**Recommendations of the SEC (Renal) made in its 05th/25 meeting held on 20.05.2025 at CDSCO HQ New Delhi:**

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| **GCT Division** | | | |
| 1. | CT/159/24<br>Online Submission (47026)<br><br>BAY 94-8862 / Finerenone | M/s Bayer Pharmaceuticals Pvt. Ltd | In light of earlier SEC Recommendation dated 15.01.2025, the firm presented phase III clinical study protocol no.: 20186 amendment 4 version 5.0 dated 21-JUN-2024.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. |
| 2. | CT/65/23<br>Online Submission (38467)<br><br>Atacicept | M/s Medpace Clinical Research India Pvt Ltd | The firm presented protocol amendment 7.0 dated 23 December 2024 protocol no. VT-001-0050.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 3. | CT/06/22<br>Online Submission (38590)<br><br>VAY736 | M/s Novartis Healthcare Private Limited | The firm presented protocol amendment version 04 dated 29 Jan 2025 protocol no. CVAY736K12301.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 4. | CT/09/24<br>Online Submission (38720)<br><br>Zibotentan 0.25mg+ Dapagliflozin 10mg<br><br>Zibotentan 0.75mg + Dapagliflozin 10mg | M/s AstraZeneca Pharma India Limited | The firm presented protocol amendment version 2.0 dated 14 Feb 2025 protocol no. D4325C00010.<br><br>After detailed deliberation, the committee opined that the firm shall submit more detailed justification for Increase the number of sample size from 1500 to1800 for further review by the committee. |
| 5. | CT/50/25<br>Online Submission (49274)<br><br>VAY736 (Ianalumab) | M/s Novartis Healthcare Private Limited | The firm presented phase III clinical study protocol no.: CVAY736L12301 version no. 00 dated 04-FEB-2025.<br><br>After detailed deliberation, the committee opined that the firm shall submit revised protocol and dose modification for further review by the committee. |
| **SND Division** | | | |

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| 6. | SND/IMP/24/000114<br><br>Calcium chloride dihydrate 100 mmol/l solution for infusion | M/s Fresenius Medical Care India Private Limited | Firm presented their proposal for grant of permission to manufacture and marketing of Calcium chloride dihydrate 100 mmol/l Solution for infusion for 'calcium substitution in continuous renal replacement therapies (CRRT), sustained low efficiency (daily) dialysis (SLEDD) and therapeutic plasma exchange (TPE) using citrate for anticoagulation. Product is indicated in adults and children' along with justification for Phase-III and Phase IV Clinical trial waiver.<br><br>The committee noted that the applied product is approved in Portugal, United Kingdom, Brazil, Switzerland, France, Denmark and other European countries.<br><br>After detailed deliberation, the committee recommended to submit basis of approval along with Phase-III clinical trial data and Post marketing surveillance data in approved countries for further deliberation by the committee |