

**Recommendations of the SEC (Analgesic & Rheumatology)) made in its 09<sup>th</sup>/25 meeting held on 29.10.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/135/25 Online Submission (51842)  LY3502970	M/s Clinical Trials Eli Lilly and Company India Pvt. Ltd.	<p>The firm presented phase III clinical study protocol no. J2A-MC-GZPT version no. Initial dated 27 Jun 2025.</p> <p>After detailed deliberation, the committee opined that the proposal will be deliberate in presence of two Endocrinologist experts for further review by the committee.</p>
<b>Medical devices Division</b>			
2.	MED-14/11/2025- eoffice  RADIOPAQUE GELIFIED ETHANOL (ABSOLUTE GEL)	M/s. ELEVATE SCIENTIFIC PRIVATE LIMITED	<p>In the light of the previous SEC recommendation held on 16.07.2025, the firm re-presented their case with available clinical study data to demonstrate the safety and efficacy of said device on pain outcomes of the patients.</p> <p>After detailed deliberation, the committee does not recommend for marketing authorization of the device at this stage in India and opined that the submitted clinical evidence is limited to 70 subjects from a non-Indian, single center study with short procedural follow-up and without long-term safety, efficacy or comparative effectiveness data. The endpoints assessed (procedure time and radiation exposure) are technical and do not establish clinical benefit or sustained safety in the target patient population.</p> <p>Therefore, the committee recommended that the firm shall conduct a multicentric Clinical Investigation on Indian population with the objective to demonstrate the safety, clinical efficacy and durability.</p> <p>Accordingly, firm need to submit the Clinical Investigation Protocol with statistically significant sample size, representative patient population and follow-up for at least 12 months, for taking further necessary action in the matter.</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>Biological Division</b>			
3.	E-85995 Infliximab powder for concentrate for solution for infusion 100 mg	M/s. Johnson & Johnson Private Limited	<p>The firm presented the proposal for update in Package Insert to include the changes in the Section 4.4 (Special warnings and precautions for use) and some administrative changes in Section 6.1 (List of excipients) and Section 6.3 (Shelf life) for the drug product Infliximab powder for concentrate for solution for infusion 100 mg based on EU SmPC dated 30 Jan 2025 and 20 Mar 2025.</p> <p>After detailed deliberation, the committee recommended the firm to submit the summary/justification of safety experience of Remicade treatment in patients who have undergone surgical procedures including arthroplasty for the proposed change in Section 4.4 of PI.</p> <p>Accordingly, requisite data should be submitted to CDSCO for further evaluation by the committee.</p>
4.	E-88360, E-71919 Secukinumab powder for solution for injection 150 mg/ml (vial) and Secukinumab solution for injection 150 mg/ml (pre-filled syringe and pre-filled pen)	M/s. Novartis Healthcare Private Limited	<p>The firm presented the proposal for update in Package Insert to include the changes in the Section 4.4 (Special warnings and precautions for use) for the drug product Secukinumab powder for solution for injection 150 mg/ml to update warning for Hepatitis B reactivation and tuberculosis based on EU SmPC dated 20 Nov 2024 and 28 Mar 2025.</p> <p>After detailed deliberation, the committee recommended the firm to submit the scientific data/evidence supporting the proposed change in Section 4.4 of PI.</p> <p>Accordingly, firm should submit the data to CDSCO for further evaluation by the committee.</p>
5.	E-89960 Tocilizumab Concentrate solution for infusion-80 mg/4 mL (r-DNA origin)	M/s Reliance Life Sciences	<p>The firm presented the proposal for the approval of revised Protocol No. RLS/IMM/2023/06 Version 4.0 dated 04 Apr 2025 to conduct Phase I Clinical Trial titled "A randomized, double-blinded, two-arms, single-dose, parallel comparative assessment of pharmacokinetics, pharmacodynamics, safety and immunogenicity of R-TPR-</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>055 (Tocilizumab) and RoActemra®/ACTEMRA® (Tocilizumab) administered by the intravenous route in normal healthy adult male participants.”</p> <p>After detailed deliberation, the committee recommended the firm to include following changes in the presented revised protocol and procedures-</p> <ol style="list-style-type: none"> <li>1. Validated early warning system (EWS) to detect SAE should be in place so that patients can be triaged for early and effective management of SAE</li> <li>2. Staff should be well equipped to understand and manage the SAE and shift the patients to nearby hospitals/medical facilities at the earliest.</li> <li>3. Firm should present the timelines and percentage of occurrence of SAE including the rarest one from the previously available published studies.</li> </ol> <p>Accordingly, firm should submit revised protocol to CDSCO for further evaluation by the committee.</p>
<b>New Drugs Division</b>			
6.	ND/MA/24/000167  Etofenamate Gel 10% w/w	M/s Micro Labs Limited	<p>The firm presented the proposal for grant of permission to manufacture and market Etofenamate Gel 10% w/w along with phase III Clinical Trial protocol before the committee.</p> <p>The firm presented international regulatory approval status of the drug product, toxicology studies along with Phase III CT protocol including study design and methodology, study objectives, inclusion and exclusion criteria, discontinuation criteria, study end points, sample size, schedule of evaluations etc.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial for drug, Etofenamate Gel 10% w/w as per protocol presented by the firm.</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
7.	ND-12011(11)/1/2025- eoffice  Gabapentin tablet 300 mg, Melatonin 3 mg, Clonidine 100 µg	Dr. Pratibha R Mudgal, AIIMS Raipur	<p>The study investigator presented protocol titled “A comparative study of effect of pre-treatment with oral Gabapentin versus Melatonin versus Clonidine on hemodynamic response to laryngoscopy and tracheal intubation in controlled hypertensive patients: A double-blinded, randomized controlled study” before the committee.</p> <p>After detailed deliberation, the committee recommended that proposed research study may be allowed as per proposal presented by the applicant.</p>