

Recommendations of the SEC (Analgesic & Rheumatology) made in its 08th/24 meeting held on 06.08.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/107/23 Online Submission (33701) Abatacept	M/s. Dr. Reddy's Laboratories Limited	The firm presented the proposal to increase the number of subjects from 100 to 200 vide approved protocol number AB-01-004. After detailed deliberation, the committee recommended for approval to increase in number of subjects from 100 to 200 as presented by the firm.
2.	CT/68/19 Online Submission (32171) Baricitinib	M/s. Eli Lilly And Company	The firm presented protocol amendment (e) dated 12Jan 2024, protocol no. I4V-MC-JAHU. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
BA/BE Division			
3.	BABE/CT05/FF/2024 / 42394 Azathioprine 100 mg/5 mL Oral Suspension	M/s. Lambda Therapeutic Research Limited	The firm presented protocol No. 0435-23 (version 1.0, dated: 20 February 2024) along with public assessment report and published reports of bioequivalence studies of this drug carried out on healthy subject. After detailed deliberation, the committee recommended for grant of permission to conduct bioavailability study as per the protocol presented.
Medical Device Division			
4.	IMP/MD/2019/14611 Dry-Socket Surgical Dressing (Brand Name: Alveogyl)	M/s. Septodont Healthcare India Pvt. Ltd.	The firm presented the Clinical Investigation report of proposed product (i.e. Dry-Socket Surgical Dressing) generated on Indian population after obtaining permission in Form MD-23, before the committee. After detailed deliberation, the committee considered the report and recommended for the grant of permission to import for commercialization of the said device with the condition that firm shall submit Periodic Safety Update Report at an interval of every 03months from the date of launch of the product in the country.

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SND Division			
5.	SND/MA/23/000272 Etoricoxib 1.2mg/ml Solution for Intravenous Infusion	M/s. Themis Medicare Limited	<p>The firm presented the proposal for grant of permission for manufacture and marketing of Etoricoxib infusion 1.2 mg/ml for additional indication “Short term use in acute painful condition in hospitalized patient of in Emergency/casualty department” along with the Pharmacokinetic Study Protocol and justification for Phase-III clinical trial waiver before the committee.</p> <p>The firm has informed that Etoricoxib injection 90mg/ml, IM is already approved by CDSCO on 28.03.2008.</p> <p>The committee noted that the proposed formulation through IV route is not available globally and firm could not produce any scientific advantage of proposed formulation over existing formulations of etoricoxib administered through alternate routes.</p> <p>After detailed deliberation, the committee recommended that the proposal of the firm may not be considered.</p>
FDC Division			
6.	FDC/MA/23/000132 Polmacoxib 2mg + Paracetamol 325mg tablets	M/s. Hetero Labs Limited	<p>In light of earlier SEC recommendation dated 07.06.2023, the firm presented BE study report and Phase III clinical trial report before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC for the indication “For the short term use in acute somatic mild to moderate painful inflammatory conditions”.</p>