**Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 221th meeting held on 21.04.2022 at CDSCO, HQ New Delhi:**

| Agenda No | File Name & Drug Name, Strength | Firm Name | Recommendation |
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| **Biological Division** | | | |
| 1. | BIO/CT/22/000018<br>SARS-CoV-2 rS Protein (COVID-19) Nanoparticle vaccine<br>COVOVAX–Booster Vaccine | M/s Serum Institute of India Pvt. Ltd. | In light of the recommendation of SEC meeting dated 04.03.2022, the firm presented revised Phase III clinical trial protocol of COVOVAX–Booster Vaccine.<br>After detailed deliberation, the committee recommended for approval of the revised Phase III clinical trial protocol of COVOVAX–Booster Vaccine. |
| 2. | BIO/MA/22/000018<br>SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2<br>CORBEVAX vaccine | M/s Biological E Ltd., Hyderabad | In light of the recommendation of SEC meeting dated 11.04.2022, the firm presented 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 uptil in the higher age group along with the cell mediated immunogenicity data and virus neutralising antibody data against variants of concern including Delta & Wuhan strains for 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. Firm also presented updated safety data for vaccination in age group >12 to 14 years from immunization program along with PI and SmPC.<br>The committee noted that the interim safety & immunogenicity data of Phase II/III clinical trial in subjects of ≥5 years to <12 years is comparable to that higher age groups. The committee also noted the safety data of vaccination in the age group of >12 to 14 years.<br>After detailed deliberation, the committee recommended for approval of vaccine in ≥5 years and above for restricted use in emergency situation with the condition to submit ongoing clinical trial data. Further, all the conditions of permissions granted for higher age groups should remain the same. |

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| 3. | BIO/MA/22/000020 Novel Corona Virus 2019-nCoV Vaccine (Recombinant) | M/s Cadila Healthcare Ltd | In light of the recommendation of SEC meeting dated 11.04.2022, the firm presented updated safety data along with the details of the dropout participants in the study for its proposal for grant of marketing authorization permission of Novel Corona Virus - 2019-nCov vaccine containing 3mg per dose for Restricted use in Emergency situation for two dose schedule of Day 0 & 28 for use in >12 years age group.<br>The firm presented updated safety data of day 112 of 2938 subjects including paediatric age group & immunogenicity data of day 56 (28 days post second dose).<br>The committee noted that the interim safety immunogenicity data of vaccine is comparable for 3 mg two dose schedule & 2 mg three dose schedule. The immunogenicity of two dose schedule of 3 mg was found to be non-inferior to three dose schedule of 2mg.<br>The committee also noted that the vaccine is proposed to be administered intradermally with Pharmajet Tropis device in two dose schedule of Day 0 & 28. Each 3mg dose consists of three shots of 0.1ml each given by needle free injector (Pharmajet Tropis device) via intradermal route at three separate sites separated by at least 5 centimeters (preferably deltoid region of both the arms, 2 shots in one arm separated by at least 5 centimeters and one shot in another arm). After detailed deliberation, the committee recommended for grant of approval of Novel Corona Virus - 2019-nCov vaccine for Restricted use in Emergency situation for additional dose of 3mg with 2 doses schedule of day 0 and day 28 when administered intradermally in ≥12 years age group with the condition to submit ongoing clinical trial data, SmPC, PI & factsheet. Further, all the conditions of earlier approval of 2 mg three doses regimen of Novel Corona Virus - 2019-nCov vaccine should remain the same. |
| 4. | BIO/CT/21/000105 HGCO-19 Lyophilized mRNA Vaccine for | M/s Gennova Biopharmaceuticals Limited, Pune | In light of the recommendation SEC meeting dated 11.04.2022, the firm presented amendments in approved clinical trial protocol for conduct of Phase II/III clinical trial of its |

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| | injection (Covid- 19 )<br><br>(Phase II/III clinical trial) | | HGCO19 Lyophilized mRNA Vaccine for Injection (COVID-19) (Active comparator trial against COVISHIELD vaccine of M/s Serum).<br>The firm proposed for the following amendments before the committee:<br>i. Change in primary objective superiority or non-inferiority<br>ii. Change in sample size for evaluation of primary endpoint accordingly and evaluation of pseudo virus neutralization assay<br>iii. Change in time points for evaluation of virus neutralization assay by surrogate assay & PRNT and cell mediated immunogenicity.<br>After detailed deliberation, the committee recommended for approval of the proposed amendments in the approved clinical trial protocol, as presented with the condition that sero response rate in comparison to comparator should not be more than minus 10% with confidence interval of 95%. |
| 5. | BIO/MA/21/000124<br><br>Whole Virion Inactivated SARS CoV 2 vaccine (BBV152) | Bharat Biotech International Limited | In light of the recommendations of SEC meeting dated 11.10.2021, the firm presented its proposal for grant of marketing authorization for additional indication of Whole Virion Inactivated SARS CoV2 vaccine (BBV152) for restricted use in emergency situation in the age group of ≥2 years to <12 years along with the interim safety & immunogenicity data of Phase III clinical trial conducted in subjects ≥2 years to <18 years before the committee.<br>The firm presented interim safety & immunogenicity data of 6 Months in the age group ≥2 years to <18 years along with the safety data from vaccination from Immunization program in age group >15 years to <18 years of age.<br>The committee also noted the safety data of vaccine in the age group of >2 years to <12 years of age.<br>After detailed deliberation, the committee recommended that the firm should submit post marketing surveillance study data of >15 to <18 years before the committee and firm assured to submit by 22.04.2022 for further review. The proposal is deferred till then. |