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Serum Institute, Novavax submit COVID-19 vaccine emergency use listing to WHO

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The submission to WHO is based on the companies' previous regulatory submission to the Drugs Controller General of India

Indian vaccine manufacturer Serum Institute of India (SII) and its US-based partner Novavax, have announced a regulatory submission to the World Health Organization (WHO) for emergency use listing (EUL) of Novavax' recombinant nanoparticle protein-based COVID-19 vaccine candidate with Matrix-M adjuvant.

The grant of EUL by the WHO is a prerequisite for exports to numerous countries participating in the COVAX Facility, which was established to allocate and distribute vaccines equitably to participating countries and economies.

In addition to the submission for WHO EUL, SII and Novavax last month completed the submission of modules required by regulatory agencies in India, Indonesia and the Philippines for the initiation of a review of the vaccine, including preclinical, clinical, and chemistry, manufacturing and controls (CMC) data.

NVX-CoV2373 is a protein-based vaccine candidate engineered from the genetic sequence of the first strain of SARS-CoV-2.