

Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 223th meeting held on 29.04.2022 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/MA/22/000025 SARS-CoV-2 rS Protein (COVID-19) Nanoparticle vaccine COVOVAX Vaccine	M/s Serum Institute of India Pvt., Ltd., Pune	<p>In light of the earlier recommendation of SEC meeting dated 11.04.2022, the firm presented:</p> <ul style="list-style-type: none"> i. Updated safety data of 3 months post 2nd dose in the age group of 7 to 11 years & 12 to 17 years. ii. Virus neutralising antibody data against variants of concern, in adult participants (\geq 18 years of age) following the primary vaccination series of Novavax vaccine. The efficacy against variants of concern/interest (VOC/VOI) was 93.2% including B.1.1.7 (Alpha) variant was 86.3% (UK study) and 93.6% (USA study). iii. Updated status of the approval in overseas countries for COVOVAX of M/s Serum & Nuvaxovid (M/s Novavax) in adults age group for its proposal for grant of marketing authorization for additional indication of SARS-CoV-2 Recombinant spike protein Nanoparticle vaccine (SARS-COV-2-Rs) with Matrix-M1 Adjuvant for use in >7 to <12 years age group for Restricted use in Emergency situation. <p>After detailed deliberation, the committee recommended to submit further safety data including:</p> <ul style="list-style-type: none"> i. Safety & immunogenicity data of all subjects in the 12 to 18 years age group of vaccine manufactured by technology collaborator M/s Novavax currently in trial and ii. Updated status of the approval & usage, if any, of vaccine in children & adolescent age group in overseas countries along with their risk management plan for further review.