**Recommendations of the SECmeeting to examine COVID-19 related proposal under accelerated approval process made in its 215th meeting held on 04.03.2022 at CDSCO (HQ), New Delhi:**

| Agenda No | File Name & Drug Name, Strength | Firm Name | Recommendation |
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| **Biological Division** | | | |
| 1. | BIO/MA/22/000012 COVOVAX Vaccine | M/s Serum Institute of India Pvt. Ltd. Pune | The firm presented its proposal for grant of marketing authorization of SARS-CoV-2 Recombinant spike protein Nanoparticle vaccine (SARS-COV-2-Rs) with Matrix-M1 Adjuvant in >12 to <18years age group for Restricted use in Emergency situation with interim safety and immunogenicity Phase II/III clinical trial data/results before the committee.<br>After detailed deliberation, the committee noted that the vaccine has been found to be safe, immunogenic in the trial.<br>The committee also noted that the safety & immunogenicity data of the vaccine manufactured by M/s Serum Institute of India is comparable to the vaccine manufactured by M/s Novavax. Further, the committee reviewed factsheet, PI, SmPC etc.<br>After detailed deliberation, the committee recommended for grant of marketing authorization of SARS-COV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-COV-2 rS) for restricted use in emergency situation subject to various regulatory provisions including following:<br>1. The vaccine is indicated for active immunization to prevent COVID-19 disease in individuals of >12 to <18 years of age.<br>2. The vaccine should be administered intramuscularly in two doses of 0.5 ml each with interval of 21 days. (Day 0 & 21). The vaccine has to be stored between 2°C to 8°C.<br>3. The firm should submit revised PI, SmPC & Factsheet to CDSCO after incorporating the latest safety & immunogenicity data and other suggestions made during the meeting.<br>4. The vaccine should be supplied along with factsheet & separate leaflet for the guidance of the healthcare provider |

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| | | | 5. The firm should ensure that factsheet for the vaccine recipient/attendant is provided prior to administration of the vaccine.<br>6. The firm should disseminate the instructions & educational material including factsheet, PI, SmPC, storage instructions etc. in their website.<br>7. The firm should submit safety, efficacy & immunogenicity data from the ongoing clinical trials in India & overseas for review as and when available.<br>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 as per the provisions and standard procedures.<br>The firm should submit India specific Pharmacovigilance and Risk management plan. |
| 2. | BIO/MA/22/000018 COVOVAX Vaccine | M/s Serum Institute of India Pvt. Ltd. Pune | The firm presented its proposal for Phase III clinical trial of SARS-CoV-2 Recombinant spike protein Nanoparticle vaccine (SARS-COV-2-Rs) (COVOVAX) booster dose.<br>After detailed deliberation and as per the discussion and request by the firm, the committee recommended for grant of permission to conduct the Phase III clinical trial with following conditions:<br>1. Inclusion criteria should be revised to enroll subjects who have completed six months after the 2nd dose.<br>2. Neutralizing antibody assessment should be made as a primary endpoint.<br>3. The objective of the study should also include atleast 2 fold rise in the neutralizing antibody titres in the investigational arm comparing with approved homologous booster vaccine.<br><br>Accordingly, the firm should submit the revised protocol to CDSCO for approval. |

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| 3. | BIO/MA/21/000108 Sputnik Light | M/s Hetero | The firm presented its proposal for grant of marketing authorization with Phase III clinical report of Sputnik Light vaccine.<br>After detailed deliberation, the committee noted the clinical evidences including NAB titres of Sputnik-V (Component-I) manufactured by the firm in comparison to the results of Sputnik Light of Gamalyea Institute and recommended for grant of marketing authorization for Sputnik Light vaccine for restricted use in emergency situation subject to various regulatory provisions including following:<br>1. The vaccine is indicated for active immunization to prevent COVID-19 disease in individuals of ≥ 18 years of age.<br>2. The vaccine should be administered intramuscularly in single doses of 0.5 ml The vaccine has to be stored at -18°C.<br>3. The vaccine should be supplied along with factsheet & separate leaflet for the guidance of the healthcare provider.<br>4. This permission is for restricted use in emergency situation in public interest.<br>5. Vaccine to be supplied for Immunization programme.<br>6. The firm should ensure that factsheet for the vaccine recipient/attendant is provided prior to administration of the vaccine.<br>7. The firm should disseminate the instructions & educational material including factsheet, PI, SmPC, storage instructions etc. in their website.<br>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 as per the provisions and standard procedures.<br>9. The firm should submit India specific Pharmacovigilance and Risk management plan. |
| 4. | BIO/CT/21/0000156 Sputnik Light | M/s Dr. Reddy's Lab. | The firm presented its proposal for Phase III clinical trial of Sputnik Light vaccine for Booster Dose.<br>After detailed deliberation and discussion with the firm and as per the request of the firm, the |

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| | | | committee recommended for grant of Phase III clinical trial with condition to initiate the trial with Sputnik Light vaccine for which the firm is holding marketing authorisation permission in the country and that:<br>1. The objective of the study should also include atleast 2 fold rise in the neutralizing antibody titres in the investigational arm comparing with approved homologous booster vaccine. Randomization between the arms should in the ratio of 1:1. Accordingly, the sample size shall be recalculated.<br>2. Cell mediated immunity should be assessed in subset population.<br>Accordingly, the firm should submit revised clinical trial protocol to CDSCO for approval. |