Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 219th meeting held on 11.04.2022 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/MA/22/000018	M/s Biological E Ltd., Hyderabad	The firm presented its proposal for grant of marketing authorization for additional indication in SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2 for restricted use in emergency situation in the age group of ≥ 5 years to <12 years along with the interim safety & immunogenicity data of Phase II/III clinical trial conducted in subjects ≥ 5 years to <18 years before the committee. The firm presented interim safety data (day 56: 28 days post dose 2 in 312 subjects & interim immunogenicity data of day 42 (14 day's post dose 2) in 229 subjects including Neutralising Antibody titres in 220 subjects for the age group of ≥5 years to <12 years along with comparison with adult age group of earlier Phase II/III and Phase III trials. After detailed deliberation, the committee recommended that firm should submit following data for further review by the committee: 1. Updated Safety data 2 to 3 months post 2nd dose in the proposed age group along with the safety data available from the doses used up till in the higher age group. 2. Cell mediated immunogenicity data as proposed in protocol. 3. Virus neutralising antibody data against variants of concern, if any.
2.	BIO/MA/22/000025 SARS-CoV-2 Recombinant spike protein Nanoparticle vaccine (SARS-COV-2-Rs) with Matrix-M1 Adjuvant	M/s Serum Institute of India Pvt. Ltd. Pune	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 >7 to <12 years age group for Restricted use in Emergency situation along with interim safety and immunogenicity Phase II/III clinical trial data/results before the committee. The firm presented interim safety data of 2 months post second dose follow up &

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			immunogenicity data of day 36 (14 days post second dose) for 225 participants in >7 to <12 years age group. The firm also presented additional safety data of >12 to <18 years age group with median follow up of 168 days wherein no SAE & AESI related to vaccine were observed. The committee noted the interim safety & immunogenicity data of Phase II/III trial. 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. After detailed deliberation, the committee recommended that the firm should submit following data for further review by the committee: 1. Safety data 2 to 3 months post 2nd dose. 2. Cell mediated immunogenicity data in proposed age group. 3. Updated status of the approval in overseas countries. 4. Virus neutralising antibody data against variants of concern, if any.
3.	BIO/CT/21/000150 Phase IV clinical trial [Covishield, Covaxin]	PGIMS, Chandigarh	In light of the recommendations of SEC meeting dated 15.02.2022, the Institute presented revised clinical trial protocol for conduct of Phase IV (academic) clinical trial for assessment of safety, tolerability & immunogenicity of COVID-19 vaccines (COVISHIELD & COVAXIN**)** in homologous prime/boost schedule as compared with heterologous prime/boost schedule amongst adults in North India region. After detailed deliberation, the committee recommended for grant of permission to conduct proposed clinical trial subject to following conditions: 1. Institute should submit revised risk mitigation plan for monitoring of study

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			participants up to 30 minutes post vaccine administration. 2. Th2 parameter, soluble IL4 levels should be included in cell mediated immunogenicity assessment. 3. Immunogenicity assessment at 6, 9 & 12 months post administration of heterologous booster to be carried out. Accordingly, the Institute should submit revised clinical trial protocol to CDSCO for approval.
4.	BIO/MA/21/000063 Novel Corona Virus - 2019-nCov vaccine 3mg, Two dose schedule	M/s. Cadila Healthcare Ltd., Ahmedabad	The firm presented its proposal for grant of marketing authorization permission of Novel Corona Virus - 2019-nCov vaccine for Restricted use in Emergency situation for additional indication as two dose schedule of Day 0 & 28 for use in >12 years age group along with interim safety and immunogenicity data of Phase I/II & Phase III clinical trials before the committee. The firm presented safety & immunogenicicty data of day 56 (28 days post second dose) The committee noted that the Novel Corona Virus - 2019-nCov vaccine is approved with three dose schedule of Day 0, 28 & 57 for use in >12 years age group for Restricted use in Emergency situation. The firm has stated to have completed the safety assessment of day 90; however did not submit & present the data to the committee. After detailed deliberation, the committee recommended that the firm should submit updated safety data along with the details of the dropout participants in the study for further review by the committee.
5.	BIO/CT/22/000004 HGCO-19 Lyophilized mRNA Vaccine for injection (Covid- 19) (MA Restricted use in emergency situation)	M/s Gennova Biopharmaceuticals Limited, Pune	The firm presented its proposal for grant of marketing authorization of HGCO19 Lyophilized mRNA Vaccine for Injection (COVID-19) 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 along with

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			proposal for various amendments to the clinical trial protocol. The firm presented safety data of 6 months for Phase I clinical trial & interim safety data of day 57 (28 days post second dose) of 400 subjects of Phase II part and day 43 (14 days post second dose) of 2044 subjects of Phase III part. Further the firm presented interim immunogenicity data (day 43) from Phase II/III trial (active comparator) for Anti-Spike IgG Antibody, neutralising antibody, cellular response. The committee noted the safety data of Phase I & Phase II/III (active comparator) clinical trials. After detailed deliberation, the committee recommended that firm should submit the updated safety data along with the non-inferiority data in the required population as per the statistical estimation arrived based on the protocol and the proposal for amendments in the protocol should also be submitted at earliest for consideration.