Recommendations of the SEC (Analgesic & Rheumatology) made in its 06th/25 meeting held on 16.07.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/76/25 Online Submission (50097) Phenaopyridine Hydrochloride 200 mg Tablet	M/s Abiogenesis Clinpharm Private Limited	The firm presented phase III clinical study Protocol No.: PHN-301-25 Version No. 1.0 dated 06-JUN-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the firm shall submit the study CRF should also include specific adverse drug reactions during treatment and immediate follow-up of study patients, in addition to any other (new) ADRs. Already known adverse events mentioned in the summary basis approval/Product Information leaflet of their innovator molecule
Medical Devices Division			
2.	MED-14/11/2025-eoffice Radiopaque Gelified Ethanol (Absolute Gel)	M/s. Elevate Scientific Private Limited	The firm presented Clinical study data generated globally (Iran, Italy etc.) alongwith Post marketing data on said device for the waiver of one of the conditions of the permission for manufacturing obtained under Form MD-27 and allow them to market the product for domestic use. After detailed deliberation, the committee observed that the clinical study data presented by the firm does not demonstrate the safety and efficacy on pain outcomes of the patients. Therefore, the committee recommended that the firm shall conduct the Clinical Investigation on Indian population with the objective to demonstrate the safety & efficacy on lower back pain. Accordingly, firm need to submit the Clinical Investigation Protocol with

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			statistically significant sample size, for taking further necessary action in the matter.
3.	CI/MD/2023/95467 Crosssslinked Sodium Hyaluronate 88 mg with Triamcinolone Hexacetonide 18 mg (Cingal)	M/s. Modi-Mundipharma Private Limited	The firm presented proposal for grant of permission to conduct Post Market Clinical Investigation on proposed medical device Cross linked Sodium Hyaluronate 88 mg with Triamcinolone Hexacetonide 18 mg (Cingal) in the country on Indian population before the committee. After detailed deliberation the committee recommended for the grant of permission to conduct Post Market Clinical Investigation on Indian Population as per Study Protocol no. CT-CG-PMS-2023, Version 2.0 dated 20.05.2023.
Biological Division			
4.	E-67275 Etanercept Solution for Injection, 25 mg Pre-filled Syringe and 50 mg Pre-filled Pen	M/s. Pfizer Limited	The firm presented the proposal for update in Package Insert for the changes in the Section 4.4, Section 4.8, Section 5.2 of the drug product Etanercept Solution for Injection, 25 mg Pre-filled Syringe and 50 mg Pre-filled Pen based on the review of post marketing data, literature review and clinical trial data via PSURs . The proposed changes include the updates in the PI Version LPDENB102023, LPDENB032024 and LPDENB072024 in line with approved EU SmPC Version July 2024. After detailed deliberation, the committee recommended for approval of updated package insert LPDENB072024 (Version July 2024) for the proposed changes
SND Division			
5.	SND/CT/25/000070 Tofacitinib Tablets 10 mg	M/s MSN Laboratories Private Limited	The firm did not turn up for the presentation.