

**Recommendations of the SEC (Renal) made in its 04<sup>th</sup>/25 meeting held on 17.04.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/45/21 Online Submission (37932) LNP023 (Iptacopan)	M/s. Novartis Healthcare Private Limited	The firm presented Protocol Amendment Version 03 dated 19 Dec 2024 Protocol no. CLNP023B12301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/48/22 Online Submission (37947) LNP023 (Iptacopan)	M/s. Novartis Healthcare Private Limited	The firm presented Protocol Amendment Version 02 dated 07 Jan 2025 Protocol no. CLNP023K12201. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/52/23 Online Submission (38140)  LNP023 (Iptacopan)	M/s. Novartis Healthcare Private Limited	The firm presented Protocol Amendment Version 05 dated 17 Dec 2024 Protocol no. CLNP023B12001B. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/29/25 Online Submission (48494) Felzartamab	M/s PPD Pharmaceutical Development India Private Limited	The firm presented phase III clinical study Protocol no. 299IG301 Version No. 2.1 dated 13 Feb 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
5.	CT/126/23 Online Submission (38326) BION-1301 (zigakibart)	M/s PPD Pharmaceutical Development India Private Limited	The firm presented Protocol Amendment 5, Version 6.0 dated 01 Nov 2024 Protocol no. CHK02-02. After detailed deliberation, the committee recommended for approval of protocol amendment with the conditions that optional ICF shall be modified to include the following: 1. There will be no benefits to the patients in terms of treatment and assessment from kidney biopsy and it will be for research purpose only. 2. Actual expenses such as travel, food etc. will be reimbursed on submission of invoices for kidney biopsy.
<b>New Drugs Division</b>			
6.	ND/CT/24/000083  Finerenone film coated tablets 10mg	M/s Bayer Pharmaceuticals Pvt. Ltd	The firm presented their proposal to carry out a Retro-prospective, non-interventional, database study to access Real-world experience with drug Finerenone film coated tablets 10mg/20mg (Study No. 22549, V1.0, dated 28,

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			<p>Aug, 2024), before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct proposed Retro-prospective non-interventional, Real-world experience database study as per the protocol presented by the firm with the condition that participating study centre should have an electronic patient record or should be maintaining patient record at the hospital.</p>
<b>SND Division</b>			
7.	SND/IMP/24/000114 Calcium chloride dihydrate 100 mmol/l	M/s Fresenius Medical Care India Private Limited	The firm did not turn up for the presentation.