Recommendations of the SEC (Renal) made in its 07th/24 meeting held on 20.08.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/135/23 Online Submission (33756) Tebipenem pivoxil hydrobromide (TBP-PI-HBr, previously known as SPR994)	M/s. PSI CRO Pharma Pvt. Ltd.	The firm presented protocol amendment 2, version 3.0 dated 31 January 2024 protocol no. SPR994-305. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/86/24 Online Submission (44106) Sodium zirconium cyclosilicate (SZC)	M/s. Fortrea Development India Private Limited	The proposal may be deliberated in presence of Paediatric Nephrologist.
3.	CT/25/21 Online Submission (34005) Atrasentan	M/s. IQVIA RDS (India) Private Limited	The firm didn't turn up for presentation.
Biological Division			
4.	BIO/CT21/FF/2024/42131 Reteplase 3.6mg lyophilized powder for injection	M/s. Reliance Life Sciences	The firm presented the proposal for approval of additional strength of already approved drug i.e. Recombinant Tissue Plasminogen Activator (Reteplase) for injection 3.6mg (2U) in a vial for manufacturing, sale & distribution for indication of restoration of function to central venous access devices as assessed by the ability to withdraw blood with waiver of Clinical Trial. After detailed deliberation, the committee recommended the firm to submit clinical trial protocol for generating clinical data for approval of the proposed indication. Further, the committee also recommended that while designing the clinical trial protocol, the firm has to consider the different types of catheters available in the market (Dual-lumen cuffed tunnelled dialysis catheters etc) along with dose requirement.
SND Division			

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5.	SND/MA/23/000226 Tolvaptan Tablets 7.5mg	M/s. MSN Labs Private Limited	The firm presented the proposal for grant of permission to manufacture and market of Tolvaptan tablets 7.5mg along with BE study report of Tolvaptan tablet 30 mg (higher strength) and justification for waiver of local Phase-III clinical trial and BE study Tolvaptan tablet 7.5 mg (lower strength) before the committee. The firm informed that Tolvaptan tablets 15mg & 30mg already approved by CDSCO on 06.09.2012 for the treatment of clinically significant hypervolemic and euvolemichyponatremia [serum sodium < 125mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction], including patients with heart failure, cirhossis and syndrome of inappropriate anti-diuretic hormone (proposed indication). Further, firm informed that Tolvaptan tablets 7.5mg, 15mg, 30mg already approved in Netherlands on 03.08.2009 indicated in adults for the treatment of hyponatremia secondary to the syndrome of inappropriate anti-diuretic hormone secretion (SIADH). The committee noted that the presented published data of prospective and retrospective case series data of Tolvaptan tablets 7.5mg wherein Indian/Asian population were not found participated in any of the studies. Therefore, after detailed deliberation, the committee opined that the firm should submit additional efficacy data of Tolvaptan tablets 7.5mg generated on the Indian/Asian population to CDSCO for further review by the committee.
FDC Division			
6.	FDC/MA/24/000133 Dapagliflozin Propanediol eq. to Dapagliflozin 10mg +	M/s. Exemed Pharmaceuticals	The firm presented the proposal before the committee along with BE study protocol. After detailed deliberation, the committee recommended for grant of permission to

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Eplerenone IP 25mg film coated tablets		conduct the BE study. The result of the BE study should be presented before the committee for review along with Phase III clinical trial protocol.