

Recommendations of the SEC (Analgesic & Rheumatology) made in its 11th meeting held on 14.11.2024 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	GCT/PostAppr/2024/33002 Online Submission (33002) EKS-001	M/s Inventiv	In light of earlier SEC Recommendation dated 12.06.2024 & 13.06.2024, now the firm presented protocol amendment 1 version 4.0 dated 29.1.2024 protocol no. ESK-001-010. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	GCT/PostAppr/2024/35408 Online Submission (35408) Baricitinib	M/s Eli Lilly	The firm presented protocol amendment (f) dated 28 June 2024 protocol no. I4V-MC-JAHU. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	GCT/PostAppr/2024/35637 Online Submission (35637) Afimetoran	M/s. BMS	The firm presented protocol amendment 04 dated 20 November 2023 protocol no. IM026-024. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
4.	BIO/CT04/FF/2024/45124 Denosumab 60 mg prefilled syringe solution for injection (60 mg/mL)	M/s. Lupin Limited	The firm presented the proposal to conduct Phase I study titled “An open label, randomized, single-dose, single-period, three-treatment, parallel comparative pharmacokinetic, pharmacodynamic and immunogenicity study of Lupin’s Denosumab 60 mg prefilled syringe solution for injection (60 mg/mL) with US and EU approved Prolia® (Denosumab) 60 mg solution for injection (60 mg/mL) in pre-filled syringe in healthy, adult, human male subjects” vide Protocol No. LBC-P-097-24 dated 09.07.2024. After detailed deliberation, the committee recommended the firm to conduct the Phase I study with following changes in the protocol- 1. Serum Calcium and Vitamin D levels should be in normal range for inclusion of subjects in the

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			<p>study.</p> <ol style="list-style-type: none"> Patients with history of Osteonecrosis of the jaw should be excluded from the study. Serial assessment of levels of Serum Calcium and Vitamin D should be done at each visit of the study subject. <p>Accordingly, the firm should submit revised protocol to CDSCO for further evaluation.</p>
5.	r-DNA-11016(13)/28/2024-e-office Denosumab Injection 60mg/ml (r-DNA Origin)	M/s. Enzene Biosciences Ltd	<p>The firm presented the safety and efficacy results of the Phase IV clinical trial conducted in India for Denosumab Injection 60mg/ml (r-DNA Origin) vide Protocol No. ALK23/DEN3 Version: 2.1 Date: 10-Mar-2022.</p> <p>After detailed deliberation, the committee noted the results of the study.</p>
6.	r-DNA-11016(13)/29/2024-e-office Teriparatide Recombinant Human Parathyroid Hormone (rhPTH1-34) Injection (r-DNA Origin) in Prefilled cartridge (250 mcg/mL)	M/s. Enzene Biosciences Ltd	<p>The firm presented the safety and efficacy results of the Phase IV clinical trial conducted in India for Teriparatide Recombinant Human Parathyroid Hormone (rhPTH1-34) Injection (r-DNA Origin) in Prefilled cartridge (250 mcg/mL) vide Protocol No. ALK05-TERI2 Version: 2.1 dated 24.02.2022.</p> <p>After detailed deliberation, the committee noted the results of the study.</p>