

**Recommendations of the SEC (Analgesic & Rheumatology) made in its 10<sup>th</sup>/24 meeting held on 03.10.2024 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/121/24 Online Submission (45401)  PF-06823859	M/s. Pfizer Limited	The firm presented phase 3 clinical study protocol no. C0251010 version original dated 08 April 2024.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/08/24 Online Submission (35227)  VAY736 (Ianalumab)	M/s. Novartis Healthcare Private Limited	The firm presented protocol amendment version 02 dated 24 July 2024 protocol no. CVAY736A2301E1.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm with the condition that study shall not be used to compare efficacy and superiority of various delivery systems (PFS, Autoinjector).
3.	CT/120/23 Online Submission (35146)  SAR441566 50 mg and 100 Tablets	M/s. Sanofi Healthcare India Private Limited	The firm presented protocol amendment 3 version 01 dated 03 July 2024 protocol no. DRI17821 and increase in number of subjects from 10 to 24.  After detailed deliberation, the committee recommended for approval of protocol amendment and increase in number of subjects from 10 to 24 in India as presented by firm
4.	CT/55/23 Online Submission (33002)  EKS-001	M/s. InVentiv International Pharma Services Private Limited	The firm didn't turn up for presentation.
<b>Biological Division</b>			
5.	BIO/CT18/FF/2024/43682  Ixezumab Solution for Injection, 80 mg/mL	M/s. Eli Lilly and Company	The firm presented the proposal for the approval of additional indication i.e. Ankylosing Spondylitis and Non-radiographic Axial Spondyloarthritis of Ixezumab solution for injection, 80mg/ml in prefilled auto injector and prefilled syringe (r-DNA origin) with request for local clinical trial waiver.  The firm has presented safety and efficacy results of global clinical trials

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			<p>(COAST V, W, X and Y) conducted in the proposed indication.</p> <p>After detailed deliberation, the committee noted that there is no efficacy data in Indian subject.</p> <p>The committee recommended the firm to submit efficacy data of Indian population for the approval of proposed indications.</p>
6.	E-30733 Golimumab 50mg and 100 mg in PFS	M/s. Reliance Life Sciences Pvt. Ltd.	<p>In light of earlier SEC recommendations dated 13.03.2024, the firm presented the study data of non- responders at Week 14 in comparison with Week 24 of the conducted Phase III clinical trial for the drug product Golimumab solution for Injection (50 mg/0.5 ml &amp; 100 mg/ml)(r-DNA origin) Single use prefilled syringe for subcutaneous injection.</p> <p>After detailed deliberation, the committee noted the results of the study.</p>
<b>SND Division</b>			
7.	SND/MA/24/000032 Diclofenac Injection IP 75mg/ml Containing Diethylene Glycol Monoethyl Ether (Transcutol-P)	M/s. Themis Medicare Ltd.	<p>The firm presented the proposal for grant of permission to conduct Active Post marketing surveillance study as per the submitted protocol before the Committee.</p> <p>After detailed deliberation, the committee recommended to conduct active post marketing surveillance study as per presented protocol (Protocol no. TML/DIL/01, version no. 01, dated 01-MAR-2024).</p>
8.	SND/MA/23/000241 Paracetamol Oral Suspension IP 500mg/5ml	M/s. Naxpar Pharma Pvt. Ltd.	<p>In light of the earlier SEC recommendation dated 02.05.2024, the firm presented the bioequivalence study report before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Paracetamol Oral Suspension IP 500mg/5ml for the treatment of mild to moderate pain and treatment of fever for adult and adolescents over 16 years of population.</p>