Recommendations of the SEC (Analgesic & Rheumatology) made in its 02nd/25 meeting held on 25.02.2025. at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/77/24 Online Submission (37047) Anifrolumab (MEDI-546) Solution for Injection	M/s AstraZeneca Pharma India Limited	The firm presented protocol amendment version 4.0 dated 14 November 2024 protocol no. D3463C00003. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
2.	r-DNA-15011(12)/5/2024-eoffice Dy no 45788 Tocilizumab 162mg/0.9ml (r-DNA origin)	M/s. Cipla Ltd.	Under Discussion
3.	E-59948 Secukinumab 150mg/mL solution for injection	M/s. Novartis Healthcare Private Limited	In light of earlier SEC recommendation dated 12.06.2024 & 13.06.2024, the firm presented the justification for the waiver of PMS study condition as part of the approval granted for additional indications of psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis. After detailed deliberation, the committee reiterated its earlier recommendation for generating the PMS data in the country to assess patient safety for the indications of psoriatic arthritis, Ankylosing spondylitis and non-radiographic axial spondyloarthritis.
SND Division			
4.	SND/CT/25/000009 Tofacitinib 10 mg film coated tablets	M/s Synokem Pharmaceuticals Limited	The firm presented Phase IV Clinical Trial Protocol No. SYN/CT/007/TOF/2022, version No.1.0 dated 11.10.2022 before the committee. After detailed deliberation, the committee recommended to conduct Phase IV Clinical Trial as per protocol presented

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			by the firm with the following changes- 1) To include serum NT-pro BNP in the screening tool for participant recruitment to rule out 'significant cardiovascular disease'. 2) Serum lipid profile shall be performed on the last follow up visit. Accordingly, the firm should submit revised protocol to CDSCO.
5.	SND/MA/22/000123 Tofacitinib Extended Release Tablets 11mg	M/s Synokem Pharmaceuticals Limited	The firm presented active PMS study protocol No. CT22-004, version No.01 dated 25.11.2022 before the committee. After detailed deliberation, the committee recommended to conduct Phase IV Clinical Trial as per protocol presented by the firm with the following changes- 1) To include serum NT-pro BNP in the screening tool for participant recruitment to rule out 'significant cardiovascular disease'. 2) Serum lipid profile shall be performed on the last follow up visit. Accordingly, the firm should submit revised protocol to CDSCO.
6.	SND/CT/25/000010 Iguratimod Tablets 25 mg	M/s Synokem Pharmaceuticals Limited	The firm presented Phase IV Clinical Trial protocol No. CT22-005, version No.01 dated 03.12.2022 before the committee. After detailed deliberation, the committee recommended to conduct Phase IV Clinical Trial as per protocol presented by the firm with the following change- - Firm need to specify the eGFR (MDRD formula) or CKD stage in the exclusion criteria, serum NT-proBNP to be included as screening tool for significant cardiovascular disease. Accordingly, the firm should submit

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			revised protocol to CDSCO.
New Drug Division			
7.	ND-11011(15)/2/2025-eoffice Baricitinib 2mg and 4 mg tablets	M/s Eli Lilly	The firm presented proposal for amendment in Package Insert (Section 4.4: (Hypoglycaemia in patients treated for diabetes) of drug Baricitinib 2mg and 4 mg tablets before the committee. After detailed deliberation, the committee recommended for grant of approval of amendment in section 4.4 of Package Insert of Baricitinib 2 mg and 4 mg tablet, as presented by the firm which is detailed below. Hypoglycaemia in patients treated for diabetes: There have been reports of hypoglycaemia following initiation of JAK inhibitors, including baricitinib, in patients receiving medication for diabetes. Dose adjustment of anti-diabetic medication may be necessary in the event that hypoglycaemia occurs).