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

LOK SABHA
UNSTARRED QUESTION NO. 4976
TO BE ANSWERED ON 01st APRIL 2022

SAFETY AND EFFICACY DATA OF CORBEVAX VACCINE

4976. SHRI ADHIKARI DEEPAK (DEV)

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

(a) whether the Government has given approval to a new COVID-19 vaccine named Corbevax for vaccinating children in the age group 12-14 year, after ascertaining the safety and efficacy data of the vaccine, if so, the details thereof;
(b) whether the data on the above vaccine has been peer reviewed, if so, the details thereof;
(c) whether the use of Corbevax in the above age group is yet to be approved by NTAGI, if so, the details thereof;
(d) whether the protein sub unit used in the vaccine is from the wild Wuhan type SARS-CoV-2 virus, if so, the details thereof; and
(e) whether the Government has any data regarding its efficacy against omicron and other variants, if so, the details thereof?

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

(a) to (e) Based on the interim safety & immunogenicity data of Phase II/III clinical trial conducted in subjects of ≥ 5 to <18 years age group, Central Drugs Standard Control Organisation (CDSCO), the National Regulator in consultation with Subject Expert Committee (SEC) has granted permission to manufacture SARS-CoV-2 vaccine [CORBEVAX] of M/s Biological E Limited for restricted use in emergency situation in ≥ 12 to <18 years age group.

Peer review of clinical trial results of specific vaccines are usually done by domain knowledge experts and scientists who have developed and manufactured these vaccines or who have knowledge of such vaccines and vaccination process.

Government of India has expanded the COVID-19 vaccination to beneficiaries aged 12-14 years from 16th March 2022 on the recommendation of domain knowledge experts.

CORBEVAX vaccine has been tested for Neutralizing Antibody (nAb) Titers against Wuhan, Delta and Beta variants in its Phase II/III clinical trial & Phase III (immunogenic superiority) clinical trial conducted in the country & its reported to be immunogenic. The potential impact of Omicron variant on existing countermeasures including vaccine is scrutinized by technical groups worldwide. Vaccines used in National Covid-19 Vaccination Program remain effective to prevent the risk of severity due to COVID-19.

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