Recommendations of the SEC (Cardiovascular) made in its 1/24meeting held on 09.01.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/135/23 Online Submission (40226) Dated 30/10/2023 Tebipenempivoxilhydrobromide (TBP-PI-HBr, previously known as SPR994)	M/s. PSI CRO Pharma Pvt. Ltd	The committee opined that the proposal should be deliberated in SEC (Renal).
2.	CT/47/21 Online Submission (29945) Dated 05/12/23 LIB003	M/s. Medpace Clinical Research India Pvt Ltd	The firm presented protocol amendment, version 1.2 dated 15-Aug-2022, protocol No. LIB003-007. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm
3.	CT/43/21 Online Submission (29948) Dated 05.12.23 Atacicep	M/s. Medpace Clinical Research India Pvt Ltd.	The committee opined that the proposal should be deliberated in SEC (Renal).
4.	CT/65/23 Online Submission (29991) Dated 06.12.23 Atacicept	M/s. Medpace Clinical Research India Pvt Ltd	The committee opined that the proposal should be deliberated in SEC (Renal).
5.	CT/164/23 Online Submission (41051) Dated 21/12/2023 XXB750	M/s Novartis Healthcare Private Limited	The firm presented Phase II clinical study protocol No. CXXB750A12201. After detailed deliberation, the committee recommended for grant of permission to conduct the trial with subject to condition that (1) approximate 50% sites and subjects shall be enrolled from Govt. sites. (2) private study sites of university medical college only shall be included in the study.
6.	CT/166/23 Online Submission (41060) Dated 22/12/2023 Ziltivekimab	M/s Novo Nordisk India Pvt Ltd	The firm presented Phase III clinical study protocol No. NN6018-4914. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
7.	CT/66/23 Online Submission (30338) Dated 22/12/2023 Mavacamten	M/s Bristol-Myers Squibb India Pvt. Ltd	The firm presented protocol amendment 02 dated 02 August 2023 protocol No. CV027031. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm
8.	CT/20/23 Online Submission (29252) Dated 26/10/2023 KJX839 (Inclisiran)	M/s Novartis Healthcare Private Limited	The firm presented protocol amendment version 01 dated 14 July 2023 protocol No. CKJX839D12302. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm
BA/BE Division			
9.	File No. 12-09/2023/BA-BE/MISC-43/DC (BABE/CT05/FF/2023/39924)	M/s. Cliantha Research Limited, Ahmedabad	The firm presented protocol No. C1B03509, version No.01 dated 22-SEP-2023. After detailed deliberation, the committee recommended for approval of the protocol as presented by the firm
SND Division			
10.	SND/MA/23/000057 24.01.2023 Sacubitril and valsartan Tablets 25mg	M/s Lupin Limited	The firm presented their proposal along with justification for BE waiver & Phase-III CT waiver before the committee. After detailed deliberation, the committee opined that more justification on the proposed dose and its rationality should be submitted for further review by the committee.
FDC Division			
11.	FDC/MA/22/000406	M/s. Synokem Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 22.11.2023, the firm presented its proposal along with request to reconsider BE study report and revised Phase III clinical trial protocol before the committee. After detailed deliberation, the committee considered BE report and recommended for grant of permission to conduct the Phase III CT study. Accordingly, the firm should submit Phase III CT study report to CDSCO for

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			review by the committee.