Recommendations of the SEC (Cardiovascular) made in its 10th/24 meeting held on 22.05.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/45/21 Online Submission (32523) Iptacopan (LNP023)	M/s. Novartis	The committee opined that the proposal to be deliberated in SEC Renal.
2.	CT/131/23 Online Submission (32227) AbeLacimab	M/s. Fortrea	The firm presented protocol amendment version 6.0 dated 14 March 2024 protocol No. ANT-010. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/09/23 Online Submission (32244) Ziltivekimab	M/s. Novo Nordisk	The firm presented protocol amendment version 5.0 dated 19.12.2023 protocol No. EX6018-4915. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. (Dr. Sandeep Bansal didn't participate in the deliberation)
4.	CT/118/23 Online Submission (32309) BI 456906	M/s. IQVIA RDS	The firm presented protocol amendment version 2.0 dated 03.08.2023 and protocol amendment version 3.0 dated 12.01.2024 protocol No. 1404-0040 After detailed deliberation, the committee opined that more justification for major protocol amendment (version 2.0 & 3.0) shall be submitted to CDSCO for further review by the committee
5.	CT/06/22 Online Submission (32071) Ianalumab	M/s. Novartis	The committee opined that the proposal to be deliberated in SEC Renal.
BA/BE Division			
6.	File No. 12-09/2024/ BA-BE/MISC-31/DC BABE/CT05/FF/2024	M/s. Lambda Therapeutic Research Limited, Ahmedabad -	The firm presented the protocol No.: 0503-23; version No.: 1.0 dated 17.02.2024 for conducting Comparative Bioavailability Study for export purpose.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	/42111 Telmisartan/ Amlodipine/ Indapamide 80 mg/10 mg/ 2.5 mg tablets	382481	The committee observed that the applied product (FDC of Telmisartan/ Amlodipine/ Indapamide 80mg/10mg/2.5mg tablets) is not approved Globally. After detailed deliberation, the committee opined that the firm is required to justify the Rationality, Essentiality, Desirability and Practicability of the proposed FDC. Accordingly, the firm should submit the above information for re-deliberation before the SEC.
SND Division			
7.	SND-12012/2024-e-office Ticagrelor Tablets I.P. 60mg & 90mg (Brillinta)	M/s. Astrazeneca Pharma India Limited	The firm presented the proposal for updation in package insert of Ticagrelor tablets IP 60mg & 90mg with respect to proposed changes in posology & method of administration and special warning condition & special precautions for use before the committee. After detailed deliberation, the committee recommended for updation of proposed changes in package insert with the condition that the firm should submit the copy of approval from county of origin for such PI update.
FDC Division			
8.	04-01/2022-DC (Misc. 2) (Pt.1) Ramipril + Amlodipine 2.5mg+5mg, 5mg+5mg, 10mg+5mg tablets	M/s. Sanofi India Limited	The firm presented the proposal for update prescribing information of the FDC changes based on the updated company core data sheet (CCDS) version 6 dated Jan 2023. After detailed deliberation, the committee noted that justification/literature for version 5 is not submitted/ presented. Accordingly, firm should submit justification/ literature along with summary of changes in tabular form for both version 5 and version 6 to CDSCO for further review by the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
9.	04-380/2014-DC (Pt.1) Perindopril Erbumine BP 4mg + Indapamide IP 1.25mg + Amlodipine Besilate IP 5mg tablet	M/s. Servier India Pvt. Ltd.	The firm presented the proposal for update prescribing information of the FDC changes based on the updated company core data sheet (CCDS) version 5 dated 28.09.2023. After detailed deliberation, the committee recommended for grant of approval for the proposed update in prescribing information as presented by the firm.
10.	FDC/MA/22/000302 Rosuvastatin Calcium IP eq. to Rosuvastatin+ Bempedoic acid (5mg+180mg, 10mg + 180mg, 20mg + 180mg) tablet	M/s. Exemed Pharmaceuticals	The proposal is put up for re-deliberation.