Recommendations of the SEC (Cardiovascular & Renal)made in its 104th meeting held on 22.06.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/22/000171 Bempedoic acid 180mg/180mg/180mg /180mg+Rosuvastatin calcium eq. to Rosuvastatin 5mg/10mg/20mg/40mg tablets	M/s Akums	The firm presented their proposal along with BE study protocol in higher strength along with the request for Phase III CT study waiver for all proposed strengths before the committee. Based on the presentation made, the committee did not recommend the proposed lower strengths i.e. Bempedoic acid 180mg/180mg/180mg +Rosuvastatin calcium eq. to Rosuvastatin 5mg/10mg/20mg tablets. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study with condition to include GFR in the study. As regard to clinical trial study waiver, the committee recommended that the firm should initially present the BE study results before the committee for further consideration of Phase III CT waiver at that point of time
2.	FDC/MA/22/000171 Efonidipine HCL 40mg +Telmisartan IP 40 mg	M/s Ajanta	The firm did not turn up for presentation.
GCT Division			
3.	CT/35/22Sibeprenlimab	M/s George Clinical India	The firm presented the proposal along with the Phase III Clinical Trial protocol no. 417-201-00007, Amendment No. 1 dated 03 Jan 2022 before the committee. **Risk versus benefit to the patients-** The safety profile of the study drug from preclinical, toxicity studies and clinical studies justify the conduct of the trial. **Innovation vis-a-vis existing therapeutic-** Immunoglobulin A nephropathy is one of the most prevalent chronic primary glomerular diseases worldwide. Sibeprenlimab (VIS649) is a humanized IgG2 mAb. The current study is to evaluate the Efficacy and Safety of Sibeprenlimab administered

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			subcutaneously in subjects with Immunoglobulin A Nephropathy. **Unmet medical need in the country-**The proposed trial is to detect a clinically significant treatment effect for both the primary endpoint of Proteinuria at 9 months and the key secondary endpoint of eGFR at approximately 24 months. After detailed deliberation, the committee opined that the firm should present Phase I and Phase II clinical trial data along with SAEs details and its causality assessment before the committee for further review.
Medical Device			
4.	IMP/MD/2021/50727 Sirolimus-Eluting coronary stent system	M/s Biotronik Medical Device India Pvt. Ltd	The firm presented their proposal before the committee. After detailed deliberation, the committee recommended for grant of import & market permission for orsiro mission with same indications as approved for orisro coronary stent system. Further, for extended indication for orsiro mission , the firm should submit the Indian patient data to support the extended indication for further review by the committee.