Recommendations of the SEC meeting to examine (COVID-19) related proposal under accelerated approval process made in its 240th meeting held on 11.01.2023 at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/MA/22/000109 SAR-CoV-2 Rs Protein (COVID-19) Nanoparticle Vaccine [COVOVAX]	M/s. Serum Institute of India Pvt. Ltd.	The firm presented its proposal for grant of permission to manufacture and market of SARS-CoV-2 Recombinant spike protein Nanoparticle vaccine (SARS-COV-2-Rs) with Matrix-M1 Adjuvant (COVOVAX) for the additional indication for administration of heterologous booster (third) dose to individuals of age ≥18 years after 6 months of primary vaccination (two doses) of either COVAXIN or COVISHIELD vaccines along with the interim data of Phase III clinical trial conducted in the country. The firm presented clinical trial data for all (372) subjects including safety data up to 180 days & immunogenicity data of day 28 post administration of booster dose including Anti-S IgG by ELISA & Neutralizing antibodies (nAbs), cell mediated immunogenicity and neutralizing antibodies against variants of concern (VOC) including Omicron. The committee reviewed the clinical trial data of Phase III heterologous booster dose. The committee noted that the vaccine is approved for restricted use in emergency situation in age of 7 years and above for primary vaccination (two doses at day 0 & 28). The committee also reviewed summary of product Characteristics (SmPC), prescribing Information (PI) & factsheet presented before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market SARS-CoV-2 Recombinant spike protein Nanoparticle vaccine (SARS-COV-2-Rs) with Matrix-M1 Adjuvant (COVOVAX) for additional indication for administration of heterologous

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			booster (third) dose to individuals aged ≥18 years after 6 months of primary vaccination (two doses) of either COVAXIN or COVISHIELD vaccines for restricted use in emergency situation with condition that the firm should continue to review & submit the safety follow up data after heterologous booster dose.
2.	BIO/CT /22/000060 SAR-CoV-2 Rs Protein (COVID-19) Nanoparticle Vaccine [COVOVAX]	M/s. Serum Institute of India Pvt. Ltd.	The firm presented its proposal for grant of permission to conduct Phase III Clinical trial of SARS-CoV-2 Recombinant spike protein Nanoparticle vaccine (SARS-COV-2-Rs) with Matrix-M1 Adjuvant (COVOVAX) for administration of homologous booster (third) dose to individuals of age ≥2 to <18 years after 6 months of primary vaccination who had participated in the Phase II/III trial conducted in the country. COVOVAX vaccine is approved for restricted use in emergency situation for primary immunization to prevent COVID-19 caused by SARS Cov-2 in individuals 7 years of age and older. The firm presented that the NUVAXOVID vaccine which is manufactured by technology collaborator M/s Novavax is being evaluated in Phase II/III randomized, observer-blinded, placebo-controlled, age de-escalation trial with 3600 children of 6 months to 11 years of age, in USA to evaluate the safety and immunogenicity of 2 primary doses and a booster dose of NVX CoV2373 given 21 days apart in paediatric participants (in 3 age cohorts; 6 to < 12 years, 2 to < 6 years, and 6 to < 24 months of age). The trial is ongoing. After detailed deliberation, the committee recommended that the firm is required to submit more safety data and experience of use of the vaccine in the age group ≥2 to <6 years and further recommended for grant of permission to conduct Phase III clinical trial of SARS- CoV-2 Recombinant spike protein

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			Nanoparticle vaccine (SARS-COV-2-Rs) with Matrix-M1 Adjuvant (COVOVAX) for administration of homologous booster (third) dose to individuals of age ≥7 to <18 years after 6 months of primary vaccination who have participated in the Phase II/III clinical trial conducted in the country (as the approval of COVOVAX for restricted use in emergency situation for primary immunization is accorded in this age group).Accordingly, firm needs to submit the revised protocol for approval by CDSCO.
3.	BIO/CT/22/0000090 SAR-CoV-2 Rs Protein (COVID-19) Nanoparticle Vaccine [COVOVAX]	M/s. Serum Institute of India Pvt. Ltd.	The firm presented its proposal for grant of permission to conduct Phase III clinical trial of SARS-CoV-2 Recombinant spike protein Nanoparticle vaccine (SARS-COV-2-Rs) with Matrix-M1 Adjuvant (COVOVAX) for administration of heterologous booster (third) dose to individuals of age ≥12 to <18 years who have received primary vaccination against Covid-19 COVOVAX vaccine is approved for restricted use in emergency situation for primary immunization to prevent COVID-19 caused by SARS Cov-2 in individuals 7 years of age and older. After detailed deliberation, the committee recommended to submit and present additional safety data on booster trials which are being conducted overseas specifically with justification on proposed age group and proposed sample size.
New Drug Division			
4.	IND/CT/22/000081 NV COV-1	M/s. Karveer Meditech Pvt. Ltd.	The firm presented its proposal to conduct Phase I clinical trial along with preclinical data before the committee. After detailed deliberation, the committee recommended grant of permission to conduct Phase I clinical trial.
5.	IND/CT/22/000078 ProLectin-I	M/s Samahitha Research	The firm presented its proposal to conduct Phase I clinical trial along with preclinical

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	Injection"	Solutions	data before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase I clinical trial.
GCT Division			
6.	CT/145/22 GS-5245	M/s PPD	The applicant presented Phase III clinical trial protocol no GS-US-611-6272 before the committee. The committee noted that the firm has submitted Phase III clinical trial protocol without conduct of Phase II trial. After detailed deliberation, the committee recommended that the firm should conduct phase II clinical trial along with other developmental studies before proposing phase III clinical trial.
7.	CT/54/21 SARS-CoV-2 Adjuvant Recombinant Protein Vaccines	M/s Sanofi	The applicant presented protocol amendment 1, version no 5.0 dated 08-09-2021 and protocol amendment 4 version no 8.0 dated 08-09-2022. The applicant informed that version no 5.0 has been superseded with version no 8.0. After detailed deliberation, the committee recommended for approval of protocol amendment 4 version 8.0 dated 08-09-2022.