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Novavax, Serum Institute seek nanoparticle COVID-19 vaccine approval in India

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Filing for World Health Organization Emergency Use Listing expected in August 2021



US-based Novavax with its partner, Serum Institute of India (SII), has announced that the companies have filed regulatory submissions for emergency use authorization of Novavax' recombinant nanoparticle protein-based COVID-19 vaccine candidate with Matrix-M adjuvant. The submission was recently made to the Drugs Controller General of India (DCGI)

In addition, the companies have also applied to the regulatory agencies in Indonesia and the Philippines.

SII and Novavax have now completed the submission of all modules required by regulatory agencies in India, Indonesia and the Philippines for the initiation of the review of the vaccine, including preclinical, clinical, and chemistry, manufacturing and controls data. A Good Manufacturing Practice joint site inspection of SII was successfully completed by DCGI in May 2021.

A submission to the World Health Organization (WHO) for emergency use listing (EUL) based on the DCGI submission is expected to be filed in August. 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.

Novavax' COVID-19 vaccine is packaged as a ready-to-use liquid formulation in a vial containing ten doses. The vaccination regimen calls for two 0.5 ml doses (5 microgram antigen and 50 microgram Matrix-M adjuvant) given intramuscularly 21 days apart. The vaccine is stored at 2°- 8° Celsius, enabling the use of existing vaccine supply and cold chain channels.

SII is manufacturing, and developing, and is responsible for commercializing the vaccine in India. Novavax and SII have cumulative commitments to provide more than 1.1 billion doses to the COVAX Facility.