

Recommendations of the SEC (Cardiovascular & Renal) made in its 93rd meeting held on 08.12.2021 & 09.12.2021 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/IMP/21/000085 Finerenone 10mg and 20mg film coated tablets	M/s. Bayer Pharmaceuticals Pvt. Ltd	The firm didn't turn up for presentation.
2.	ND/MA/20/000097 Bempedonic Acid 180mg and Ezetimibe 10mg tablet	M/s. Akums Drugs and Pharmaceuticals.	The firm presented their proposal for grant of permission to manufacture and sale of Bempedonic Acid 180mg and Ezetimibe 10mg tablet along with BE study results and Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial.
SND Division			
3.	SND/IMP/20/000105 Empagliflozin 10mg/25 mg tablet	M/s. Boehringer Ingelheim	The firm presented their proposal for approval of updated package insert of Empagliflozin Tablets 10mg & 25mg. After detailed deliberation, the committee opined that the firm should submit detailed clinical trial data of patients with eGFR values between 30ml and 45ml/minute/1.73m ² for review by the committee.
4.	SND/MA/21/000308 Ticagrelor SR Tablets 180mg	M/s. Ravenbhel Healthcare	The firm presented their proposal along with BE protocol. After detailed deliberation, the committee recommended for grant of permission for conduct of the BE study as per the protocol presented subject to condition that the blood sampling should be done for up to 72 hrs post dosing of the study drugs. Accordingly, the firm should submit the revised protocol prior to initiation of the BE study. Further, the committee opined that the clinical trial protocol should be reviewed based on the results of BE study.
5.	SND/MA/21/000502 Rosuvastatin Sprinkle	M/s. Sun Pharma	The firm presented the proposal along with the results of BE study report.

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	Capsules 10 mg/20mg/40mg		After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of Rosuvastatin Sprinkle Capsules 10 mg/20mg/40mg.
6.	SND/MA/20/000210 Ticagrelor SR Tablets 180mg	M/s. MSN Laboratories	The firm presented the proposal along with Bioequivalence study report. After detailed deliberation, the committee recommended that the firm should present the clinical trial protocol along with raw data of the Bioequivalence study report for further review by the committee.
FDC Division			
7.	FDC/MA/21/000091 Telmisartan 40mg + Azelnidipine 16mg tablets	M/s. Akums Drugs and Pharmaceutical Ltd	In light of the earlier recommendations of the SEC dated 10.11.14.June.2021, the firm presented revised Bioequivalence study and Phase III clinical trial protocol before the committee for the proposed lower strength. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study. As regard to clinical trial the firm should revise the Phase III protocol by taking appropriate comparator and submit the revised protocol to CDSCO for further necessary action.
GCT Division			
8.	CT/95/21 Online Submission (27310) OMS721	M/s. Kendle	The firm presented the Phase III clinical trial proposal before the committee. Assessment of risk vs. Benefit to the patients: The safety profile of the study drugs from preclinical toxicology studies including repeat dose toxicity study and Phase I & II clinical study data justify the conduct of the trial. Innovation vis-à-vis Existing Therapeutic option: The purpose of the study is to evaluate the effect of OMS721 in patients with IgA nephropathy (IgAN) on proteinuria assessed by 24-hour urine protein excretion (UPE) in g/day at 36 weeks from baseline. Unmet Medical need in the country: The test drug may potentially provide treatment in patients with Immunoglobulin A (IgA) nephropathy (ARTEMIS – IGAN).

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			After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III study.
9.	CT/120/21 Online Submission (28280) Anifrolumab	M/s. AstraZeneca	<p>The firm presented Phase III protocol D3466C00001 version no 1.0 dated 28/07/2021 before the committee.</p> <p>Assessment of risk versus benefit to the patient: The safety profile of trial drug from various pre-clinical toxicity studies and clinical studies, may justify the conduct of the proposed trial.</p> <p>Innovations Vs existing therapeutic option: The primary objective of the study is to evaluate the efficacy of Anifrolumab compared with placebo as added to SOC in active proliferative LN on the proportion of participants achieving CRR.</p> <p>Unmet medical need in the country: There is a need for new, effective, and safe therapies targeting novel pathways that remains for treatment of active LN to improve renal remission rates, reduce flares, and prevent ESKD while reducing the need for glucocorticoids. The trial drug may be an alternative treatment option in subjects with active proliferative lupus nephritis.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study in its presented form. (Dr S. K. Agarwal did not participate in deliberation).</p>
10.	CT/146/21 Online Submission (28804) Cefepime-zidebactam vs. Meropenem	M/s. Wockhardt	<p>The firm presented phase III clinical trial protocol W-5222-301 version 1.0 dt 04/07/2019 before the committee.</p> <p>After detailed deliberation, the committee did not recommend to conduct the proposed study and opined to conduct a phase II trial in India as proof of concept study prior to conduct of the proposed phase III study in India.</p>
Medical Device Division			
11.	CI/MD/2021/45487	M/s. Taevs Life Sciences Private	The firm presented their proposal for post marketing clinical investigation before the

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	Tensor Tip (Blood Pressure Monitoring Device)	Limited	committee. After detailed deliberation, the committee observed that presentation made by the firm is not clear in many respects like objectives of the study, methodology, clinical investigation site etc. The committee recommended that the firm should present the proposal addressing the above aspects for Redeliberation the proposal by the committee.
12.	CI/MD/2021/37651 Abluminus, Abluminus DES+	M/s. Envision Scientific private Limited	The firm presented their proposal for clinical investigation before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical investigation of the proposed product in the country.
13.	IMP/MD/2021/41889 Selution TM Pro 014 PTCA	M/s. Bio India Interventional Technologies Pvt. Ltd	The firm didn't turn up for presentation.