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Government approves COVID-19 vaccines for children aged 5-12 yrs

26 April 2022 | News

This includes Bharat Biotech's Covaxin and Biological E's Corbevax

Drugs Controller General of India (DCGI) has given its nod for emergency use authorisation of Bharat Biotech's BBV152 (COVAXIN) and Biological E (BE)'s CORBEVAX in children 5-12 years of age.

Bharat Biotech had conducted phase II/III, open-label, and multicenter studies to evaluate the safety, reactogenicity, and immunogenicity of COVAXIN in healthy children and adolescents in the 2-18 age group.

Fresh stocks of COVAXIN are available and ready for supplies. Bharat Biotech has readily available more than 50 million doses of COVAXIN in vials, and more than 200 million doses as drug substance. Additional production capacity is also available to meet product demand.

On the other hand, BE performed a multi-centric, Phase 2/3 clinical trial in 624 children aged between 5 and 18 in two age sub-sets, i.e., ?12 to <18 years and ?5 to <12 years. As a part of the trial, children were administered two doses of 0.5 ml each of the vaccine or placebo in a gap of 28 days.

BE has manufactured 30 crore doses of CORBEVAX and have already supplied nearly 10 crore doses to the Government of India. Currently, over 3 crore doses of CORBEVAX have been administered in children between 12-15 years of age.