

Recommendations of the SEC (Cardiovascular & Renal) made in its 106th meeting held on 28.07.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT/22/000048 Finerenone 10mg & 20mg film coated tablets	M/s. Bayer Pharmaceuticals Pvt. Ltd	The firm presented their proposal for 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.
SND Division			
2.	SND/MA/21/000482 Ticagrelor SR Tablet 120/180mg	M/s. Theon Pharmaceuticals	The firm didn't turn up for presentation.
Additional Proposal-GCT Division			
3.	CT/33/22 Online Submission (31451) Sibeprenlimab (VIS649)	M/s. George Clinical	The firm presented the proposed phase II/III trial protocol no. 417-201-000012, version 3.0 dated 11-Oct-2021 before the committee. After detailed deliberation, the committee opined that applicant should submit details of Phase I and Phase II Clinical trial data to support that the test drug has improved eGFR and reduced uPCR in patient with IgAN.
4.	CT/48/22 Online Submission (31905) LNP023	M/s. Novartis	The firm presented the proposed Phase II trial protocol no. CLNP023K1220, version 00 dated 26-Oct-2021 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase II study as presented.