

**Recommendations of the SEC (Analgesics, Anesthetics & Orthopedics) made in its 05<sup>th</sup>/26 meeting held on 07.05.2026 at CDSCO HQ New Delhi:**

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/55/26 Online Submission (55956)  Cenerimod Film-Coated Tablets 4 mg	M/s. Mylan Pharmaceuticals Private Limited	The firm presented phase III clinical study protocol no.: ID-064A303 final version no. 3 dated 13-AUG-2025.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/63/26 Online Submission (56180)  BI 3000202	M/s. IQVIA RDS (India) Private Limited.	The firm presented phase II clinical study protocol no.: 1509-0004, Version no. 1.0 dated 11-NOV-2025.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
<b>Biological Division</b>			
3.	Receipt no. E-94888  Etanercept for injection (r-DNA origin)	M/s. Reliance Life Sciences Pvt. Ltd.	In light of the earlier recommendation of the SEC (Analgesic & Rheumatology) meeting dated 26.08.2025, wherein the firm presented the Clinical Study Report (CSR) for the Phase IV Clinical Trial conducted with the similar biologic Etanercept vide Protocol No. RLS/PMS/2018/03; Version 3.0, dated 14 Oct 2019, the following was noted:  In the said meeting, the Committee observed that there was one death during the trial and recommended that the firm present a detailed causality assessment report of the death before the Committee.  The firm has now presented the detailed causality assessment report of the death before the Committee and informed the Committee about the compensation paid to the nominee of the deceased in compliance with DCGI Order dated 10.10.2025.  The Committee noted the results of the aforesaid Phase IV study and recommended that the firm shall include the following in the warning section of package insert: if any patient shows elevated WBC, neutrophils, or CRP levels, the treating physician must evaluate for an underlying active infection before starting or continuing treatment with Etanercept.

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			Accordingly, the firm shall include the same in the package insert of Etanercept and submit the revised package insert to CDSCO.
4.	BIO/CT04/FF/2026/54 596  Rituximab Solution for Infusion 100 mg/10 mL and 500 mg/50 mL	M/s. Virchow Biotech Private Limited	<p>The firm presented the proposal for grant of permission to conduct a Phase IV clinical trial titled “A Phase IV Multi-Centric Post-Marketing Study Evaluating the Safety, Immunogenicity and Efficacy of Virchow Biotech Rituximab” vide Protocol No. VBRTXM01/2024-CT1, Version 1.0, dated 24.10.2024.</p> <p>After detailed deliberation, the Committee recommended grant of permission to conduct the Phase IV clinical trial as per the protocol presented by the firm, subject to the condition that if any patient shows elevated WBC, neutrophils, or CRP levels, the treating physician must evaluate for an underlying active infection (including Procalcitonin) before starting or continuing treatment. Screening for active tuberculosis should also be conducted before starting or continuing Rituximab treatment.</p> <p>Accordingly, the firm shall make the necessary changes in the aforesaid protocol and submit the revised protocol to CDSCO for evaluation.</p>
5.	Receipt No. 135274.  Infliximab powder for concentrate for solution for infusion 100 mg	M/s. Johnson & Johnson Private Limited	<p>The firm presented the proposal for update of the Prescribing Information (PI) dated 13 March 2025 for the drug product Infliximab powder for concentrate for solution for infusion 100 mg, based on the EU SmPC dated 30 Jan 2025 and 20 Mar 2025.</p> <p>After detailed deliberation, the Committee recommended the proposed update of the Prescribing Information (PI) dated 13 March 2025 for the drug product Infliximab powder for concentrate for solution for infusion 100 mg, based on the EU SmPC dated 30 Jan 2025 and 20 Mar 2025.</p>