Recommendations of the SEC (Analgesic & Rheumatology) made in its 101st meeting held on 05.10.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/23/000005 Methadone Oral Solution 1 mg/ml	M/s. Rusan Pharma Ltd.	In light of earlier SEC recommendations dated 13.04.2023, the firm presented justification for waiver of BA/BE study before the committee. The firm informed that the Methadone HCl oral solution 1mg/ml is approved in other countries such as UK in year 1983, Ireland in year 1995 and New Zealand in year 2013 for the treatment of opioid drug addiction as a narcotic abstinence syndrome suppressant. The committee noted that CDSCO has already approved Methadone HCI syrup 5mg/ml & 10mg/ml in year 2009 for the treatment of opioid dependence and in maintenance treatment for opioid dependence and Methadone HCI tablet 5mg & 10mg for the treatment of chronic refractory moderate to severe pain. After detailed deliberation, the committee opined that since the formulation is in solution form, the bioequivalence study may be waived. In such a case, conduct of a Phase IV study becomes imperative. The committee thus recommended for grant of permission to manufacture and market of Methadone HCI oral solution 1mg/ml with waiver of Phase III clinical trial & bioequivalence study subject to condition that the firm should conduct Phase IV clinical trial study. Accordingly, the firm should submit Phase IV clinical trial protocol within 3 months of approval of the drug for review by the committee.
Biological Division			
2.	BIO/CT21/FF/2023/37090 Adalimumab 100mg/ml	M/s. Enzene Biosciences Limited	The firm presented the proposal for approval of additional indications for Adalimumab injection.The Adalimumab injection is earlier approved for the indication ‘‘Ankylosing Spondylitis’’. The firm intend to extrapolate the

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			following additional indications: 1.Rheumatoid arthritis 2.Psoriatic arthritis 3.Juvenile idiopathic arthritis After detailed deliberation, the committee recommended for approval of indications. i.e., Rheumatoid arthritis and Psoriatic arthritis. The indication of Juvenile idiopathic arthritis will be deliberated in the presence of Pediatrician for approval and other applied indications may be deliberated in SEC (Gastroenterology and Dermatology).
3.	BIO/CT04/FF/2023/38250 Olokizumab 160 mg	M/s. Dr. Reddy's Laboratories Limited	The firm presented the proposal to conduct Phase III clinical trial titled "A phase III, randomized, double-blind, placebo-controlled, parallel-group, multicentre study to evaluate the efficacy and safety of olokizumab in moderate to severe rheumatoid arthritis patients with inadequate response to methotrexate" vide protocol number OKZ-01-002,version 1.0 dated 17 Jan 2023. After detailed deliberation, the committee recommended that the firm should revise the protocol as single arm study and avoid the placebo arm since the patients are having moderate to severe RA with inadequate response to MTX and rescue therapy is proposed only after twelve weeks as per the protocol presented. Accordingly, the firm should submit revised protocol to CDSCO for further evaluation by the committee.
FDC Division			
4.	4-46/2018-DC Ropivacaine HCl eq. to Anhydrous Ropivacaine HCl 7.5mg + Dextrose 80mg Injection	M/s. Neon Laboratories	In light of earlier SEC recommendation dated 14.12.2021 and as per condition of Form CT-23 dated 13.08.2021, the firm presented the Active PMS report before the committee. After detailed deliberation, the committee noted and agreed the results of the report.
5.	FDC/MA/21/000084 Alcohol IP + Ketoprofen IP 36.8%	M/s. Akums Drugs & Pharmaceutical Ltd.	In light of earlier SEC recommendation dated 12.10.2022, the firm presented their proposal along with Phase III clinical trial study report before the committee.

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	v/w + 2.5%w/w Gel		After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC.
GCT Division			
6.	CT/47/19 Online Submission (27168) Baricitinib	M/s. Eli Lilly	The firm presented protocol amendment protocol number I4V-MC-JAHX (e) dated 09 June 2023 before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented.