Recommendations of the SEC (Cardiovascular & Renal) made in its 94th meeting held on 11.01.2022 & 12.01.2022 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/21/000179 Bempedoic Acid 180mg Tablets	M/s. Theon	The firm presented their proposal for grant of manufacturing and marketing permission of the drug Bempedoic Acid 180 mg tablet along with Phase III clinical trial protocol and BABE study protocol before committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study and the firm should conduct the BE study and submit the BE study results before the committee for further consideration.
2.	ND/MA/21/000197 Bempedoic Acid Tablets 180mg	M/s. Logos Pharma	The firm presented their proposal for grant of manufacturing and marketing permission of the drug Bempedoic Acid 180 mg tablet along with Phase III clinical trial protocol and BE study protocol before committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study and the firm should conduct the BE study and submit the BE study results before the committee for further consideration.
3.	ND/IMP/21/000085 Finerenone 10mg, 20mg Film coated tablets	M/s. Bayer Pharmaceuticals Pvt. Ltd.	The firm presented their proposal for grant of import and marketing permission of the drug Finerenone 10mg and 20mg film coated tablets along with justification for clinical trial waiver before the committee. The committee noted that the drug is already approved in countries like US, Australia, Switzerland etc. The committee opined that the drug is indicated for a disease which is serious and life threatening and there is an unmet medical need in the country. After detailed deliberation, the committee recommended for grant of permission to import and marketing of Finerenone 10mg and 20mg film coated tablets subject to following conditions: 1. The drug should be sold by retailer

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			under prescription of Nephrologist/ Cardiologist only. 2. The firm should conduct Phase IV clinical trial in the country for which the protocol should be submitted to CDSCO within 3 months of approval for marketing.
4.	ND/MA/21/000196 Bempedoic Acid 180mg Tablets	M/s. Mascot Health Series Pvt. Ltd	The firm presented their proposal for grant of manufacturing and marketing permission of the drug Bempedoic Acid 180 mg Tablet along with Phase III clinical trial protocol and BE study protocol before committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study and the firm should conduct the BE study and submit the BE study results before the committee for further consideration.
5.	ND/IMP/20/000061 Ferric Pyrophosphate citrate solution, for parenteral administration with bicarbonate concentration, 27.2 mg Fe/5 ml	M/s. Sun Pharma Lab Limited.	In light of earlier recommendation of SEC dated 08.10.2021 and 10.10.2021 the firm presented the revised clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial subject to following conditions: 1. Quantiferon gold test instead of Tuberculin test should be used for screening of subjects. 2. In the inclusion criteria "Prescribed Dialyzer blood flow rate (QB) prior to randomization ≥ 250 ml/min" should be substituted with "Dialyzer blood flow rate (QB) prior to randomization ≥ 250 ml/min".
SND Division			
6.	SND/MA/21/000482 Ticagrelor SR Tablets 120/180mg (Sustained Release Dosage form)	M/s. Theon Pharmaceuticals	The firm presented BE protocol for Ticagrelor SR tablets 180mg only where as they have submitted BE protocols for both 120 mg SR tablets and 180 mg SR tablets. The committee opined that the firm should clarify the above point and present the study protocols for further consideration by the committee.

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7.	SND/IMP/21/000092 Sacubitril/Valsartan 50mg, 100mg & 200mg tablets	M/s. Novartis	The firm presented their proposal for import and marketing of Sacubitril/Valsartan 50mg, 100mg & 200mg tablets for expanded indication "to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal". After detailed deliberation, the committee recommended that the firm should submit detailed justification for the proposed expanded indication to consider the matter further.
FDC Division			
8.	FDC/MA/18/000073 Rosuvastatin + Teneligliptin (5mg + 20mg, 10mg + 20mg & 20mg + 20mg) tablets	M/s. Synokem Pharmaceuticals	The firm presented the Phase III clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC.
GCT Division			
9.	CT/48/17 Online Submission (11974) Edoxaban	M/s. IQVIA	The firm didn't turn up for the presentation.
10.	CT/45/21Online Submission (14416) Iptacopan (LNP023)	M/s. Novartis	The firm presented their protocol amendment V00-IN.01 dated 01 Nov 2021 before the committee. After detailed deliberation, the committee did not recommend for approval of the said protocol amendment. The committee opined that the concomitant medication affecting primary end point of the study should not be part of standard of care in the proposed study. Accordingly, the firm should submit revised protocol to CDSCO for further review by the committee.
11.	CT/47/17 Online Submission (11021) Bempedoic Acid (ETC-1002)	M/s. IQVIA RDS	The firm presented justification in light of previous SEC recommendation before the committee. After detailed deliberation, the committee did not recommend for approval of the

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			protocol amendment version 5 dated 24.09.20 as the enrollment was over.
Medical Device Division			
12.	CI/MD/2021/45487 Tensor Tip (Blood Pressure Monitoring Device)	M/s. Taevas Life Sciences Pvt. Ltd.	The proposal was deferred to the next meeting.
13.	IMP/MD/2021/44614 Cytosorb (Polymer Based Adsorbent Cytosorb 300ml Device)	M/s. Biocon Biologics Limited	In light of earlier SEC recommendations dated 07.12.2021, the firm presented their proposal before the committee. After detailed deliberation, the committee recommended for grant of import permission of the proposed product for restricted use under emergency situation to treat patients of 18 years of age or older with confirmed COVID-19 admitted to the ICU with confirmed or imminent respiratory failure by reducing pro-inflammatory cytokine levels, which may ameliorate a cytokine storm due to the overabundance of pro-inflammatory cytokines and, in turn, provide clinical benefit to such patients. But for the rest of two indications, the committee opined that the firm should submit the regulatory approval in other countries and adequate clinical data for further review by the committee.
14.	IMP/MD/2021/41889 Selution Pro 14 PTCA	M/s. Bio India Interventional Technologies Pvt. Ltd.	The firm didn't turn up for the presentation.