Recommendations of the SEC (Cardiovascular) made in its 16th/24 meeting held on 20.08.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/92/24 Online Submission (44397) BI 690517	M/s. IQVIA RDS	The firm presented Phase III clinical trial protocol No. 1378-0020 version 2.0 dated 26 March 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with the condition that more geographically distributed sites shall be included in the study.
2.	CT/95/24 Online Submission (44420) Olezarsen (ISIS 678354)	M/s. Medpace Clinical Research India Pvt. Ltd.	The firm presented Phase III clinical trial protocol No. ISIS 678354-CS15 protocol amendment 2 dated 29 June 2023 After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/09/23 Online Submission (34232) Ziltivekimab B 15mg/ml	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented protocol amendment version 6.0 dated 29 April 2024 and recruitment of additional 100 patients for ongoing clinical study in India protocol No. EX6018-4915. After detailed deliberation, the committee recommended for approval of protocol amendment version 6.0 dated 29 April 2024 and recruitment of additional 100 patients for ongoing clinical study in India subject to condition that "In case of pregnancy, during the trial, the patient will be closely followed-up during the pregnancy period till 6 weeks postpartum or 6 weeks after termination of pregnancy".
Medical Devices Division			
4.	CI/MD/2022/69781 Delivery System (Brand: ACURATE Neo2 Transfemoral Delivery System), Aortic valve (Brand: ACURATE	M/s. Boston Scientific India Private Limited	Reference to one of the conditions of the Import license which was granted to the firm for the conduct of Post Marketing Clinical Investigation on the devices "Delivery System", Aortic valve and Cerebral Protection System" and recommendations of the SEC dated 08.02.2023, the firm has presented the revised clinical study protocol before the

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	neo2 Aortic valve), Cerebral Protection System (Brand: Sentinel)		committee for deliberation. After detailed deliberation, the committee agreed with the revised clinical study protocol and recommended for grant of permission to conduct the proposed study in Indian population.
BA/BE Division			
5.	BABE/CT05/FF/2024/42248 Amlodipine and Chlorthalidone Tablet 10/25mg	M/s. Jeevan Scientific Technology Limited	The firm presented the protocol No.: 24-017 version No. 01 protocol date 28.02.2024 and protocol No.: 24-018 version No. 01 protocol date 28.02.2024 for BA/BE study for export purpose only. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study for export purpose only.
6.	BABE/CT05/FF/2024/42562 Atorvastatin and Fenofibrate Tablets 80 mg/160 mg	M/s. Aizant Drug Research Solutions Private Limited	The firm presented the protocol No.: C24112 ver. 00 dated 01.03.2024 for BA/BE study for export purpose only. After detail deliberation, the committee did not recommend the proposed BE study due to lack of rationality and safety concern.
FDC Division			
7.	FDC/MA/23/000063 Dapagliflozin Propanediol monohydrate 5mg/5mg/10mg/10mg + Metoprolol Succinate IP eq. to Metoprolol tartrate (ER) 25mg/50mg/ 25mg/50mg tablets	M/s. Exemed Pharmaceuticals	In light of earlier SEC recommendation dated 11.10.2023, the firm presented the proposal along with Phase III clinical trial report for two strengths i.e. Dapagliflozin 10mg/10mg+ Metoprolol Succinate IP eq. to Metoprolol tartrate (ER) 25mg/50mg tablet before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the product in above two strengths.