Recommendations of the SEC (Cardiovascular & Renal) made in its 60th meeting held on12.02.2019 at CDSCO HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Introductory remarks			
New Drug Division			
1	12-38/15-DC(Pt-A) FDC of Telmisartan 40mg/80mg & Azelnidipine 8mg/16mg tablets	M/s Windlas Biotech Private Limited	Firm presented their proposal before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct the BE study as already recommended earlier for other applicant. However, since Azelnidipine is not yet approved, the proposal of the firm for CT should not be considered at this stage.
Biological Division			
2	4-13/Boehringer/PAC-R-Alteplase/17BD Alteplase*	M/s Boerhinger-Ingelheim India Pvt Ltd	The firm presented their proposal for update in package insert of Alteplase. After detailed deliberation, the committee recommended for approval to the proposed changes subject to the conditions that the following should not be included :- 1. Under the contraindication section and wherever it occurs, amendment w.r.t age group between 16 to 18 years. 2. Dosing table for acute ischemic stroke.
FDC Division			
3	FDC/MA/18/000034 Benidipine Hydrochloride IP 4mg + Telmisartan IP 40mg film coated tablets	M/s. Akums Drug	Firm presented the BE & phase III protocol before the committee. After detailed deliberation the committee recommended for grant of approval for conduct of BE study & phase III clinical trial subject to the following modifications in the phase III protocol: 1. The title of the study should be amended to include stage II Hypertension instead of stage I Hypertension 2. The visit scheduled for 56±2 Days should be rescheduled to 14±2Days at which time kidney function test should be done. 3. Adequate no. of Government centres should be included for the study. The Indication "long term prophylactic management of Angina pectoris" proposed

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			for the FDC should not be considered.
4	FDC/MA/18/000065 Benidipine Hydrochloride 4mg/4mg+Metoprolol Succinate 23.75mg/47.50mg eq. to Metoprolol 2artrate 25mg/50mg tablets	M/s. Akums Drugs	Firm presented the BE & phase III protocol before the committee. After detailed deliberation the committee recommended for grant of approval for conduct of BE study & phase III clinical trial subject to the following modifications in the phase III protocol: 1. The title of the study should be amended to include stage II Hypertension instead of stage I Hypertension 2. The visit scheduled for 56±2 Days should be rescheduled to 14±2Days at which time kidney function test should be done. 3. Adequate no. of Government centres should be included for the study.
Medical Device Division			
5	4-MD/CT-76/2011-DC ON-X and St.Jude Heart Valve	M/s. I Process Clinical marketing Pvt. Ltd.,-	Firm didn't turn up for the presentation.
GCT Division			
6	CT/48/17 Edoxaban	Quintiles	In light of recommendations of the SEC dated 18/12/2018, the firm presented their justification/Clarification for the proposed protocol amendments before the committee. After detailed deliberation, committee recommended for grant of approval of protocol amendments.
7	CT/69/18 Edoxaban Tosylate	Quintiles	In light of recommendations of the SEC dated 27/11/2018, the firm presented their justification/Clarification for the proposed Clinical trial. **Risk versus benefit to the patients-** The safety profile of the investigator drug from various pre clinical studies Single dose, Repeated dose , Reproductive Toxicity, Carcinogenicity and clinical phase I,II, III studies justify the conduct of the study. **Innovation vis-a-vis existing therapeutic-** To compare the safety of edoxaban with the standard of care (SOC) in pediatric subjects with cardiac diseases at risk of thromboembolic complications who need

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			primary or secondary anticoagulant prophylaxis with regard to the combination of major and clinically relevant non-major (CRNM) bleedings per International Society on Thrombosis and Haemostasis [ISTH] definition1occurringin the Main Treatment Period: from the date of first dose of study drug to Month 3 Visit, or to the date of last dose of study drug if study treatment is discontinued. **Unmet medical need in the country-** The test drug may be an alternative treatment option in children from 38 weeks gestational age to less than 18 years of age with cardiac diseases at risk of thromboembolic events. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial subject to condition that post trial access of the study drug should be extended to the enrolled subjects as per the recommendation of investigator and/or Ethics committee, if any, along with the consent of the patients/LAR.
8	CT/59/14 Roxadustat	AstraZeneca	Firm presented their proposal for proposed amendment in the CT protocol before the committee. Committee noted that the study is already over & hence the approval of the proposed amendment (Version 6 dated 31/08/2018) cannot be considered for approval.
SND Division			
9	SND/IMP/18/000045 Everolimus tablet 0.25mg/0.5mg/0.75mg/1.0mg (additional indication)	M/s Novartis India Ltd.	Firm presented their proposal before the committee. The firm presented that the drug is approved for the proposed indication in 70 countries. The committee noted that the heart transplants in the country are about few hundred & hence the proposed condition is rare. After detailed deliberation, the committee recommended for approval of the proposed indication subject to the condition that the firm should conduct post marketing surveillance for 2 Years.

S.No	SEC –Experts Name & Designation	Signature
1.	Dr. Sandeep Bansal, Prof. & Head, Dept. of Cardiology, VMMC & Safdarjung Hospital, New Delhi	
2.	Prof. K. L. Gupta, Professor & Head, Department of Nephrology, PGIMER, Chandigarh	
3.	Dr. Lalit Kumar Gupta, Professor, Dept. of Pharmacology, Lady Hardinge Medical College, Delhi.	12/2/19
4.	Dr. Ajay U Mahajan, Professor, Dept. of Cardiology, LTMG Sion Hospital, Mumbai	
5.	Dr. S. K. Agrawal, Professor & Head, Dept. Of Nephrology, AIIMS, New Delhi	
6.	Prof. Shyam Sunder Kothari, Professor, Dept of Cardiology, AIIMS, New Delhi	
7.	Dr. Manjari Tripathi, Professor, Dept. Of Neurology, AIIMS, New Delhi	
8.	Dr. A. H. Ansari, Associate Professor, Dept. of Cardiology, VMCC & Safdarjung Hospital, New Delhi.	12/02/19