

**Recommendations of the SEC (Renal) made in its 09<sup>th</sup>/25 meeting held on 18.09.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/121/25 Online Submission (51423)  Mezagitamab (TAK-079)	M/s. PPD Pharmaceutical Development India Private Limited	Under Discussion.
<b>New Drugs Division</b>			
2.	ND- 11012(19)/22/2025- eoffice  Sodium Zirconium Cyclosilicate Powder for Oral Suspension 5 mg/10 mg [LOKELMA]	M/s. AstraZeneca India Pharma Limited	<p>The firm presented proposal for updating the prescribing information version 2, dated 24.04.2025 for drug product, Sodium Zirconium Cyclosilicate Powder for Oral Suspension 5 gm/10 gm as per CDS version 8 dated Dec 2024 before the committee.</p> <p>The key changes in the proposed prescribing information are related to editorial changes in the posology &amp; method of administration, special warnings and precautions for use, undesirable side-effects, list of adverse reactions and pharmacodynamics effects etc.</p> <p>After detailed deliberation, the Committee recommended for grant of approval for the proposed update in prescribing information as presented by the firm.</p>
<b>SND Division</b>			
3.	SND/CT/25/000075 (SND/IMP/23/000037)  Empagliflozin tablets 10 mg/25 mg	M/s. Boehringer Ingelheim India Private Limited	<p>The firm presented the summary of ongoing Phase III Global Clinical Trial Protocol (EASi-KIDNEY) vide Protocol No. 1378-0006 and requested to consider the data generated from India patient with Empagliflozin Tablets 10 mg as the compliance of Phase-IV Clinical Trial condition of import &amp; marketing permission dated 18.01.2024 issued for Empagliflozin Tablets 10 mg and 25 mg for CKD indication.</p> <p>Also, it was informed by the firm that Empagliflozin Tablets 25 mg is not marketed in approved indication issued vide permission dated 18.01.2024 and</p>

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			<p>stated that the firm would submit the withdrawal request for same to CDSCO.</p> <p>After detailed deliberation, Committee recommended to submit the separate Phase IV Clinical Trial Protocol for compliance with condition of import &amp; marketing permission dated 18.01.2024 within 01 month to CDSCO.</p>