Recommendations of the SEC (Cardiovascular & Renal) made in its 129th meeting held on 06.07.2023 & 07.07.2023 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 prefilled syringe 284 mg/1.5ml	M/s. Novartis Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 19.05.2022, the firm presented Interim data of Phase-III global clinical trial before the committee. The committee noted the details and also the fact that Inclisiran is already approved in 84 countries including ICH countries such as EU countries, United States, United Kingdom, Canada, Singapore, Australia and Switzerland and there is an unmet medical need in the country. After detailed deliberation, the committee recommended for grant of permission to import and market Inclisiran solution for injection in prefilled syringe 284 mg/1.5 ml for the proposed indication subject to following conditions: 1. The firm should submit ongoing global clinical trial report within 3 months to CDSCO. 2. The drug should be sold by retail under prescription of Cardiologist only. 3. The firm should conduct Phase-IV clinical trial for which the firm should submit Phase IV clinical trial protocol within 3 months of approval of the drug for review by the committee.
Biological Division			
2.	F. No. X - 11026/188/2020-BD Anti-Platelet, Anti-Coagulant (APAC) Unfractionated Heparin-Serum Albumin Conjugate	M/s. Cadila Pharmaceuticals Limited, Ahmadabad.	In light of earlier SEC recommendation the firm presented amendment in protocol version-02 dated-21/02/2022 and presented the protocol version-03 dated-18/11/2022. The SEC committee recommended for approval of all the changes in exclusion criteria, however the committee did not agree with proposed changes in inclusion criteria as approved in earlier protocol ver. 2.0.
3.	BIO/CT04/FF/2023/ 36502	M/s Hetero Biopharma	The firm presented the Phase IV study protocol titled "A Phase IV, post-

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	Tenecteplase 30mg/6ml, 40mg/8ml, & 50mg/10ml; Lyophilized powder for injection in vial	Limited	marketing, prospective, multicentre, single arm clinical study to evaluate the safety, efficacy and immunogenicity of Hetero- Tenecteplase for thrombolysis in acute myocardial infarction" vide protocol HCR/IV/TENESTEMI/02/2023 version 1.0 dated 06.02.2023 along with request to change the Phase IV study sample size condition stipulated in New Drug permission dated 01.02.2023 for manufacture and market Tenecteplase 30 mg/6 ml, 40 mg/8 ml, 50 mg/10 ml Lyophilized powder for injection in vial (r-DNA origin) to 200 evaluable patients instead of 400 patients. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV study as per protocol presented by the firm with condition to submit the PSUR data of patients on the drug every six months for further review by CDSCO.
SND Division			
4.	SND/MA/23/000010 Bisoprolol Fumarate Tablet 1.25mg/3.75mg/7.5 mg	M/s. Windlas Biotech Ltd.	The firm did not turn up for presentation.
5.	SND/IMP/23/000037 Empagliflozin Tablets 10mg & 25 mg	M/s. Boehringer Ingelheim	The firm did not turn up for presentation.
6.	SND/CT/23/000042 Torsemide ER Tablets 24 mg	M/s. Syngene International Limited	The firm presented the proposal for conduct of Phase II clinical trial of Torsemide ER Tablets 24 mg along with the phase II clinical trial protocol. After detailed deliberation, the committee opined that the protocol does not have proof of concept and criteria are not defined for the overactive bladder in CHF patients. Hence the committee did not recommend for approval of the protocol in its present form. Accordingly, the committee

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			recommended that firm should submit proof of concept for clinical trial along with revised clinical trial protocol for further review by the committee.
FDC Division			
7.	FDC/MA/22/000242 Bisoprolol Fumarate IP 5mg/2.5mg +Cilnidipine IP 10mg/10mg Tablets	M/s. Ajanta Pharma Limited	The firm did not turn up for presentation.
8.	FDC/MA/23/000071 Bisoprolol Fumarate 5mg/5mg/2.5mg/ 2.5mg+Cilnidipine 10mg/10mg/10mg/ 10mg+ Chlorthalidone 12.5mg/6.25mg/ 12.5mg/6.25mg tablets	M/s. Ajanta Pharma Limited	The firm did not turn up for presentation.
9.	FDC/MA/23/000127 Bisoprolol Fumarate 5mg/2.5mg+ Cilnidipine 10mg/10mg + Telmisartan 40mg/40mg tablets	M/s. Ajanta Pharma Limited	The firm did not turn up for presentation.
10.	FDC/IMP/23/000034 Calcium chloride dihydrate 3.6800 g/L + Magnesium chloride hexahydrate 2.4400 g/L +Sodium Chloride 6.4400g/L + Sodium Hydrogen Carbonate 2.9200 g/L =Potassium Chloride 0.3140 g/L + Disodium Phosphate Dihydrate 0.2250 g/L	M/s. Baxter India Pvt. Ltd.	The firm presented their proposal along with justification for Phase III clinical trial waiver for Import and market of proposed FDC before the committee. After detailed deliberation, the committee recommended that the firm should submit justification/data for the below mentioned points for further review by the committee: 1. Data justifying that there is no probability or evidence, on the basis of existing knowledge, of difference in Indian population or any factor affecting safety &

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	Solution		efficacy of the FDC. 2. Whether permission to conduct global clinical trial which is ongoing in India has been taken from CDSCO. 3. Undertaking should be given in writing to conduct Phase IV clinical trial to establish safety and effectiveness as per design approved by CLA. 4. Whether there is any unmet medical need.
11.	FDC/MA/23/000063 Dapagliflozin Propanediol monohydrate 5mg/5mg/10mg/ 10mg+ Metoprolol Succinate IP eq. to Metoprolol tartrate (ER) 25mg/50mg/ 25mg/50mg tablets	M/s. Exemed Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 12.04.2023 and 07.06.2023, the firm presented the revised Phase III clinical trial study protocol before the committee. After detailed deliberation, the committee reiterated its earlier recommendation dated 12.04.2023 i.e. for grant of permission to conduct the BE study and Phase III clinical trial study with condition that BE study results should be presented in SEC meeting before initiating the Phase III clinical trial study.
GCT Division			
12.	CT/134/22 Online Submission (34602) TIN816	M/s. Novartis	In light of earlier SEC recommendation dated 20.03.2023, the firm presented proposal for grant of permission to conduct Phase IIa clinical trial before the committee. After detailed deliberation, the committee recommended that firm should submit revised protocol considering the following- 1. Considering all the inclusion criteria, the only criteria for "at risk for AKI" following cardiac surgery is renal dysfunction defined at point no. 7 as GFR < 60 ml/min with different values for three different age groups. GFR < 60 ml/min can be either AKI, or AKD or CKD. There is no other 4th category. Therefore, the firm should clarify the point no. 7 in inclusion criteria

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			is related to which of the three groups. 2. Point No. 6 in inclusion criteria should be part of exclusion criteria. 3. Amendment in point no. 6 of inclusion criteria "(ideally obtained at least 3 weeks before the screening visit) is not appropriate. Accordingly revised protocol should be submitted for review by the committee.
13.	CT/34/23 Online Submission (36886) LY3502970	M/s. Eli Lilly	In light of earlier SEC recommendation dated 07.06.2023, the firm Phase III clinical trial proposal before the committee in presence of Endocrinologist. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III clinical trial subject to the following. 1. The Principal investigator should be cardiologist and Co-Investigator should be endocrinologist in each site in the proposed study. 2. The applicant should include 50% Govt sites and 50% subjects should be enrolled from Govt sites. 3. The applicant should submit pre-clinical carcinogenicity data on bi-annual basis to CDSCO.
14.	CT/43/23 Online Submission (37230) Milvexian, an Oral Factor XIa Inhibitor	M/s. IQVIA	The firm presented their proposal for Phase III clinical trial before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed trial subject to condition that the 50% trial sites should be Govt. sites and 50% subjects should be enrolled from Govt. sites. Dr. K.M.K Reddy did not participate in the deliberation.
15.	CT/06/22 Online Submission (25034)	M/s. Novartis	The firm presented justification/explanation with respect to clinical trial NOC condition No: 1 & 2 before the committee. After detailed deliberation, the committee

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	Ianalumab		recommended to omit the condition number 1 & noted that the firm has agreed with condition No. 2 of clinical trial NOC.