Recommendations of the SEC (Analgesic & Rheumatology) made in its 03rd/25 meeting held on 16.04.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT21/BO/2024/46327 Rituximab Injection 100mg/10mL and 500mg/50mL vial	M/s. Virchow Biotech Private Limited	The firm presented the proposal for grant of permission to manufacture and market Rituximab injection 100 mg/10mL and 500 mg/50mL vial (r-DNA origin) based on the results of comparative Phase III clinical trial conducted in India for the indication of Rheumatoid Arthritis to establish the efficacy, safety, pharmacokinetics and immunogenicity of the drug product. The firm has also applied for the approval of following additional indications by the way of extrapolation of indications approved for the innovator product as per Similar Biologics Guidelines. i. Non–Hodgkin's Lymphoma (NHL) ii. Chronic Lymphocytic Leukemia (CLL) iii. Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) iv. Pemphigus Vulgaris (PV) After detailed deliberation, the committee recommended for grant of permission to manufacture and market Rituximab injection 100 mg/10mL and 500 mg/50mL vial (r-DNA origin) for the proposed indications i.e. RA, NHL, CLL, GPA (& MPA) and PV subject to the condition that the firm shall conduct Phase IV study in the country for the indications of NHL, CHL and RA. Accordingly, the protocol to conduct the Phase IV study shall be submitted within three months of grant of marketing authorization permission to manufacture and market the product.
2.	E-58084 Secukinumab 150mg/mL solution for injection	M/s. Novartis Healthcare Pvt. Ltd.	The firm presented the Package insert dated 25.07.2023 based on EU SmPC dated 24.05.2023 of Secukinumab 150 mg/mL solution for injection in pre filled pen as per the condition of approval i.e.

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			"The usage of dose upto 300mg only in patients who continues to have active Psoriatic Arthritis and active ankylosing spondylitis." After detailed deliberation the committee recommended for approval of Package insert dated 25.07.2023 for the proposed changes.
SND Division			
3.	SND/MA/24/000246 Naproxen injection 5 mg/mL	M/s Leiutis Pharmaceuticals LLP	The firm presented the proposal for manufacturing & marketing of Naproxen injection 5 mg/mL for the treatment of moderate to severe acute pain after major skeletal trauma alone or in combination with non-NSAID analgesics along with proposal for conduct of Pharmacokinetic study (Part-A) & Phase-III study (Phase-B) vide protocol No. CT-006/2024 Version 3.0 dated 09.04.2025 before the committee. The committee noted that the Naproxen injection is not approved anywhere in the world and no human clinical data is available for Naproxen IV injection. Naproxen is highly protein-bound drug and $t_{1/2}$ of Naproxen is approximately 15 hours. The experts opined that ADME of Naproxen injection in humans need to be established. After detailed deliberation, the committee recommended for conduct of Pharmacokinetic study (Part-A) as per the presented protocol and submission of the report for further deliberation
FDC Division			
4.	FDC/MA/25/000052 Polmacoxib 2mg + Thiocolchicoside 8mg Capsules	M/s Precise Biopharma Pvt. Ltd	The firm presented the rationality of the proposed FDC before the committee. After detailed deliberation, the committee opined the following: 1. Firm did not justify the combining of two different half-life drugs. i.e. shorter half-life (Thiocolchicoside) & longer half-life (Polmacoxib). 2. Firm did not present adequate justification/rationale for the proposed FDC.

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			3. More published scientific literature in peer reviewed journal in support of rationality and desirability of proposed FDC should be submitted. 4. Justification in light of standard therapeutic treatment guidelines should be presented. 5. Firm should submit international approval status of proposed FDC. Accordingly, the firm should submit above data for further review by the committee.