Recommendations of the SEC (Cardiovascular) made in its 05th/24 meeting held on 07.03.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/17/20 Online Submission (26510) TQJ230	M/s. Novartis	The proposal was deliberated in SEC dated 22.11.2023 and it was recommended that "In light of earlier SEC recommendation the proposal was deliberated on 6.09.23, the firm presented protocol amendment version 04 dated 10 May 2023 and version 05 dated 19 September 2023 protocol No. CTQJ230A12301 After detailed deliberation, the committee recommended for approval of the protocol amendment version 04 dated 10 May 2023 however, version 5 was not recommended for approval and more substantive justification to be submitted for version 5 for review of the committee'. Now the firm has presented justification. After detailed deliberation, the committee opined that as the recruitment in India is already over therefore post hoc amendment (version 5) as presented by the firm cannot be allowed.
2.	CT/37/23 Online Submission (27405) Milvexian	M/s. IQVIA	The firm presented waiver to the condition No.1 i.e. 50% sites should be Govt. sites and 50% trial subjects should be enrolled in these Govt. sites protocol No. 70033093AFL3002. After detailed deliberation, the committee recommended that condition No. 1 may be modified as "Atleast 50% more geographically distributed Government sites should be included in the study".
3.	CT/43/23 Online Submission (27867) Milvexian	M/s. IQVIA	The firm presented waiver to the condition No.1 i.e. 50% sites should be Govt. sites and 50% trial subjects should be enrolled in these Govt. sites protocol No. 70033093ACS3003. After detailed deliberation, the committee recommended that condition No. 1 may be modified as "Atleast 50% more geographically distributed Government sites should be included in the study".

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4.	CT/20/24 Online Submission (41784) Lepodisiran	M/s. Eli Lilly	The firm didn't turn up for presentation.
5.	CT/03/23 Online Submission (31260) Olezarsen (ISIS 678354)	M/s. Medpace	The firm didn't turn up for presentation.
6.	CT/40/22 Online Submission (31413) Inclisiran	M/s. Novartis	The firm presented protocol amendment version 01 dated 16 August 2023 and protocol amendment version 02 dated 23 November 2023. After detailed deliberation, the committee opined that detail justification to be submitted for following: • Removing restrictions from earlier protocol (Section 3.2): Moderate Intensity Statin Doses, Low Intensity Statin Doses to allow background therapy of any dose of any statin. • Removing restrictions from earlier protocol (Section 5.1): threshold from ≥70 mg/dL to ≥55 mg/dL The firm has to submit the justification for further review by the committee.
Biological Division			
7.	E receipt No. 2683 Tenectaplase 30mg/40mg/50mg/vial	M/s. Reliance	The firm presented the clinical study report of Phase IV study conducted in India for the product Tenecteplase for injection titled "Prospective, multi-centre, randomized, two-arm, parallel group, active-control, comparative clinical study to evaluate efficacy and safety of *R-TPR-012*/ Metalyse® in Patients with ST segment elevation Myocardial Infarction (STEMI)" vide protocol No. RIS/CAD/2015/02, version 3.0, dated 28 Jun 2019. After detailed deliberation, the committee noted the results of the study and recommended that the firm should update the results of Phase IV study in the

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			package insert of the product. (Dr. Ajay Mahajan didn't participate in the presentation).
FDC Division			
8.	FDC/MA/24/000002 Sacubitril + Valsartan (as sodium salt complex) 50mg (24mg+26mg)/ 100mg(49mg+51mg)/ 200mg (97mg + 103mg)/ 400mg(194mg+ 206mg) Film coated sustained release tablet	M/s. Exemed Pharmaceuticals	The firm presented the proposal along with BE study protocol on FDC of Sacubitril + Valsartan (as sodium salt complex) 400mg (194mg+ 206mg) sustained release tablet before the committee. After detailed deliberation, the committee opined that there could be safety concerns with FDC of Sacubitril + Valsartan (as sodium salt complex) 400mg (194mg+ 206mg) sustained release tablet. However, the committee recommended that the firm may submit revised BE protocol inproposed lower strengths i.e. Sacubitril + Valsartan (as sodium salt complex) 100mg (49mg+51mg) or 200mg (97mg + 103mg sustained release tablet for further review by the committee.