

Recommendations of the SEC meeting to examine (COVID-19) related proposal under accelerated approval process made in its 244th meeting held on 13.03.2023 at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/MA/20/000073 Mycobacterium w (Heat Killed) Injection	M/s Cadila Pharmaceuticals Limited	<p>The firm presented its proposal for grant of permission to manufacture & market Mycobacterium w (Heat Killed) Injection with new (additional) indication as below: “For the treatment of Coronavirus Disease 2019 (COVID-19), for critically ill patients suffering from COVID 19 infection in age 18 years or more in combination with standard of care of COVID 19.</p> <p>The firm presented Phase III clinical trial data conducted in the country to evaluate the safety and efficacy of Mycobacterium W in 236 critically ill patients suffering from COVID 19 infection.</p> <p>The committee reviewed the Phase III clinical trial data.</p> <p>After detailed deliberation, the committee recommended that the firm is required to generate more efficacy and safety data.</p>
2.	BIO/MA/23/000003 Novel Corona Virus 2019-nCoV Vaccine (Recombinant)	M/s Zydus Lifesciences Limited	<p>The firm presented its proposal for grant of permission to manufacture and market Novel Corona Virus 2019-nCoV Vaccine (Recombinant) (3 mg) [ZyCoV-D] for the additional indication for administration of heterologous booster (third) dose to individuals of age ≥ 18 years after 6 months of primary vaccination (two doses) of either COVAXIN or COVISHIELD vaccines along with the interim data of Phase III clinical trial conducted in the country.</p> <p>The firm presented clinical trial data for all (576) subjects including safety data up to 84 days & immunogenicity data of day 28 post administration of booster dose including Anti-S1 IgG (Wuhan strain) by ELISA & Neutralizing antibodies (nAbs), cell mediated immunogenicity and neutralizing antibodies against variants of concern (VoC) including Omicron.</p> <p>The committee reviewed the clinical trial data of Phase III heterologous booster dose. The committee noted that the vaccine is approved for restricted use in emergency situation in age of 12 years and above for</p>

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			<p>primary vaccination (two doses at day 0 & 28).</p> <p>The committee also reviewed summary of product Characteristics (SmPC), prescribing Information (PI) & factsheet presented before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market Novel Corona Virus 2019-nCoV Vaccine (Recombinant) (3 mg) [ZyCoV-D] for additional indication for administration of heterologous booster (third) dose to individuals aged ≥ 18 years after 6 months of primary vaccination (two doses) of either COVAXIN or COVISHIELD vaccines for restricted use in emergency situation with condition that the firm should continue to review & submit the safety and immunogenicity follow up data after heterologous booster dose.</p>
SND Division			
3.	SND/CT/21/000033 Doxazosin Tablets 2 mg	M/s Strand Life Science Pvt. Ltd.	<p>The firm presented the interim analysis report of ongoing Phase II clinical trial of Doxazosin Tablets 2mg (Protocol No. SLS-JHM-02, Version No.: 2.0 Dated 23.06.2021; CT NOC No.: CT/SND/119/2021 dated 09.08.2021) and requested for extension of total no. of subjects 1000 in the study, before the committee.</p> <p>The firm mentioned that the said clinical trial is ongoing and was approved for 300 subjects. The subject recruitment is in progress and 124 subjects have been recruited. Out of 124 subjects 68 have completed follow-ups till 6 months without any safety concern.</p> <p>In the interim study report, the firm has mentioned that there is no report of any safety issue or AEs/SAEs among the subjects who have participated in the trial.</p> <p>After detailed deliberation, the committee recommended that firm has to complete the approved study in 300 subjects as proposed</p>

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			in previous meeting. After completion of the study in 300 subjects the firm should present the study report before the committee for further extension of total no of study subjects.
GCT Division			
4.	CT/145/22 GS-5245	M/s. PPD	<p>The firm presented its proposal in line with earlier recommendations of SEC dated 11.01.2023 before the committee.</p> <p>After detailed deliberation, the committee reiterated its earlier recommendation that the firm should first conduct Phase-II study in the country.</p>
5.	CT/09/22 ES16001	M/s. Cliantha	<p>The firm presented its proposal of protocol amendment version 2.6 dated 11 Oct 2022 of study protocol no. GNC_ESE_COVID19_P2-301 before the committee.</p> <p>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.</p>
6.	CT/172/22 Bemnifosbuvir Hemisulfate (BEM; AT-527)	M/s. IQVIA	<p>The firm presented its proposal of grant of Phase III clinical trial permission with Protocol no. AT-03A-017 version 1.0 dated 08 SEP 2022.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm.</p>