Recommendations of the SEC (Cardiovascular & Renal) made in its 99th meeting held on 17.03.2021 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/IMP/22/000001 Empagliflozin 10mg/25 mg tablet	M/s. Boehringer Ingelehlheim	The firm presented their proposal for the import and marketing permission of Empagliflozin tablets 10mg & 25mg before the committee for additional indication based on the results of study conducted in India and abroad. After detailed deliberation, the committee recommended for grant of permission for Import and marketing permission of Empagliflozin tablets 10mg & 25mg to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure subject to condition that the drug should be prescribed only to the patients with eGFR more than 30ml/min/1.73m^2. Further, the committee opined that the firm should submit more clinical data for use in patients with eGFR 20 to 30ml/min/1.73m^2 for which the firm should submit separate application to CDSCO as per the rules.
GCT Division			
2.	CT/88/21 Online Submission (15880) Finerenone	M/s. Bayer Pharmaceuticals	The firm presented their proposal for protocol amendment for protocol no 21177, protocol amendment 1.0, version 3.0 dated 01-Dec-2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
Medical Device Division			
3.	IMP/MD/2021/51377 Epic™ Plus Stented Tissue Valve (Aortic and Mitral), Epic™ Plus Supra Stented Tissue Valve (Aortic)	M/s. St. Jude Medical India Pvt. Ltd.	The firm presented their proposal before the committee. After detailed deliberation, the committee agreed in principle for approval of the proposal. However, the committee opined that the comment of cardiac surgeon should be obtained. Therefore, the proposal should be discussed in next meeting in presence

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			of cardiac surgeon.
4.	MFG/MD/2021/52404 Transcatheter aortic valve System (Vienna, Reli, Re Valve, Champion)	M/s. Relisys Medical Devices	The firm presented their proposal before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of the product in the country with the condition that the firm should conduct post market clinical investigation on atleast 30 patients in the country. Accordingly, the firm should submit post marketing clinical investigation protocol to CDSCO within three months from the date of approval of manufacturing and marketing permission for further review by the committee.