

**Recommendations of the SEC (COVID-19) made in its 03<sup>rd</sup>/24 meeting held on 29.08.2024 at CDSCO (HQ), New Delhi:**

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>Biological Division</b>			
1.	<p>File No: BIO/MA/24/000092</p> <p>COVID-19 Vaccine with variant SARS-CoV-2-RBD203-N1_XBB.1.5</p>	M/s. Biological E Ltd. Hyderabad	<p>The firm presented the proposal for the grant of permission to manufacture COVID-19 Vaccine with variant SARS-CoV-2-RBD203-N1_XBB.1.5 for sale and distribution in India for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals of age <math>\geq 5</math> years.</p> <p>The committee noted that the CORBEVAX vaccine with variant SARS-CoV-2-RBD219-N1C1 (ancestral strain) is approved for restricted use in emergency situation for age group <math>&gt;5</math> years and above in two dose schedule i.e. day 0 &amp; day 28 and the vaccine is also approved as heterologous booster dose to individuals previously vaccinated with COVAXIN/COVISHILED.</p> <p>The committee also noted that the COVID-19 Vaccine SARS-CoV-2-RBD203-N1_XBB.1.5 is for strain change/update in the approved COVID-19 vaccine.</p> <p>The Firm presented report of the Phase III active comparator clinical trial conducted for COVID-19 Vaccine SARS-CoV-2-RBD203-N1_XBB.1.5 in the country in 360 subjects of age <math>\geq 5</math> to <math>\leq 80</math> years including safety &amp; immunogenicity data including GMT of anti-XBB.1.5.RBD neutralizing antibodies (pseudovirus), GMT of Anti-XBB.1.5-RBD-IgG at day 28 &amp; day 42. Additionally firm has presented data for protection against the JN.1 strain in terms of neutralizing antibody titres against JN.1 strain (pseudovirus).</p> <p>The committee reviewed the results of Phase III trial including safety &amp; immunogenicity and noted:</p> <ol style="list-style-type: none"> <li>1. <u>Risk versus benefit:</u> The safety profile of the vaccine from preclinical and clinical studies conducted justifies the grant of permission.</li> <li>2. <u>Innovation vis-a-vis existing therapeutic option:</u> The vaccine elicits broadly cross-reactive neutralizing antibody responses against circulating SARS-CoV-2 variants including XBB.1.5 &amp; JN.1.</li> </ol>

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			<p>3. <u>Unmet medical need in the country:</u> Presently, there is only one vaccine with XBB.1.5 strain approved in the country &amp; this may be used as an alternate option.</p> <p>After detailed deliberation, based on the above observations, the committee recommended for strain change/update in the approved COVID-19 vaccine and grant of permission of the COVID-19 Vaccine SARS-CoV-2-RBD203-N1_XBB.1.5, for restricted use in emergency situation, subject to various regulatory provisions including following:</p> <ol style="list-style-type: none"> <li>1. The vaccine is indicated for active immunization to prevent COVID-19 disease in individuals of 5 years of age and above who have received primary vaccination series &amp; to be administered in two dose schedule (0.5mL each) 28 days apart (Day 0 &amp; Day 28).</li> <li>2. Firm should submit revised PI, SmPC &amp; factsheet after incorporating the suggestions made during the meeting.</li> <li>3. The vaccine should be supplied along with factsheet &amp; separate leaflet for the guidance of the healthcare provider.</li> <li>4. The firm should ensure that factsheet for the vaccine recipient / attendant is provided prior to administration of the vaccine.</li> <li>5. The firm should disseminate the instructions &amp; educational material including factsheet, PI, SmPC, storage instructions etc. in their website.</li> <li>6. The firm should submit safety data including the data on AEFI and AESI with due analysis as per the provisions and standard procedures.</li> <li>7. The firm should submit Pharmacovigilance and Risk management plan.</li> </ol>
<b>GCT Division</b>			
2.	CT/82/24 Online Submission (40490)  Ensitrelvir, S-217622	M/s. Clinnex Research Private Limited	<p>The firm presented Phase III Clinical Trial Protocol No. 018/ACTIV, Version 1.0, dated 11 Nov 2022 before the committee.</p> <p>After detailed deliberation, the committee opined that:</p> <ol style="list-style-type: none"> <li>1. Respiratory symptoms/involvement in</li> </ol>

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			<p>inclusion criteria should be more explicit and elaborated.</p> <ol style="list-style-type: none"> <li>2. Exclusion criteria and primary endpoints (alive, not recovered and then “death” (worst)) should be elaborated.</li> <li>3. Handling &amp; documentation of comorbidities and use of other antiviral drugs by the investigator should be mentioned in the protocol.</li> </ol> <p>Accordingly, revised protocol should be submitted to CDSCO for further review by the committee.</p>