (c) whether the Government has approved/ proposes to allow the phase three trials of the COVAXIN vaccine even before the availability of data of phase 2 trails and if so, the details thereof; and
- (d) the details of the vaccine efficacy data of COVAXIN vaccine dependent upon to make this decision?

ANSWER

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

(a) to (d): The result of phase I/II clinical trials of COVAXIN vaccine have been made available by M/s Bharat Biotech. 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 relevant rules.

M/s Bharat Biotech's detailed data from Phase I and II clinical trial, and the animal challenge data along with the proposal to conduct Phase III clinical trial was presented and discussed in the SEC meeting held in CDSCO 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.
