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Novavax' COVID-19 vaccine receives DCGI approval for adolescent population

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Novavax and Serum Institute of India announce first emergency use authorization of Novavax' COVID-19 vaccine in adolescents in India



US-based Novavax, Inc. and Serum Institute of India (SII) have announced that the Drugs Controller General ofIndia (DCGI) has granted emergency use authorization (EUA) for Novavax' protein-based COVID-19 vaccine for adolescents aged ?12 to <18 years in India.

The vaccine, also known as NVX-CoV2373, is manufactured and marketed in India by SII under the brand name Covovax and is the first protein-based vaccine authorized for use in this age group in India.

Covovax is the fourth vaccine to receive EUA from the DCGI for use among adolescents 12 and older. The safety and efficacy of Covovax in adolescents aged less than 12 years have not yet been established; however, studies evaluating the safety and immunogenicity of Covovax for the age groups of ?7 to <12 and ?2 to <7 years in India are underway.

A Phase 2/3, observer-blinded, randomized, controlled study in a total of 460 Indian adolescents aged ?12 to <18 years was conducted to evaluate the safety and immunogenicity of Covovax. The study demonstrated that Covovax was well-tolerated with a reassuring safety profile.