

Recommendations of the SEC (Cardiovascular & Renal) made in its 114th meeting held on 24.11.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/19/000025 Pantoprazole Sodium 20mg/20mg + Aspirin 81mg/150mg Capsules	M/s. Alkem Laboratories	In light of the SEC meeting held on 07.09.2021 & 08.09.2021, the firm presented the BE study report and Phase III clinical trial report before the committee. The committee noted that the firm has conducted clinical trial on the higher strength. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of both applied strengths with the condition that the firm should conduct active post marketing surveillance study. The protocol should be submitted within 3 months from the date of approval for review by the committee.
2.	FDC/MA/19/000013 Azilsartan Medoxomil 80mg/40mg + Amlodipine 5mg/5mg tablets	M/s Inventia Healthcare Pvt. Ltd.	In light of the SEC meeting held on 15.07.2021 to 19.07.2021, the firm presented the Phase III clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the product.
GCT Division			
3.	CT/149/21 Online submission (17548) B1 690517	M/s. Parexel	The firm has presented updated protocol amendment version-3, dated 30-Mar-2022 as local amendment version 1.0 dated 1-Sep-2022 as recommended by the earlier SEC held on 19.07.2022. After detailed deliberation, the committee recommended to grant permission to conduct the study as per the amended protocol.
Medical Device Division			
4.	IMP/MD/2022/60582 VitaFlow Liberty Transcatheter Aortic Valve system	M/s. Purple Microport cardiovascular Pvt. Ltd.	The firm presented their proposal before the committee. After detailed deliberation, the committee recommended that the firm should conduct clinical investigation with the proposed product in the country. Accordingly, the firm should submit the protocol before the committee for further

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			review by the committee.
5.	MD/Post Apr/2022/10894 Export Advance Aspiration Catheter	M/s. India Medtronic Pvt. Ltd.	The firm presented their post approval change in indication before the committee. After detailed deliberation, the committee recommended for grant of permission for post approval change in indication as export aspiration catheters are indicated in clinical conditions in which a vascular occlusion has occurred in vessels \geq 2.0 mm diameter, due to soft thromboembolic formation located in the coronary arteries.
6.	CI/MD/2022/62136 Transcatheter bicaval Valves system	M/s. Relisys medical Devices limited	The firm presented their post market clinical investigation protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the post market clinical investigation with proposed device in the country. Accordingly, the firm should submit the report for further review by the committee.
GCT Division			
7.	CT/87/19 Online Submission (16548) LCZ696	M/s. Novartis	The firm didn't turn up for presentation.
8.	CT/66/22 Online Submission (33152) Crovalimab 340mg/2ml	M/s. Roche	The firm presented the proposed Phase III study protocol no. BO42353 version 4 dated 08-Apr-2022 before the committee. After detailed deliberation, the committee recommended that the inclusion & exclusion criteria w.r.t. protocol submitted should be modified as discussed during presentation and the firm should submit revised protocol for further deliberation.
9.	CT/91/22 Online Submission (33690) Macitentan 75 mg versus Macitentan 10mg	M/s. J & J	The firm presented the proposed Phase III study protocol no. AC-055-315 amendment 3 version 4 dated 08-Feb-2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct clinical trial with the directions to closely monitor the anemic conditions during the trial.

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10.	CT/98/22 Online Submission (33732) Tenecteplase Lyophilized	M/s. JSS Medical Research	In light of earlier recommendation of SEC dated 20.10.2022, the firm presented data with reference to safety and efficacy. After detailed deliberation, the committee recommended that the submitted safety and efficacy data are presently not adequate to take a decision regarding the conduct of the trial in India.