Recommendations of the SEC (Cardiovascular) made in its 14th/24 meeting held on 18.07.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/164/23 Online Submission (33275) XXB750	M/s. Novartis	The firm presented for waiver of conditions. Approximate 50% subjects shall be enrolled from government sites. Protocol no. CXXB750A12201. After detailed deliberation, the committee recommended that condition (i) may be modified as "Approximate 50% sites shall be included in the study and maximum subjects shall be enrolled from government sites." (Dr.Ajay Mahajan did not participate in the discussion).
2.	CT/166/23 Online Submission (33421) Ziltivekimab C 30 mg/ml/ placebo	M/s. Novo Nordics	The firm presented protocol amendment version 4.0 dated 07. 03.2024 protocol no. NN6018-4914. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/164/23 Online Submission (33331) XXB750	M/s. Novartis	The firm presented protocol amendment version 01 dated 06 February 2024 and protocol amendment version 02 dated 23. 02.2024 protocol no. CXXB750A12201. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. (Dr. Ajay Mahajan did not participate in the discussion)
4.	CT/66/23 Online Submission (32890) Mavacamten	M/s. Bristol-Myers	The firm presented for waiver of condition (i) 50% trial sites should be Govt. sites & 50% subjects shall be enrolled from Govt. Sites. Protocol No:CV027031. After detailed deliberation, the committee accepted the waiver of condition (i) 50% trial sites should be Govt. sites & 50% subjects shall be enrolled from Govt. Sites as presented by the firm.
SND Division			

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
5.	SND/MA/23/000057 Sacubitril & Valsartan 25mg Tablets	M/s. Lupin Limited	In light of earlier SEC recommendations dated 09.01.2024, the firm presented justification on the proposed dose and its rationality along with Phase-III clinical trial protocol before the committee. After detailed deliberation, the committee reiterated its earlier recommendations to submit more justification on the proposed dose and its rationality to CDSCO for further review by the committee.
6.	SND/MA/23/000240 Sacubitril & Valsartan Tablets 25 mg	M/s. Bajaj Healthcare limited	The firm presented their proposal for grant of permission to manufacture and market of Sacubitril & Valsartan Tablets 25 mg (additional strength) along with Phase-II clinical trial protocol before the committee. A similar proposal of another firm was deliberated before the committee on dated 21.03.2024 with Phase-II clinical trial protocol wherein the committee asked the firm to submit more justification on the proposed dose and its rationality. After detailed deliberation, the committee reiterated its earlier recommendations to submit more justification on the proposed dose and its rationality to CDSCO for further review by the committee
FDC Division			
7.	FDC/MA/23/000162 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg/10mg/ 10mg/10mg+ Bisoprolol fumarate IP 1.25mg/2.5mg/ 5mg/10mg film coated tablet	M/s. Eris Lifesciences Limited	In light of earlier SEC recommendation dated 07.06.2023, the firm presented their proposal along with Phase III clinical trial report for two strengths i.e. Dapagliflozin 10mg/10mg+ Bisoprolol fumarate 5mg/10mg tablet before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC.