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

LOK SABHA
UNSTARRED QUESTION NO. 1040
TO BE ANSWERED ON 03rd DECEMBER, 2021

DATA ON COVAXIN

1040: SHRIMATI MALA ROY:

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

(a) the details of the data that was available with the Drug Controller General of India (DGCI) in January on Covaxin when it was given Emergency Use Authorization (EUA); and

(b) the nature of the data sought by World Health Organisation (WHO) in its frequent correspondence and on the October 26,2021 meeting of the Strategic Advisory Group of Experts on Immunization (SAGE) for approval of Covaxin?

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

(a): Central Drugs Standard Control Organisation (CDSCO), in consultation with Subject Expert Committee (SEC), has granted permission to manufacture the COVID-19 vaccine of M/s Bharat Biotech International Limited, Hyderabad in light of the urgent need due to COVID pandemic in the country, as per the provisions of New Drugs and Clinical Trials Rules, 2019 (ND & CT Rules 2019) under Drugs and Cosmetics Act, 1940.

M/s Bharat Biotech International Limited, Hyderabad had submitted following data to CDSCO at the time of grant of permission to manufacture COVAXIN vaccine.

1. Animal data including immunogenicity & animal toxicity.
2. Safety and Efficacy data from Non-human primate challenge study.
3. Interim Safety and Immunogenicity data of ongoing Phase I trial and Phase II trial conducted in the country.

4. Interim safety data including Serious Adverse Events (SAE) data of the ongoing Phase III clinical trial in the country.

(b) The manufacturer submits the application to World Health Organization (WHO) directly for prequalification of Vaccine.

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