Recommendations of the SEC (Cardiovascular & Renal) made in its 103rd meeting held on 19.05.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/21/000062 Inclisiran Solution for injection in pre-filled syringe 284 mg/1.5 mL	M/s. Novartis	In light of earlier SEC recommendation dated 08.10.2021, the firm presented the proposal with request for local clinical trial waiver with the commitment to conduct Phase IV Clinical Trial before the committee. The committee observed that justification submitted by the firm for the said purpose was not adequate. After detailed deliberation, the committee recommended that the firm should submit the interim results on Indian subset of patients from the ongoing global clinical trial where India is one of the participating countries to consider the matter further.
2.	ND/MA/21/000097 Bempedoic Acid 180 mg and Ezetimibe 10 mg Tablet	M/s. Akums	The firm presented their proposal for Phase III clinical trial waiver of Bempedoic Acid 180 mg and Ezetimibe 10 mg Tablet along with the justification and published data before the committee. The committee noted that the Phase III clinical trial permission was already granted to the firm on 16.12.2021. After detailed deliberation, the committee recommended that the firm should submit the progress in respect of conduct of the trial for further consideration by the committee.
3.	12-01/18-DC(Pt-337) Mannitol & Hypokalaemia	SRP-NCC-PvPI	The SRP recommendation received from PvPI was deliberated by the committee. After detailed deliberation, the committee recommended that CDSCO should request the State Drug Controllers to direct the manufacturers of the drug to include mannitol induced Hypokalaemia in the corresponding package insert of the drug.
FDC Division			

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
4.	FDC/MA/22/000129 L-Tyrosine 90.0000mgU.S.P. + L-Histidine 114mg U.S.P. + L-Tryptophan 69 mg U.S.P + L-Threonine 159 mg U.S.P. + L-Lysine Acetate 315mgU.S.P. + Calcium-DL-2-hydroxy-4-(methylthio)-butyrate (-hydroxyanalogue of methionine,Calcium-salt) =177mg + Calcium-3-methyl-2-oxobutyrate(-ketoanalogue of valine,Calcium salt) =258 mg+ Calcium-2-oxo-3-phenylpropionate (-ketoanalogue of phenylalanine, Calcium salt)204 mg + Calcium-4-methyl-2-oxovalerate(-ketoanalogue of leucine,Calcium salt) 303mg + Calcium-3 -methyl-2-oxovalerate (-ketoanalogueofisoleucine, Calcium salt)201 mg granules	M/s. Pharose Remedies Ltd.	The firm presented their proposal before the committee. The committee noted that the FDC is not yet approved in other countries. Also, safety & efficacy of the product is not established. After detailed deliberation, the committee recommended that the firm should submit the Phase III clinical trial protocol and comparative study with approved tablet dosage form.
GCT Division			
5.	CT/146/21 Online Submission (28804) Cefepime-Zidebactam vs. Meropenem	M/s.Wockhardt	In light of earlier SEC recommendation dated 08.12.2021 and 09.12.2021, the firm presented their justification before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study.
6.	CT/20/22 Online submission (30523) Selexipag	M/s. Parexel	The firm did not turn up for presentation.

SEC (Cardiovascular & Renal) meeting dated 19.05.2022