

**Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 212<sup>th</sup> meeting held on 15.02.2022 at CDSCO, HQ New Delhi:**

<b>Agenda No</b>	<b>File Name &amp; Drug Name, Strength</b>	<b>Firm Name</b>	<b>Recommendation</b>
<b>Biological Division</b>			
1.	BIO/CT/21/000051  Equine COVID 19 Antiserum (Liquid Injection)	Bharat Serums & Vaccines Ltd.	The firm presented protocol amendments in Phase I/II clinical trial of Equine COVID 19 Antiserum (Liquid Injection) before the committee with respect to change in exclusion criteria & study assessment as follows: <ul style="list-style-type: none"> <li>i. Removed criteria of requirement of Seronegative at baseline.</li> <li>ii. Addition of patients with history of immunization including vaccination for COVID-19 within 28 days of screening.</li> </ul> <p>After detailed deliberation, the committee recommended for approval of the proposed amendments.</p>
2.	File No. 12-01/BBIL/2022-BD  Whole-virion Inactivated SARS-CoV-2 Vaccine  (BBV152) COVAXIN	M/s Bharat Biotech International Limited, Hyderabad	The firm presented its proposal for conduct of Post market surveillance study of Whole Virion Inactivated SARS-CoV-2 Vaccine (BBV152) [COVAXIN] in the age group of 15 to 18 years before the committee. <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Post market surveillance study of Whole Virion Inactivated SARS-CoV-2 Vaccine (BBV152) [COVAXIN] in the age group of 15 to 18 years with following conditions:</p> <ul style="list-style-type: none"> <li>i. Sample size should be revised to 5100 with 1700 subjects in each age group of 15 to 16 years, 16 to 17 years &amp; 17 to 18 years.</li> <li>ii. Follow up should be made till 60 days after vaccination of each dose.</li> <li>iii. Investigators participating in the study should be paediatricians.</li> </ul> <p>Accordingly, the firm should submit revised protocol to CDSCO for approval.</p>

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3.	BIO/CT/21/000092  COVISHIELD, COVAXIN & COVOVAX	CMC Vellore	<p>The Institute presented its proposal for amendment in homologous &amp; heterologous Booster (third) dose administration to already vaccinated with COVAXIN &amp; COVISHIELD vaccines as a part of Phase IV clinical trial before the committee.</p> <p>Institute proposed to include COVOVAX vaccine arm in the homologous &amp; heterologous Booster (third) dose as a part of the proposed trial.</p> <p>The committee noted that the current trial is double blind &amp; addition of COVOVAX arm will change the study design to open label.</p> <p>After detailed deliberation, as interacted &amp; proposed by the Institute, the committee, in the light of original study being double blind and progressed to nearly final stages, recommended that the Institute should propose separate clinical trial protocol for conduct of Open label study for homologous &amp; heterologous Booster (third) dose of proposed vaccines with statistically significant sample size.</p>
4.	BIO/MA/21/000108  Recombinant human adenovirus serotype number 26 (rAd26) COVID-19 vaccine  [SPUTNIK LIGHT]	M/s Hetero Biopharma Ltd, Hyderabad	<p>The firm presented its proposal for grant of permission to manufacture Recombinant human adenovirus serotype number 26 (rAd26) COVID-19 vaccine [SPUTNIK-Light] for restricted use in emergency situation in the age group of 18 years and above along with the clinical data of Sputnik V (vaccine) Component I from its Phase III clinical trial. The firm also presented some clinical data points from Dr. Reddy's for Sputnik Light vaccine.</p> <p>The committee noted that the interim safety, efficacy &amp; immunogenicity of Sputnik Light has already been shown by the Dr. Reddy's lab. Further, M/s Hetero is already holding permission to manufacture Sputnik V vaccine which contains Component I and II for restricted use in emergency situation and the specifications of component I and Sputnik Light vaccine has been stated to be similar by the firm.</p> <p>After detailed deliberation, the committee recommended that the firm should submit the evidences for clinical equivalence of their product.</p>

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5.	BIO/CT/21/000150 Phase IV clinical trial [Covishield, Covaxin]	PGIMS, Chandigarh	<p>In light of the recommendations of SEC meeting dated 24.11.2021, the Institute presented revised clinical trial protocol for conduct of Phase IV clinical trial for assessment of safety &amp; immunogenicity of COVID-19 vaccines (Covishield &amp; Covaxin) after interchangeability of second dose.</p> <p>The committee noted that the study is limited to North India region.</p> <p>After detailed deliberation, as per guidance sought by the Institute, the committee recommended that Institute should prepare a revised clinical trial protocol including following points:</p> <ol style="list-style-type: none"> <li>i. Interchangeability should be replaced with the appropriate term as per the trial design.</li> <li>ii. Tolerability should be included in the objective.</li> <li>iii. AESI to be included in SAE monitoring follow up.</li> <li>iv. Risk mitigation plan for medical emergency situations including anaphylaxis to be included in the protocol.</li> <li>v. Study visits to be planned as per dosing intervals of approved vaccines.</li> <li>vi. Inclusion criteria for serostatus of subjects.</li> </ol> <p>For the above the Institute has stated that they will incorporate the suggestion in the protocol &amp; submit it at the earliest.</p> <p>Accordingly, the Institute should submit the revised clinical trial protocol for further review by the committee.</p>