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Novavax, Serum Institute of India file for COVID-19 vaccine EUA in South Africa

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The vaccine is currently under review by multiple other regulatory agencies worldwide



Novavax, Inc. and Serum Institute of India have announced a regulatory submission to the South African Health Products Regulatory Agency (SAHPRA) for emergency use authorization (EUA) of Novavax' recombinant nanoparticle protein-based COVID-19 vaccine candidate with Matrix-M™ adjuvant.

If authorized, the vaccine (known as NVX-CoV2373) will be manufactured by and commercialized by SII in South Africa under the brand name Covovax™.

The submission for the regulatory evaluation by SAHPRA of NVX-CoV2373 includes data from two pivotal Phase 3 clinical trials: PREVENT-19, which enrolled approximately 30,000 participants in the U.S. and Mexico and was published in the New England Journal of Medicine (NEJM); and a trial with almost 15,000 participants in the U.K. which was also published in NEJM. In both trials, the vaccine demonstrated high efficacy with a reassuring safety profile. Serious and severe adverse events were low in number and balanced between vaccine and placebo groups.