

**Recommendations of the SEC (Analgesic & Rheumatology) made in its 07<sup>th</sup>/25 meeting held on 26.08.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/134/24 Online Submission (40733)  Cenerimod Film-Coated Tablets 4 mg	M/s Mylan Pharmaceuticals Private Limited	The firm presented protocol amendment 3.0 dated 24 June 2025 protocol no. ID-064A301 (OPUS-1).  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/145/24 Online Submission (40743)  Cenerimod Film-Coated Tablets 4 mg	M/s Mylan Pharmaceuticals Private Limited	The firm presented protocol version 3.0 dated 03 July 2025 protocol no. ID-064A302 (OPUS-2).  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
<b>Biological Division</b>			
3.	E- 94888  Etanercept for injection (r-DNA origin)	M/s Reliance Life Sciences Pvt. Ltd.	The firm presented the CSR of Phase IV study titled "A prospective, multi-centre, phase IV study to evaluate safety and efficacy profile of EtanerRel <sup>TM</sup> (etanercept manufactured by Reliance Life Sciences Pvt. Ltd.) conducted vide Protocol No.: RLS/PMS/2018/03; Version 3.0, Dated: 14 Oct 2019.  The committee noted that there was one death during the trial. After detail deliberation the committee recommended that the firm shall present the detailed causality assessment report of death before the committee.
<b>SND Division</b>			
4.	SND/CT/25/000071  Tofacitinib Oral Solution 1 mg/ml	M/s MSN Laboratories Private Limited	The firm presented the proposal for grant of permission to conduct Phase IV Clinical Trial Protocol vide protocol No. 010/TFCB-OS/MSN/2025, Version 1.0 dated 23.Apr.2025 before the Committee.  After detailed deliberation, the committee recommended for approval to conduct the Phase IV trial as per the protocol presented by the firm, subject to the condition that the Phase IV clinical trial protocol shall be revised to incorporate the following: -  <ul style="list-style-type: none"> <li>• The dosing regimen shall be stratified across at least two distinct age groups and accordingly, statistical evaluation</li> </ul>

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			<p>shall be performed to assess age-specific responses and dosing appropriateness.</p> <ul style="list-style-type: none"> <li>In exclusion criteria, Latent Tuberculosis Infection (LTBI) shall be incorporated as part of the clinical protocol.</li> </ul> <p>Accordingly, firm shall submit revised Phase IV clinical trial protocol to CDSCO.</p>
5.	SND/MA/22/000080 Tofacitinib Extended Release Tablets 11 mg	M/s Optimus Pharma Private Limited	The firm did not turn up for the presentation.
6.	SND-11011/45/2025 – eoffice Tofacitinib Extended Release Tablets 11 mg	M/s Sun Pharmaceutical Industries Limited	<p>Firm has presented Report of Active PMS of Tofacitinib Extended Release Tablets 11 mg for the treatment of Adult Patients with Rheumatoid Arthritis, Psoriatic Arthritis and ulcerative colitis before the committee.</p> <p>After detail deliberation the Committee accepted the report presented by the firm</p>
7.	SND-16011(11)/226/2024- eoffice Methadone Hydrochloride oral Solution IP 1 mg/ml	M/s Rusan Pharma Ltd.	<p>The firm presented the proposal for updating package insert along with specimen of carton and draft label before the committee.</p> <p>After detailed deliberation, the committee recommended for approval of updated package inserts for the proposed changes along with specimen of carton and draft label.</p>
8.	SND/MA/23/000303 Flurbiprofen Lozenges 8.75 mg	M/s. Unique Pharma Laboratories ( A division of JB chemicals & Pharma Limited)	<p>In light of the earlier SEC meeting dated 12.06.2024 &amp; 13.06.2024, firm has presented the Local availability study protocol of Flurbiprofen 8.75 mg Lozenges Sugar Free Orange Flavour vide protocol no. C25139 version no: 01 dated 13.05.2025.</p> <p>After detailed deliberation, the committee recommended to conduct Local availability study as per protocol presented by the firm and submit the report to CDSCO for further consideration by the committee</p>
9.	SND/CT/25/000070 Tofacitinib Tablets 10	M/s MSN Laboratories Private Limited	The firm presented the proposal for grant of permission to conduct Phase IV Clinical Trial Protocol vide protocol No.

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	mg		011/TFCB/MSN/2025, Version 1.0 dated 23.04.2025 before the Committee.  After detailed deliberation, the committee recommended for approval to conduct the Phase-IV study as per the protocol presented by the firm.