Recommendations of the SEC (Cardiovascular & Renal) made in its 137th meeting held on 22.11.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/20/000077 Azelnidipine IP + Metoprolol Succinate IP eq. to Metoprolol Tartrate IP (SR) 8mg/8mg/16mg/16mg +25mg/50mg/25mg/ 50mg film coated bilayered tablet	M/s. Akums Drugs & Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 11.10.2023, the firm presented the raw data of the Phase III clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC.
2.	FDC/MA/22/000406 Torsemide IP 10mg/ 20mg + Eplerenone IP 25mg/25mg film coated tablet	M/s. Synokem Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 12.04.2023, the firm presented its proposal along with BE study report before the committee. The committee noted that firm has not conducted the BE study with individual innovator drug as reference product. After detailed deliberation, the committee recommended that the firm should conduct BE study with individual innovator drug as reference product. Accordingly, the firm should submit the BE protocol to CDSCO for further review.
3.	FDC/MA/23/000327 Dapagliflozin propendiol monohydrate eq. To Dapagliflozin + Telmisartan IP (10mg + 40mg/ 10mg+80mg) tablet	M/s. Exemed Pharmaceuticals	The firm presented its proposal along with BE & Phase III clinical trial study protocol before the committee. After detailed deliberation, the committee recommended that the reference product should be changed to individual innovator drug in the BE study. The committee also recommended for conduct of Phase III CT study as per presented CT protocol. Accordingly, the revised BE study protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit BE study report for further review by the committee before initiation of the Phase III clinical trial.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
4.	CT/17/20 Online Submission (26510) TQJ230	M/s. Novartis	In light of earlier SEC recommendation the proposal was deliberated on 16.09.23, the firm has presented protocol amendment version 04 dated 10May 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 10May 2023 however, version 5 was not recommended for approval and more substantive justification to be submitted for version 5 for review of the committee.
5.	CT/99/23 Online Submission (39003) Pegozafermin	M/s. Medpace	The firm presented Phase III clinical study protocol No. BIO89-100-231. After detailed deliberation, the committee recommended for grant of permission to conduct the trial.
6.	CT/118/23 Online Submission (39700) BI 456906 Survodutide	M/s. IQVIA RDS	The proposal was deferred for next SEC meeting.
7.	CT/116/23 Online Submission (39668) Sibeprenlimab (VIS649)	M/s. George Clinical India	The proposal was deferred for next SEC meeting.
8.	CT/114/23 Online Submission (39566) Baxdrostat Tablets 1mg/ 2mg/Placebo	M/s. AstraZeneca	The proposal was deferred for next SEC meeting.
9.	CT/136/22 Online Submission (28040) Sodium Zirconium Cyclosilicate	M/s. AstraZeneca	The proposal was deferred for next SEC meeting.
10.	CT/111/21 Online Submission (28279) Inclisiran	M/s. Novartis	The proposal was deferred for next SEC meeting.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
11.	CT/63/21 Online Submission (28535) Ziltivekimab	M/s. Novo-Nordisk	The proposal was deferred for next SEC meeting.
Medical Device Division			
12.	CI/MD/2023/96521 ADI COPD Device	M/s. Analog Devices India Private Limited	In light of earlier SEC (Cardiovascular and Renal) recommendation dated 07.11.2023, the firm presented their protocol No. ADI COPD-001, version 2.0 dated 19.04.2023, for conduct of Pilot Clinical Investigation which is an observational study for data collection on device "ADI COPD" before the committee in presence of pulmonary expert. After detailed deliberation, the committee recommended for the grant of permission to conduct the clinical investigation of the said device in the country. However, the committee suggested that the timing of recording the data should be after 10 mins of relaxation of the patient.