

**Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 232<sup>th</sup> meeting held on 06.07.2022 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/21/000148 Adenoviral-Vector Based Vaccine (VXA-CoV2-1.1-S)	M/s Syngene International Limited	The firm didn't turn up for presentation.
2.	BIO/CT/21/0000156 Sputnik-Light	M/s Dr. Reddy's Laboratories Ltd.	The firm presented its proposal for planned protocol deviation in ongoing Phase III clinical trial of SPUTNIK Light vaccine for Heterologous & Homologous booster dose administration along with justifications before the Committee. After detailed deliberation, the committee recommended for the proposed protocol amendment in ongoing Phase III clinical trial of SPUTNIK Light vaccine.
3.	12-01/Bharat/2021-BD Whole-virion Inactivated SARS-CoV-2 Vaccine (BBV152) COVAXIN	M/s Bharat Biotech International Limited, Hyderabad	The firm presented the Post Marketing Surveillance Study (PMS) report of Whole-virion Inactivated SARS-CoV-2 Vaccine conducted in >18 years age group. After detailed deliberation, the committee noted the results of PMS report.
4.	1202/PMS/BBIL/2022-BD Whole-virion Inactivated SARS-CoV-2 Vaccine (BBV152) COVAXIN	M/s Bharat Biotech International Limited, Hyderabad	The firm presented the Post Marketing Surveillance Study (PMS) protocol of Whole-virion Inactivated SARS-CoV-2 Vaccine conducted in >6 to 12 years age group. After detailed deliberation, the committee recommended for approval of proposed PMS study.
<b>GCT Division</b>			
5.	CT/09/22 ES16001 COVID-1	M/s. Cliantha	In light of earlier SEC recommendation, the applicant presented phase II/III clinical trial protocol before the committee along with clinical and pre-clinical data generated with proposed drug. The committee opined that the applicant needs to comply with NDCT Rules, 2019 w.r.t CMC part of proposed phyto-pharmaceutical.

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			After detailed deliberation, the committee recommended for grant of permission to conduct phase II part of the proposed study first and there after submit phase II data for review by the committee for further consideration of phase III part of the proposed protocol.
6.	CT/38/22 Anti-COVID-19 AKS-452 Vaccine	M/s. Veeda	In light of earlier SEC recommendation, the applicant presented phase III clinical trial protocol of booster dose of Anti-Covid -19 AKS-452 vaccine along with interim analysis data of ongoing phase II/III from India before the committee. After detailed deliberation, the committee opined that the applicant should submit clinical study report of phase II/III study conducted in India for further review by the committee.
7.	CT/51/21 C21	M/s. QED	The applicant presented protocol amendment version 5.0 dated 13/04/2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed Protocol Version no 5.0 dated 13/04/2022.
8.	CT/100/21 Anti-COVID-19 AKS-452 Vaccine ( Protocol Version no 4.0 dated 24/03/2022)	M/s. Veeda	In light of earlier recommendation, the applicant presented proposed Protocol Version no 4.0 dated 24/03/2022 with justification before the committee. After detailed deliberation, the committee recommended for approval of the proposed Protocol Version no 4.0 dated 24/03/2022.
<b>FDC Division</b>			
9.	FDC/MA/22/000005 Combikit of Aspirin GR tablets 50mg & Promethazine HCL tablets 5mg & Multivitamin-minerals tablets.	M/s Meyer Vitabiotics	In light of earlier SEC recommendation dated 21.01.2022 the firm presented their proposal along with justification. After detailed deliberation, the committee reiterated its earlier recommendation dated 21.01.2022 and did not recommend for approval of the proposed combipack.