

Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 230th meeting held on 24.06.2022 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/CT/22/000027 Lyophilized mRNA Vaccine Injection (COVID-19) [HGCO19]	M/s Gennova Biopharmaceuticals Limited	<p>In light of the recommendations of SEC meetings dated 11.04.2022 & 21.04.2022, the firm presented its proposal for grant of marketing authorization permission of Lyophilized mRNA Vaccine for Injection (COVID-19) [HGCO19] in >18 years age group for Restricted use in Emergency situation along with interim safety and immunogenicity data of Phase I & Phase II/III (active comparator) clinical trials before the committee.</p> <p>The firm presented overall summary of pre-clinical studies data including immunogenicity, toxicity studies in Rats, Mice & Hamster and challenge study conducted in Hamster.</p> <p>The firm also presented interim clinical trial data for Phase I trial & Phase II/III trial (active comparator) conducted in the country as below:</p> <p>Phase I: Safety data of 6 months & immunogenicity data of day 43 (14 days post second dose).</p> <p>Phase II part: Interim safety data of day 119 (3 months post second dose) and immunogenicity data of day 43 (14 days post second dose) for 400 subjects.</p> <p>Phase III part: Interim Safety data of Day 119 (3 months post second dose) of 3200 subjects of Phase III part and immunogenicity data for 714 subjects (immunogenicity cohort) day 43 (14 days post second dose) including Anti-Spike IgG antibody, neutralising antibody (including live virus, surrogate assay & pseudovirus) and cellular response.</p> <p>The committee noted that the safety data of Phase I & Phase II/III (active comparator) clinical trials was satisfactory and also noted that the vaccine is observed to be non-inferior to COVISHIELD vaccine.</p> <p>The committee also reviewed the package</p>

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			<p>insert, factsheet and SmPC of the vaccine. After detailed deliberation, as the trial was conducted during the period when Omicron was dominant variant in the country and in the light of current pandemic situation, the committee recommended for grant of permission for manufacture and marketing of Lyophilized mRNA Vaccine for Injection (COVID-19) [HGCO19] for restricted use in emergency situation subject to various regulatory provisions including following:</p> <ol style="list-style-type: none"> 1. The vaccine is indicated for active immunization to prevent COVID-19 disease in individuals of aged 18 years and above. 2. The vaccine should be administered intramuscularly in two doses (0.5 ml each) at day 0 & day 28. 3. Firm should submit revised PI, SmPC & Factsheet to CDSCO after incorporating the latest safety, immunogenicity data and other suggestions made during the meeting. 4. The vaccine should be supplied along with factsheet & separate leaflet for the guidance of the healthcare provider 5. The firm should ensure that factsheet for the vaccine recipient/attendant is provided prior to administration of the vaccine. 6. The firm should disseminate the instructions & educational material including factsheet, PI, SmPC, storage instructions etc. in their website. 7. The firm should submit safety & immunogenicity data from the ongoing clinical trials in the country for review as and when available. 8. The firm should submit safety data including the data on AEFI and AESI with due analysis every 15 days for the first two months & monthly thereafter till the completion of the ongoing clinical trial in the country. Thereafter, the firm should submit the safety data

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			<p>as per the provisions and standard procedures.</p> <p>9. The firm should submit Risk management plan.</p>
2.	<p>BIO/MA/22/000025</p> <p>SARS-CoV-2 rS Protein (COVID-19) Nanoparticle vaccine COVOVAX Vaccine</p>	<p>M/s Serum Institute of India Pvt., Ltd., Pune</p>	<p>In light of the earlier recommendation of SEC meeting dated 11.04.2022 & 29.04.2022, the firm presented Safety & immunogenicity data of all subjects in the 12 to 18 years age group of NUVAXOVID vaccine manufactured by technology collaborator M/s Novavax currently in trial. The firm stated that the NUVAXOVID vaccine which is manufactured by technology collaborator M/s Novavax has been recommended by the Committee for Medicinal Products for Human Use (CHMP) of European Medicines Agency (EMA) for use in age >12 years. Firm has submitted risk management plan for NUVAXOVID vaccine of technology collaborator M/s Novavax, for its proposal for grant of marketing authorization permission for additional indication of SARS-CoV-2 Recombinant spike protein Nanoparticle vaccine (SARS-COV-2-Rs) with Matrix-M1 Adjuvant (COVOVAX) for use in ≥ 7 to <12 years age group for Restricted use in Emergency situation.</p> <p>The committee reviewed the interim immunogenicity and safety data of Phase II/III clinical trial conducted in the age group of ≥ 7 years to <12 years .</p> <p>The committee also reviewed the SmPC & PI of the vaccine</p> <p>After detailed deliberation, in the light of pandemic situation the committee recommended for grant of permission for manufacture and marketing of SARS-CoV-2 rS Protein (COVID-19) Nanoparticle vaccine (COVOVAX) for age group of ≥ 7 to <12 years for restricted use the in emergency situation with the condition to submit ongoing clinical trial data. Further, the conditions of earlier permissions granted to use of vaccine for</p>

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3.	BIO/MA/22/000062 SARS-CoV-2 rS Protein (COVID-19) Nanoparticle vaccine COVOVAX Vaccine	M/s Serum Institute of India Pvt., Ltd., Pune	<p>higher age groups should remain unchanged.</p> <p>The firm presented 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 >2 to <7 years age group for Restricted use in Emergency situation along with interim safety and immunogenicity data of Phase II/III clinical trial before the committee.</p> <p>The firm presented interim safety data of 2 months post second dose follow up & immunogenicity data of day 36 (14 days post second dose) for 228 participants in >2 to <7 years age group.</p> <p>The firm also presented additional safety data of age groups ≥ 7 to <12 years & >12 to <17 years wherein no SAE & AESI related to vaccine were observed.</p> <p>The committee reviewed the interim immunogenicity and safety data of Phase II/III clinical trial conducted in the age group of >2 years to <7 years.</p> <p>The committee also noted that the vaccine manufactured by technology collaborator M/s Novavax is not approved in the proposed age group in overseas countries & also no clinical trial has been conducted in the proposed age group.</p> <p>After detailed deliberation, the committee recommended that the firm should submit following data for further review by the committee:</p> <ol style="list-style-type: none"> 1. Safety data 2 to 3 months post 2nd dose in adequate number of population. 2. Experience of usage of vaccine in >7 to <12 years age group with respect to safety (AEFI & AESI) 3. Cell mediated immunogenicity data in proposed age group. 4. Updated status of the clinical trial or approval in overseas countries in the proposed age group of >2 to <7 years. 5. Virus neutralising antibody data against

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			variants of concern, if any.