Recommendations of the SEC (Analgesic & Rheumatology) made in its 01st/25 meeting held on 28.01.25. at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/145/24 Online Submission (46587) Cenerimod	M/s MYLAN PHARMACEUTICALS PRIVATE LIMITED	Under Discussion
2.	CT/134/24 Online Submission (46317) Cenerimod (ACT-334441)	M/s MYLAN PHARMACEUTICALS PRIVATE LIMITED	Under Discussion
3.	CT/150/24 Online Submission (46840) JNJ-77242113	M/s Johnson & Johnson Pvt. Ltd	The firm presented phase 3 clinical study protocol no. 77242113PSA3001 Amendment 1 dated 18 Nov 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
4.	CT/151/24 Online Submission (46909) JNJ-77242113	M/s Johnson & Johnson Pvt. Ltd	The firm presented phase 3 clinical study protocol no. 77242113PSA3002 amendment 1 dated 18 November 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
5.	BIO/CT04/FF/2024/45903	M/s. Johnson and Johnson	The firm presented the proposal to conduct Phase IV clinical trial titled "A Phase-IV, Multicenter, Non-Comparative, Open-Label Study Evaluating the Safety and Efficacy of Guselkumab Administered Subcutaneously in the Treatment of Indian Patients with Psoriatic Arthritis" vide protocol number: CNTO1959PSA4018. After detailed deliberation, the committee

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			recommended for approval to conduct the clinical trial as per the protocol presented by the firm.
SND Division			
6.	SND/MA/24/000137 Paracetamol tablets IP 1000mg	M/s. Alkem Laboratories Ltd	Under Discussion
FDC Division			
7.	FDC/MA/24/000270 Calcium Citrate Malate IP Eq. to Elemental Calcium 250mg + Vitamin D3 IP 1000 IU + Magnesium hydroxide IP Eq. to elemental magnesium 100mg + Manganese Sulphate Monohydrate BP Eq. to elemental Manganese 1.8mg + Zinc Sulphate Monohydrate IP Eq. to elemental zinc 7.5mg + Copper Sulphate Pentahydrate BP Eq. to elemental copper 1.0 mg + Sodium borate BP Eq. to elemental Boron 1.0 mg	M/s Torrent Pharmaceuticals Ltd.	The firm presented their proposal along with justification for BE & phase III CT waiver before the committee. After detailed deliberation, the committee opined that : 1. The product in proposed strength is not approved internationally. 2. There is no scientific literature available from good indexed journal/peer reviewed journal in support of proposed FDC. 3. Firm did not show the superiority of the proposed product with already approved similar product (in different strengths) in clinically. 4. Firm did not justify adding the Boron strength in proposed FDC. In view of above, the committee did not consider Phase III CT waiver. However, the committee considered the request for BE waiver. Accordingly, firm should submit Phase III CT protocol to CDSCO for further review by the committee.