**Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 130th meeting held on 09.12.2020 at CDSCO, HQ New Delhi:**

| Agenda No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| **Biological Division** | | | |
| 1. | BIO/CT/20/000182<br><br>mRNA vaccine (Phase I/II) | M/s Gennova Biopharmaceuticals Limited, Pune | The firm presented their proposal for grant of permission to conduct Phase I/II clinical trial along with animal toxicity study data before the committee.<br>After detailed deliberation, the committee recommended for grant of permission to conduct Phase I/II clinical trial subject to the condition that the interim results of Phase I study shall be submitted to the committee before proceeding to the next phase. |
| 2. | BIO/MA/20/000102<br><br>ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) (EUA) | M/s Serum Institute of India Pvt. Ltd., Pune | The firm presented their proposal for grant of Emergency Use Authorization (EUA) of ChAdOx1 nCoV-19 vaccine (COVISHIELD) along with the interim safety data from Phase II/III clinical trial carried out in the country and the interim safety and efficacy results of Phase II/III and Phase III clinical trials carried out in UK, other countries & India before the committee.<br>The committee noted that as per the condition of the permission to conduct phase II/III clinical trial in the country, the clinical data generated in the trial shall be considered along with the data from the OXFORD clinical trial outcome. Further, the firm stated that the proposal for grant of emergency use authorization is currently under evaluation with MHRA. It is also noted that the Phase II/III clinical trial is still ongoing in the country.<br>Further, the firm has submitted the safety data till 14.11.2020 only.<br>After detailed deliberation, the committee recommended that the firm should submit the following data/information for further review:<br>1. Updated safety data of the Phase II/III clinical trial in the country.<br>2. Immunogenicity data from the clinical trial in UK and India.<br>3. The outcome of the assessment of UK-MHRA for grant of EUA.<br>Dr. Sushant Meshram did not participate in the discussion. |

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| 3. | BIO/MA/20/000103<br><br>Whole Virion, Inactivated Corona Virus Vaccine (BBV152) (EUA) | M/s Bharat Biotech International Limited, Hyderabad | The firm presented their proposal for grant of Emergency Use Authorization (EUA) of Whole Virion, Inactivated Corona Virus Vaccine (BBV152) along with the interim safety and immunogenicity data of Phase I and II clinical trial carried out in the country before the committee.<br><br>After detailed deliberation, the committee recommended that the firm should present the safety and efficacy data from the ongoing Phase III clinical trial in the country for further consideration. |
| 4. | BIO/IMP/20/000110<br><br>COVID-19 mRNA Vaccine BNT162b2 | M/s Pfizer Ltd., Mumbai | The firm has requested more time for making presentation before the committee. |