Recommendations of the SEC (Cardiovascular & Renal) made in its 123rd meeting held on 12.04.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/22/000302 Rosuvastatin + Bempedoic acid (5mg+180mg, 10mg + 180mg, 20mg + 180mg) tablet	M/s. Exemed	In light of the earlier SEC recommendation dated 11.01.2023, firm presented its proposal before the committee. After detailed deliberation, the committee recommended for conducting the phase III CT study with the following conditions: 1. All proposed strengths of the product should be included in the study. 2. Study should be conducted in sufficient number of patients. 3. Study sites should be geographically distributed. Accordingly, firm should present the revised CT protocol before SEC.
2.	FDC/MA/23/000008 Ezetimibe 10mg+ Atorvastatin Calcium 80mg tablets	M/s. Windlas	In light of the earlier SEC recommendation dated 08.02.2023, the committee opined that decision on Phase III CT study waiver will be taken after reviewing the BE study result by SEC.
3.	FDC/MA/22/000248 Bisoprolol Fumarate IP 2.5mg/5mg/10mg + Telmisartan IP 20mg/40mg/80mg + Chlorthalidone IP 6.25mg / 12.5mg/12.5mg uncoated tablet	M/s. Windlas Biotech	In light of the earlier SEC recommendation dated 07.09.2022, the firm presented its proposal along with justification as well as BE study protocol. The firm informed that they are withdrawing the one strength i.e 10mg + 80mg + 12.5mg. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study with the strength of 5mg + 40mg + 12.5mg. The result of the BE study should be presented before SEC along with Phase III CT study protocol.
4.	FDC/MA/22/000097 Metoprolol Tartrate (as extended release) + Amlodipine Besilate IP eq. to Amlodipine + Chlothalidone IP (50mg+5mg+6.25mg	M/s. Ajanta Pharma Ltd.	In light of the earlier SEC recommendations dated 10.05.2022, the firm presented its proposal along with BE study report and phase III CT study report. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the product.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	& 50mg+5mg+12.5mg) tablets		
5.	FDC/MA/23/000063 Dapagliflozin Propanediol monohydrate 10mg+ Metoprolol Succinate IP eq. to Metoprolol tartrate (ER) 50mg tablets	M/s. Exemed	The firm presented its proposal before the committee along with BE study protocol and Phase III CT study protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study and Phase III CT study with condition that BE study results should be presented in SEC meeting before initiating the Phase III CT study.
6.	FDC/MA/23/000071 Bisoprolol Fumarate 5mg/5mg/2.5mg/ 2.5mg+Cilnidipine 10mg/10mg/10mg/10 mg+Chlorthalidone1 2.5mg/6.25mg/12.5m g/6.25mg tablets	M/s. Ajanta	The firm requested for deferment of its proposal.
7.	FDC/MA/23/000083 Vildagliptin (as sustained release) 100mg/100mg/100m g/+Rosuvastatin calcium IP eq. to Rosuvastatin 5mg/10mg/20mg tablets	M/s. Exemed	The firm did not turn up for the presentation.
8.	FDC/MA/23/000087 Ezetimibe 10mg + Atorvastatin Calcium 80mg tablets	M/s. Pure & Cure	The firm presented its proposal alongwith BE study protocol as well as justification for clinical trial study waiver. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study and decision on Phase III clinical trial study waiver will be taken after reviewing the BE study report by SEC.
9.	FDC/MA/22/000293 Sacubitril Sodium eq. to Sacubitril + Valsartan IP((24 + 26) (49+51) (97mg +	M/s. Intas Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 27.01.2023, the firm presented its proposal before the committee. After detailed deliberation, the committee opined that 1. It is New Drug.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	103mg) Film coated tablet		2. Firm should submit the documents as per NDCT Rules 2019 to New Drug Division.
10.	FDC/MA/20/000077 Azelnidipine 8mg/8mg/16mg/16mg + Metoprolol (SR) 25mg/ 50mg/25mg/50mg Tablet	M/s Akums Drugs & Pharmaceuticals Limited	In light of the SEC recommendation dated 11.10.2021, the firm presented its proposal along with CT study report. After detailed deliberation, Committee opined that the firm should submit the details of study sites along with raw data of the CT study to CDSCO for reviewing by the committee.
11.	FDC/MA/22/000406 Torsemide IP 10mg/20mg + Eplerenone 25mg/25mg film coated tablet	M/s. Synokem Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 11.01.2023, the firm presented its proposal before the Committee along with BE study and Phase III CT study protocol. After detailed deliberation, the Committee recommended for grant of permission to conduct the BE study and opined that the CT study protocol should be revised to scientifically justified. Accordingly, revised CT study protocol should be submitted to CDSCO and presented before SEC along with BE study results for review.
12.	FDC/MA/23/000057 Rosuvastatin calcium IP eq. to Rosuvastatin 5mg/10mg/20mg + Sitagliptin phosphate monohydrate IP eq to sitagliptin 100mg/100mg/100mg	M/s Exemed	The firm did not turn up for the presentation.
GCT Division			
13.	CT/09/23 Online Submission (35656) ZilTivekimab	M/s. Novo-Nordisk	The firm has presented phase III clinical trial protocol no. EX6018-4915, version no 1.0 dated 11-10-2022 before the committee. After detailed deliberation, the committee recommended for grant of permission for conducting the clinical trial with following conditions- 1. The standard of care treatment/ concomitant medication should be provided to the trial subjects free of cost

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			during the conduct of the study. 2. The applicant should submit interim analysis to be done after 564 cardiac events as per protocol along with DMC recommendations and the results should be submitted to CDSCO for further review by the committee.
14.	CT/03/23 Online Submission (35499) Olezarsen (ISIS678354)	M/s. Medpace	The firm has presented phase III clinical trial protocol no. ISIS678354-CS6, amendment 1.0 dated 10-08-2022 before the committee. After detailed deliberation, the committee recommended that the firm should submit the followings for further review by the committee. 1. Rationale for selection of 80mg dose for Cohort B in the proposed trial when in clinical phase II (dose ranging study) higher dose was 50mg. 2. Rationale for enrolment of trial subjects after 53 week in open label extension study (new study) without performing interim analysis of the proposed phase III study. Note- Dr. Ajay U. Mahajan did not participate in the deliberation
Medical Device Division			
15.	IMP/MD/2022/53336 LKT Disposable Perfusion Circuit, Kidney Transporter	M/s. Renovate Biologicals Private Limited	In light of the earlier SEC recommendation dated 11.01.2023, the firm presented their proposal before the committee. After detailed deliberation, the committee observed that the data presented by the firm is inadequate to ensure the safety, effectiveness of the device. The committee recommended that the firm should present adequate clinical investigation data, PMS study data to ensure the safety, effectiveness & performance of the device for further consideration.