

Minutes of the Meeting of Subject Expert Committee (SEC) – COVID-19 Vaccine to review proposals and advice Drugs Controller General (India) in matters for Biologicals & PAC proposals held on 22.01.2026 (through hybrid mode)

The Recommendations:

The SEC (COVID-19 Vaccine) deliberated the proposals on 22.01.2026 and recommended the following:

Sr. No	Name of Vaccine & File no.	Name of Firm	Recommendations
1	<p>Trivalent Nanoparticle Influenza (tNIV) Vaccine and Covid Trivalent Influenza Combination (CIC) Vaccine.</p> <p>Phase II interim clinical trial report of the Phase II/III clinical trial</p> <p>[BIO/CT/25/000066] (BIO/PostAppr/2025/43609)</p>	<p>M/s. Serum Institute of India Pvt Ltd.</p>	<p>In light of recommendation of SEC (COVID-19) meeting dated 20.06.2025, firm presented the interim safety study report of Phase II of the Phase II/III study titled “A Phase II/III, Multicentre, Observer-Blind, Randomized, Active-Controlled Study to Evaluate Immunogenicity and Safety of A Trivalent Nanoparticle Influenza Vaccine and Covid-Influenza Combination Vaccine Compared with Licensed Influenza and COVID -19 Vaccines in Adults” granted by CDSCO along with DSMB recommendation for review before proceeding to Phase III study.</p> <p>The committee noted the interim safety report of the study as per the approved protocol.</p> <p>In view of above and after detailed deliberation, the committee recommended for conduct of Phase III part of the study as per approved protocol.</p>
2	<p>COVID-19 Vaccine, Adjuvanted (SARS-CoV-2 rS Protein (COVID-19) Nanoparticle Vaccine, Omicron JN.1 Variant) with Matrix M1 adjuvant</p> <p>New Drug Permission [MA]</p> <p>[BIO/MA/25/000098]</p>	<p>M/s. Serum Institute of India Pvt Ltd.</p>	<p>Firm submitted application for grant of new drug permission of COVID-19 Vaccine, Adjuvanted (SARS-CoV-2 rS Protein (COVID-19) Nanoparticle Vaccine, (Omicron JN.1 Variant) with Matrix M1 adjuvant for active immunization to prevent COVID-19 caused by SARS- CoV-2 in individuals 12 years of age and older.</p> <p>The committee noted the following:-</p> <ol style="list-style-type: none"> 1. The firm is holding the following permissions for Covid-19 Nanoparticle Vaccine (COVOVAX): - <ol style="list-style-type: none"> i. CDSCO approval dated 28.12.2021 for the SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine (Wuhan) with Matrix M1 adjuvant for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older

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			<p>when administered in two dose schedule of day 0 & day 21 for restricted use in emergency situation.</p> <p>ii. CDSCO approval dated 09.03.2022 for the additional indication for SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine with Matrix M1 adjuvant for use in age group of ≥ 12 to < 18 years with the dose schedule of 0 & 21 days for restricted use in emergency situation.</p> <p>iii. CDSCO approval dated 28.06.2022 for the additional indication of SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine with Matrix M1 adjuvant for use in the age group of ≥ 7 to < 12 years for restricted use in emergency situation with the dose (0.5ml) schedule of 0 & 21 days.</p> <p>iv. CDSCO approval dated 16.01.2023 for the additional indication of SARS-CoV-2 rS Protein (COVID-19) Recombinant Spike Protein Nanoparticle Vaccine with Matrix M1 adjuvant for administration as heterologous booster (third) dose to individuals aged ≥ 18 years after 6 months of administration of primary vaccination (two doses) of COVAXIN or COVISHIELD vaccine for restricted use in emergency situation.</p> <p>v. CDSCO approval dated 06.06.2024 for the Covid-19 Vaccine, Adjuvanted 2023-24 Formula [SARS-CoV-2 rS Protein (COVID-19) Nanoparticle Vaccine, Omicron XBB 1.5 variant] with Matrix M1 adjuvant (COVOVAX) in multi-dose vials containing 5 doses of 0.5 mL each for restricted use in emergency situation for individuals of ≥ 12 to < 18 years of age as primary series of two doses (0.5mL each) 3 weeks apart and also as single precautionary dose in individuals of ≥ 18 years of age, who have received primary series of vaccinations.</p>
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