

Recommendations of the SEC (Cardiovascular & Renal) made in its 92nd meeting held on 10.11.2021 & 11.11.2021 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/CT21/FF/2021/28359 Bempedoic Acid Tablets 180 mg	M/s. MSN Private Limited	The firm presented their proposal along with BE and Phase III Clinical Trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the bioequivalence study and opined that the firm should submit bioequivalence study results before the committee for further consideration of proposed Clinical trial.
2.	ND/IMP/21/000076 Vericiguat 2.5 mg/5 mg/ 10 mg Film coated tablet	M/s. Bayer Pharmaceuticals Pvt. Ltd	In light of earlier recommendation of SEC dated 08.10.2021 & 11.10.2021 firm presented their proposal before the committee. The committee after detailed deliberation agreed with the justification submitted for waiver for conducting clinical trial and recommended for grant of permission to manufacture and market Vericiguat 2.5 mg/5 mg/ 10 mg film coated tablet subject to following conditions:- 1. The firm should submit Phase IV clinical trial protocol within 3 months of approval of the drug for review by the committee. The Phase IV study report should be submitted within 2 years of approval of the study. 2. The drugs should be sold by retail under prescription of a Cardiologist only. 3. The drug should be used only in patients with worsening heart failure and recurring heart failure hospitalization under standard of care treatment.
3.	ND/MA/21/00096 Bempedoic Acid Tablets 180 mg	M/s. Akums	In light of earlier recommendation of SEC dated 15.07.2021, 16.07.2021 & 19.07.2021, the firm presented BE study report and revised Phase III

SEC (Cardiovascular & Renal) meeting dated 10.11.2021 & 11.11.2021

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the protocol presented.</p>
SND Division			
4.	SND/MA/21/000126 Calcium Polystyrene Sulphonate suspension 15g/60ml	M/s. Cadila Healthcare	<p>In light of recommendation of the earlier committee meeting held on 15.07.2021, the firm presented data/justification before the committee for approval of Calcium Polystyrene Sulphonate suspension 15g/60ml.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Calcium Polystyrene Sulphonate suspension 15g/60ml indicated for the treatment of hyperkalemia associated with oliguria, anuria or dialysis.</p>
5.	SND/MA/20/000221 Ticagrelor SR Tablets 120/180mg	M/s. Akums Drugs & Pharmaceuticals	<p>The firm presented the BE study reports of Ticagrelor SR Tablets 120mg and Ticagrelor SR Tablets 180mg before the committee.</p> <p>After detailed deliberation, the committee opined that the firm should submit raw data of both BE studies for further evaluation.</p>
FDC Division			
6.	FDC/MA/21/000137 Amlodipine Besylate USP eq. to Amlodipine 10mg + Olmesartan Medoxomil USP 40mg Tablet	M/s. Torrent Pharmaceuticals Ltd.	<p>The firm presented their proposal before the committee along with their request for Phase III clinical trial waiver.</p> <p>The committee noted that the FDC is already approved by CDSCO in lower strength and the proposed FDC is already approved in USA. The firm also presented the BE study report before the Committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the additional strength of</p>

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
			the FDC.
7.	FDC/MA/21/000091 Telmisartan 80mg/40mg+ Azelnidipine16mg/16mg tablets	M/s. Akums Drugs and Pharmaceutical Ltd.	The firm didn't turn up for presentation.
8.	FDC/MA/21/000114 Aspirin + Atorvastatin (75mg+20mg) capsules	M/s. Windlas Biotech Limited	In light of earlier recommendations of SEC, the firm presented their proposal along with BE study report before the committee. The committee noted that the FDC is already approved by CDSCO in various strengths. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the FDC of Aspirin + Atorvastatin (75mg+20mg) capsules.
GCT Division			
9.	CT/111/21 Online Submission (27928) KJX839	M/s. Novartis	The firm presented their proposal for Phase III clinical study before the committee. Assessment of risk versus benefit to the patients- The safety profile of the study drug from various preclinical toxicology studies and clinical studies presented before the committee. Innovation vis-a-vis existing therapeutic- The primary objective of this study is to demonstrate the superiority of Inclisiran compared to placebo in reducing the risk of 3P-MACE (composite of CV death, non-fatal MI and non-fatal ischemic stroke) in participants with established ASCVD and a LDL-C mmol/L (70 mg/dL). Unmet need- The test drug may potentially provide alternative treatment option in patients with established cardiovascular disease (VICTORION-2 PREVENT). After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial.

SEC (Cardiovascular & Renal) meeting dated 10.11.2021 & 11.11.2021

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
10.	CT/64/21 Online Submission (25668) Tirzepatide	M/s. Eli-Lilly	<p>In light of earlier recommendation dated 15.07.2021, 16.07.2021 & 19.07.2021, the firm presented their justification as per SEC recommendation for study protocol no. I8F-MC-GPID before the Committee.</p> <p>Assessment of risk vs. benefit to the patients: The safety profile of the study drugs from preclinical toxicology, Phase I & Phase II studies including repeat dose toxicity study justify the conduct of the trial.</p> <p>Innovation vis-à-vis Existing Therapeutic option: The Purpose of the study is • To demonstrate that a maximally tolerated Tirzepatide dose up to 15 mg administered subcutaneously once weekly (SC QW) is superior to placebo based on the hierarchical composite endpoint in participants with HFpEF and BMI ≥ 30 kg/m².</p> <p>Unmet Medical need in the country: The test drug may potentially provide treatment in patients with Heart Failure with Preserved Ejection Fraction and Obesity (SUMMIT)</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial.</p>
11.	CT/48/17 Online Submission (11974) Edoxaban	M/s. IQVIA	<p>The firm presented the proposed amendment to study protocol no. DU176b-D-U312, Version 4.0, IN1 dated 29-Jun-2021 before the Committee.</p> <p>After detailed deliberation, the committee recommended that the firm should present the proposed amendment in tabular comparative format and should be further deliberated in the presence of pediatric cardiologist.</p>
Medical Device Division			
12.	CI/MD/2021/46393 MeRes100	M/s. Meril Life sciences Pvt. Ltd.	<p>The firm presented their proposal before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed</p>

SEC (Cardiovascular & Renal) meeting dated 10.11.2021 & 11.11.2021

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
			clinical investigation on Indian patients. The firm should provide medical device, follow up investigations and treatment free of cost for the proposed study.
13.	CI/MD/2021/37651 Sirolimus Eluting Coronary Stent System	M/s. Envision Scientific Pvt. Ltd	The firm did not turn up for presentation.
14.	CI/MD/2021/35229 TRIA Aortic Valve	M/s. Foldax India Pvt. Ltd	In light of earlier recommendation of SEC dated 07.09.2021 & 08.09.2021, the firm presented their revised protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical investigation on Indian population with the proposed device. The firm should submit the interim analysis report of study every 9 months to CDSCO for review.