Recommendations of the SEC (Cardiovascular & Renal) made in its 115th meeting held on 08.12.2022 & 09.12.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/22/000056 Regadenoson Injection 80 µg/ml	M/s. Wipro GE Healthcare Pvt. Ltd.	The firm did not turn up for presentation.
SND Division			
2.	SND/MA/22/000083 Polystyrene Sulphonate Jelly 20% w/w	M/s. Pharose Remedies	The firm did not turn up for presentation.
3.	SND/MA/21/000482 Ticagrelor SR Tablets120/180mg	M/s. Theon Pharma	The firm did not turn up for presentation.
4.	SND/MA/22/000268 Icosapent Ethyl Capsule 1gm	M/s. Dr. Reddy's Laboratories	The firm presented their proposal of manufacture and marketing of Icosapent Ethyl Capsule 1gm for following indication alongwith BE and CT waiver justification before the committee. (As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG)levels (150 mg/dl) and established cardiovascular disease or diabetes mellitus and2 or more additional risk factors for cardiovascular disease. as an adjunct to diet to reduce TG levels in adult patients with severe 500 mg/dl) hypertriglyceridemia. **Limitations of Use:** The effect of Icosapentethyl on the risk for pancreatitisin patients with severe hypertriglyceridemia has not been determined. **Approval status in India and other countries:** As per the data available on CDSCO website, Icosapent Ethyl Capsules 1g is not approved by office of DCG (I), however in fixed dose combination it is approved as

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			follows: (1) Eicosapentaenoic acid + Docosahexaenoic acid capsules (Each capsule contains; Eicosapentaenoic acid-180mg, Docosahexaenoic acid-120mg) 1989. (2) Regulatory Approval Status in Other Countries: Icosapent Ethyl Capsules 1g, under trade name of (Vascepa) was approved for the treatment of Expanded CVD Risk Reduction Indication in USA (Approved on 13.12.2019), Canada (Approved on 30.12.2019) and Europe (Approved on 20.04.2021). After detailed deliberation, the committee recommended that clinical trial waiver may be considered, however the firm should submit in-vitro data/ comparative data which have been submitted during approval of their product in USA, for further review by the committee.
5.	12-38/2022-DC (Pt-Misc-SND) Ivabradine Hydrochloride Tablets 5 mg and 7.5 mg	M/s. Servier India Private Limited (Formally, known as M/s. Sardia Pharmaceuticals (India) Pvt. Ltd	The firm presented their proposal of revision of "Indication wordings" for the already approved drugs product Ivabradine Hydrochloride Tablets 5 mg and 7.5 mg as per European Summary of Product Characteristics and EMA recommendation before the committee. After detailed deliberation, the committee recommended for grant of NOC/ revision of "Indication wordings" as per revised indication presented by the firm.
FDC Division			
6.	FDC/MA/21/000007 Ivabradine HCl eq. to Ivabradine 5mg/5mg + Metoprolol Tartrate 50mg/25mg tablets	M/s. Pure & Cure	In light of the condition mentioned in the permission dated 06.05.2022, the firm presented the Phase IV CT protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV CT with condition that patient with heart rate more than 70 should be included in the inclusion criteria.
7.	FDC/MA/22/000241	M/s. Windlas Biotech Ltd.	In light of earlier SEC recommendation dated 11.10.2022 & 10.11.2022, the firm presented the revised Phase III CT study protocol before the committee. After detailed deliberation, the committee

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	Chlorthalidone IP + Cilnidipine + Bisoprolol Fumarate (6.25mg/12.5mg + 5mg/10mg+5mg/ 10mg) tablets		recommended that the firm should modify the exclusion criteria on following points: 1. cerebrovascular disease should be excluded. 2. muscular dystrophy should be excluded. Accordingly, revised Phase III CT protocol should be submitted for review by the committee.
8.	FDC/MA/22/000259 Cilnidipine IP 20mg + Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (As ER) 50mg Tablets	M/s. Ajanta Pharma Ltd.	The firm did not turn up for presentation.
9.	FDC/MA/22/000330 Dapagliflozin propanediol monohydrate eq to Dapagliflozin 10mg/10mg + Sacubitril/Valsartan (as sodium salt complex) 100mg/200mg tablets	M/s. Bajaj Healthcare Ltd.	The firm presented their proposal for the proposed FDC before the committee. After detailed deliberation, the committee recommended that firm should present adequate rationality, justification as well as clinical proof of concept for the proposed FDC for further review by the committee.
10.	FDC/MA/22/000344 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg + Sacubitril/Valsartan as sodium 50mg tablets	M/s. Ravenbhel healthcare Pvt. Ltd	The firm did not turn up for presentation.
11.	FDC/MA/22/000234 Bisoprolol fumarate 2.5 mg/ 5 mg + Cilnidipine 10 mg/10 mg FDC Tablet	M/s. Windlas Biotech Limited	The firm presented their proposal before the committee along with revised Phase III CT protocol. After detailed deliberation, the committee reiterated their earlier recommendation dated 10.11.2022.

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GCT Division			
12.	CT/87/19 Online Submission (16548) LCZ696	M/s. Novartis	The firm did not turn up for presentation.
13.	CT/26/21 Online Submission (18083) Itolizumab (EQ000)	M/s. Bioinnovat	The applicant presented protocol amendment version 5 dated 03-03-2022 along with proposal for increase of no of subjects up-to 17 from India, before the committee. After detailed deliberation, the committee recommended for approval of proposed protocol amendment version 5 dated 03-03-2022. Further, the committee noted that the applicant has already randomized 11 subjects from India and now proposed for increase in number of subjects up-to 17 out of 20 global sample size for Type B portion of study and recommended that total 15 subjects should be randomized from India. Hence the applicant should randomize only additional 04 subjects from India with the condition that the applicant should submit interim safety data of Indian subjects before the committee for further review. (Dr. Sreejith Parameswaram did not participate during deliberation).
14.	CT/24/21 Online Submission (18580) Atrasentan	M/s. IQVIA	The firm presented the proposed study protocol no. CHK-01-01, amendment 3.1 IN, dated 12May2022 (The ALIGN Study) before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
15.	CT/136/22 Online Submission (34652) Sodium Zirconium Cyclosilicate	M/s. AstraZeneca	The firm presented the proposed study protocol no. D9487C00001, version 2.0 dated 05-Nov-2021 (DIALIZE-Outcomes) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study with the following conditions: 1) Dialysis dose should be measured in base

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			line visit and subsequent follow up visits. 2) Medical conditions including uncontrolled hypertension, action infection etc should be well defined under exclusion criteria. 3) The firm should submit the study Interim analysis report along with DMC recommendation to CDSCO for review. 4) All SAEs including death irrespective of its cause should be reported by PI/site/applicant/sponsor to CDSCO as per provision of NDCT Rules 2019. (Dr. Sreejith Parameswaram did not participate during deliberation).
16.	CT/56/22 Online Submission (32776) AZD9977& Dapagliflozin	M/s. Parexel	In light of earlier SEC recommendation dated 07-Sep-2022, the firm presented the justification for the proposed Phase IIb study (MIRACLE) protocol no. D6402C00001, amendment 6, version 7 dated 02-Feb-2022 before the committee. After detailed deliberation, the committee was satisfied by the justification as presented by the firm for proposed study design and recommended for grant of permission to conduct the study as per protocol with the following conditions: 1) The firm should submit the study interim analysis report to CDSCO for review. 2) The proposed study team should be composed of Nephrologists and Cardiologist (viz. study investigator should be Nephrologists with a Co-I Cardiologist or vice-versa).
Medical Device Division			
17.	CI/MD/2022/67700 TRIA mitral valve	M/s. Foldax India Pvt. Ltd	In light of earlier SEC recommendation dated 11-10-2022, the firm presented their protocol in presence of cardiac surgeon. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical investigation with the proposed device 'TRIA mitral valve' on Indian population in the country. The firm should submit the report to CDSCO for further review by the committee.
18.	MD/PostAppr/2022/ 11793	M/s. India Medtronic Private Limited	The firm presented their proposal before the committee.

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	Resolute Onyx ™ Zotarolimus Eluting coronary stent system		The committee recommended for the minor amendment in the exiting IFU as proposed by the firm as "One month of dual antiplatelet therapy (DAPT) in high bleeding risk (HBR) patients, including patients who are unable to tolerate long term DAPR".
19.	IMP/MD/2022/53336 LKT Disposable Perfusion Circuit, Kidney Transporter	M/s. Renovate Biologicals Private Limited	The firm did not turn up for presentation.