

Recommendations of the SEC (Cardiovascular & Renal) made in its 135th meeting held on 26.10.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/IMP/23/000037 Empagliflozin Tablets 10 mg & 20mg (Additional indication)	M/s. Boehringer Engelheim	<p>The firm presented the proposal for grant of permission to Import & marketing of Empagliflozin Tablets 10mg and 25mg for additional Indication along with Global Clinical Trial Data & justification of Phase-III clinical trial waiver before the committee.</p> <p>The firm informed that proposed additional indication is recently approved by US FDA on 21.09.2023 and European Union on 24.07.2023 as well as approved in Taiwan, Saudi Arabia, UAE and Egypt, and is presently being reviewed for approval in Japan, Canada, Australia, New Zealand, Switzerland, & UK.</p> <p>After detailed deliberation, the committee recommended for grant of permission to Import & marketing of Empagliflozin Tablets 10mg and 25mg for additional Indication i.e. to reduce the risk of sustained decline in eGFR (only for 30-90ml/min/1.73m²), end-stage kidney disease, renal death, cardiovascular death, and all cause hospitalization in adults with chronic kidney disease. The firm should also conduct the Phase-IV clinical trial study, the firm should submit Phase-IV clinical trial protocol to CDSCO within 03 months from date of approval of drug for further review by the committee.</p> <p>Further, firm shall provide more clinical data on Empagliflozin Tablets use in more than or equal eGFR 20 ml/min/1.73m² to establish a clinical relevance in this type of sub groups.</p> <p>In addition to above, the firm should fulfil the requirement of CMC data.</p>
2.	SND/CT/22/000013 Azelnidipine 16mg Tablets	M/s. IPCA Laboratories Limited	The firm presented the proposal for grant of permission to conduct Phase-IV clinical trial of Azelnidipine 16mg tablets

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			<p>along with Phase-IV clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct Phase-IV clinical trial study as per protocol presented by the firm i.e. Protocol No. Ipca/AZCI/PIV-21, Version No. 01 Date:19.10.2021 subject to following conditions:</p> <ol style="list-style-type: none"> 1. The firm should include geographically distributed clinical Trial sites in equal distribution in Govt and Private sites and preferentially the recruitment should be 50% each in Govt and Private sites. 2. In investigations , urinary albumin creatinine ratio & USG screening to rule out renal abnormalities is mandatory . 3. Firm should preferably increase sample size to get better statistical outcome . <p>Accordingly, the firm should modify phase IV clinical trial protocol and submit it to CDSCO .</p>
3.	SND/CT/23/000060 Trimetazidine Dihydrochloride 7.85mg immediate release tablet	M/s. Clinexel Life Science Pvt. Ltd.	<p>The firm presented the proposal for grant of permission to conduct single dose pharmacokinetics study of Trimetazidine Dihydrochloride 7.85mg immediate release tablet on 8 adults patients having moderate or severe renal impairment, 8 normal renal function volunteer before the committee.</p> <p>After detailed deliberation, the Committee observed that the firm presented proposal which is not found to have scientific rational and cannot be considered.</p>
FDC Division			
4.	FDC/MA/22/000171 Bempedoic acid + Rosuvastatin Calcium IP eq. to Rosuvastatin 180mg+5mg/180mg+ 10mg/180mg+20mg/	M/s. Akums Drugs & Pharmaceuticals Ltd.	The firm didn't turn up for presentation.

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	180mg+40mg film coated tablet		
GCT Division			
5.	CT/82/21 Online Submission (27133) LNP023	M/s. Novartis	<p>In light of the earlier SEC recommendation dated 11.10.2021, the firm presented Phase IIIB clinical trial protocol no. CLNP023A2002B before the committee,</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the trial with condition that details of all adverse events shall be submitted to CDSCO.</p>
6.	CT/134/22 Online Submission (34602) TIN816	M/s. Novartis	<p>In light of the earlier SEC on 07.07.2023, the firm presented protocol no. CTIN816A12201 to conduct Phase IIa clinical trial before the committee</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study as presented by the firm.</p>
7.	CT/03/23 Online Submission (35499) ISIS 678354 (Olezarsen)	M/s. Medpace	<p>In light of the earlier SEC Recommendation on 29.08.2023, the firm presented protocol no. ISIS 678354-C56, protocol amendment 1 dated 10.08.2023 to conduct Phase III clinical trial before the committee</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study as presented by the firm.</p> <p>Dr. Sandeep Bansal did not participate in deliberation.</p>