Recommendations of the SEC (Cardiovascular) made in its 07th/24 meeting held on 04.04.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/20/24 Online Submission (41784) Lepodisiran	M/s. Eli Lilly	The firm presented Phase III clinical trial study protocol No. J3L-MC-EZEF dated 17 December 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. KFT assessment including GFR and UTI test at 3 months shall be included in inclusion criteria. Accordingly, CKD patients should also be included, if full fill the said criteria. 2. Patient diagnosed with low GFR undergoing any form of haemodialysis should be excluded from study.
2.	CT/03/23 Online Submission (31260) Olezarsen (ISIS 678354)	M/s. Medpace	The firm presented protocol amendment 4 dated 24 January 2024 protocol no. ISIS 678354-CS6. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm with the condition that following shall be included in exclusion criteria: 1. Lactating mothers till 1year 2. Patients consuming drugs beta blockers and antihypertensive diuretics 3. Regular consumption of alcohol of patients before enrolment should be verified.
3.	CT/35/24 Online Submission (42175) Finerenone	M/s. George Clinical India	The firm didn't turn up for presentation.
4.	CT/39/24 Online Submission (42284) Retatrutide (LY3437943)	M/s. Eli Lilly	The firm presented Phase III clinical trial study protocol no. J1I-MC-GZBO dated 05 January 2024. After detailed deliberation, the committee recommended that the firm should submit revised protocol as discussed during the meeting for further review by the

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			committee.
Medical Devices Division			
5.	CI/MD/2023/97539 Hemodynamx System	M/s. Translumina Therapeutics LLP	In light of earlier SEC recommendations dated 20.12.2023, the firm presented proposal for grant of permission for conduct of Pilot clinical investigation on device Hemodynamx System in the country on Indian population before the committee. The said device Hemodynamx System is intended to increase the aortic valve EOA (Effective Orifice Area) and thus reduce the left ventricular pressure. The said study is Pilot Clinical investigation on 5 patients in India. After detailed deliberation, the committee recommended for grant of permission for conduct of Pilot clinical investigation on device Hemodynamx System in the country on Indian population subjected to the following conditions: 1. The firm should ensure audio-visual consent of patient participating in the study. 2. The firm should ensure for Medical insurance including medical management and compensation of the patients enrolled in the study, in case of any adverse events during the study. 3. The firm shall adhere with the inclusion criteria and exclusion criteria for selection of subjects as per the Clinical Investigation Plan. 4. The detailed data and report of the clinical study should be submitted to CDSCO after completion of the study for further review by the SEC.
FDC Division			
6.	FDC/MA/23/000344 Sacubitril 12mg +	M/s. Alkem Laboratories Ltd.	In light of the earlier SEC recommendation dated 06.12.2023 & 07.12.2023, the firm presented their

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	Valartan 13mg film coated tablets		proposal along with the justification on the proposed dose and its rationality. After detailed deliberation, the committee opined that: 1. The firm has not presented any scientific justification in proposed strength. 2. The firm has not presented any published scientific literature or peer reviewed journal regarding essentiality and desirability in lower strength. 3. The FDC is not rational in proposed strength. 4. The product is not approved internationally. In view of above, the committee did not recommend for approval of the proposed FDC.
7.	FDC/MA/23/000272 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg/5mg/5mg + Sacubitril and Valsartan as Sodium salt complex 50mg (24mg and 26mg), 100mg (49mg and 51mg) & 200mg (97mg and 103mg) tablet	M/s. Exemed Pharmaceutical	In light of earlier SEC recommendation dated 11.10.2023, the firm presented the proposal along with BE study report before the committee. After detailed deliberation, the committee considered the BE study report and recommended to initiate Phase III clinical trial study for which permission has already been granted by CDSCO. The Phase III clinical trial report should be submitted to CDSCO for further review by the committee.
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 Pharmaceutical	In light of earlier SEC recommendation dated 07.03.2024, the firm presented the proposal along with revised BE study protocol on FDC of Sacubitril + Valsartan (as sodium salt complex) 200mg (97mg + 103mg) sustained release tablet before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. The result of the BE study should be presented before the committee for review along with Phase III clinical trial protocol.

SEC (Cardiovascular & Renal) meeting dated 04.04.2024