Recommendations of the SEC (Cardiovascular & Renal) made in its 139th meeting held on 06.12.2023 & 07.12.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/CT/23/000055 Zinc chloride 1050 µg/ml + Sodium fluoride 210.0 µgml + Potassium iodide 16.60 µg/ml + Sodium Molybdate dihydrate 4.850 µg/ml + Sodium selenite anhydrous 17.29 µg + Copper chloride dihydrate USP 102.3 µg/ml + Manganese chloride tetrahydrate USP 19.79 µg/ml + Ferric chloride hexahydrate 540.0 µg/ml + Chromic chloride hexahydrate USP 5.330 µg/ml concentrate for Solution for Infusion	M/s. Fresenius Kabi India	In light of earlier SEC recommendation dated 21.09.2023, the firm presented the revised Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial. Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
2.	FDC/MA/23/000342 Chlorthalidone IP 6.25mg + Cilnidipine IP 5mg + Bisoprolol Fumarate IP 5mg film coated tablet	M/s. Akums Drugs & Pharmaceuticals Ltd.	The firm presented the proposal along with BE study protocol before the committee. After detailed deliberation, the committee recommended that BE protocol should be revised. Further, individual and innovators product should be taken as reference product in the proposed BE study protocol. Accordingly, the revised BE study protocol should be submitted to CDSCO for review by the committee.
3.	FDC/MA/23/000344 Sacubitril 12mg + Valartan 13mg film coated tablets	M/s. Alkem Laboratories Ltd.	The firm presented their proposal along with justification for BE waiver & Phase III CT waiver before the committee. After detailed deliberation, the committee opined that more justification on the proposed dose and its rationality should be submitted for further review by the committee.

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GCT Division			
4.	CT/135/23 Online Submission (40226) Tebipenem pivoxilhydrobromide (TBP-PI-HBr, previously known as SPR994)	M/s. PSI CRO Pharma Pvt. Ltd.	The firm presented Phase III clinical trial Protocol no. SPR994-305. After detailed deliberation, the committee opined that the proposal should be re-deliberated in presence of one microbiologist and Intensive care specialist doctor.
5.	CT/126/23 Online Submission (39979) BION-1301	M/s. PPD	The firm presented Phase III clinical trial Protocol no. CHK02-02. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
6.	CT/131/23 Online Submission (40097) Abelacimab	M/s. Fortrea Development	The firm presented Phase III clinical trial Protocol no. ANT-010. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
7.	CT/57/23 Online Submission (37717) Iptacopan (LNP023)	M/s. Novartis	In light of earlier SEC dated 09.08.2023 the proposal was deliberated. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that diagnosis of MPGN should be done from a single Nephropathologist by doing light microscopy, IF & electron microscopy.
8.	CT/06/22 Online Submission (29672) VAY736	M/s. Novartis	The firm presented Protocol amendment version 02 dated 30 November 2022, protocol no. CVAY736K12301. After detailed deliberation, the committee recommended for approval of the Protocol amendment as presented by the firm.
9.	CT/120/21 Online Submission (28995) Anifrolumab	M/s. AstraZeneca	The firm presented Protocol amendment version 2.1 dated 18 September 2023, protocol no. D3466C00001. After detailed deliberation, the committee recommended for approval of the Protocol amendment as presented by the firm.
Medical Device Division			

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10.	CI/MD/2021/38137 Pacemaker	M/s. Calyan Cardiac Therapeutics India Private Limited	The firm presented proposal for grant of permission for conduct of Pilot Clinical Investigation on proposed medical device Pacemaker in the country on Indian population before the committee. The said device the Calyan VVIR single chamber pacing system is indicated for use in patients who have Class I or II indication for implantation of a single-chamber ventricular pacemaker, according to ACC/AHA/HRS guidelines. The said study is Pilot Clinical investigation on 10 subjects in India. The committee observed that the said device has obtained Investigational medical device approval from USFDA and not commercially approved in India and in any other countries. After detailed deliberation committee recommended that the firm should submit following data for further review: 1. Details of Cadaver studies conducted on Pacemaker. 2. Details of acute and chronic animal studies conducted on proposed device.
11.	IMP/MD/2022/75609 Allegra TAVI System	M/s. Biosensors	The firm presented proposal for grant of license to import and market the proposed product Allegra TAVI System in the country before the committee. The said device is indicated for the treatment of severe calcified aortic valve stenosis in high risk patients with elevated surgical risk or in patients with a symptomatic degeneration of an aortic valve bio-prosthesis. The firm presented comparative data on substantial equivalence of the proposed device with other commercially approved devices in India before the committee. The committee observed that said device is not new/investigational medical device and similar devices are

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			commercially approved in India. After detailed deliberation committee recommended for grant of license to import and market the said device in the country with following conditions: 1. The proposed indication should be for degenerative aortic stenosis with tricuspid morphology. 2. The firm needs to conduct Post Marketing Clinical Investigation on atleast 10 patients in India. Accordingly, the firm shall submit protocol for conduct of Post-Marketing Clinical Investigation to CDSCO for further review.