Recommendations of the SEC (Analgesic & Rheumatology) made in its 98th meeting held on 27.07.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2023/36473 Denosumab Injection 60 mg/mL	M/s. Reliance Lifesciences Pvt. Ltd.	The committee opined that the proposal should be deliberated in presence of Rheumatologist in upcoming SEC meeting.
SND Division			
2.	12-1113/2017-DC Tacrolimus Liquid Tablets 0.3mg	M/s. Intas Pharmaceutics Limited	The committee opined that the proposal should be deliberated in presence of Rheumatologist in upcoming SEC meeting.
FDC Division			
3.	FDC/MA/23/000167 Ketorolac Tromethamine 10mg + Serratiopeptidase (DR)15mg Capsules	M/s. Dr. Reddy's Laboratories Ltd.	The firm presented the proposal before the committee along with request for BE study waiver and Phase III clinical trial study protocol. The committee noted that: 1. The proposed FDC is not approved anywhere in the world. 2. The PK is not matching with the FDC as Ketorolac Tromethamine should be taken post meal and Serratiopeptidase should be taken before meal. 3. There is no additional benefit of Serratiopeptidase in the FDC as the proposed duration of treatment is short for 3 to 5 days only. 4. There is no rationality for the FDC. 5. Serratiopeptidase is withdrawn from the market by the innovator company voluntarily in Japan due to efficacy issues. 6. Serratiopeptidase is not approved as a drug in any ICH countries as informed by the firm. After detailed deliberation, the committee did not recommend for approval of the FDC.
GCT Division			
4.	CT/42/23 Online Submission (37299)	M/s. Lupin	The firm presented Phase III clinical trial protocol number –IRO2201A301, version no-2.1, dated 12 April 2023 before the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Denosumab with Prolia®		After detailed deliberation, the committee recommended for grant of permission to conduct the study with conditions – 1. 50% of the sites should be Government site with 50% patients recruited from these sites. 2. PI should be preferably Orthopedic Surgeon. 3. In the exclusion criteria Vit. D deficiency needs to be treated before including the patient in the study. 4. Vit. D dose should be 1000 IU instead of 400 IU as part of standard treatment.
Biological Division			
5.	BIO/CT18/FF/2022/35426 Guselkumab Solution for Injection 100 mg/ml in Single use pre-filled syringe and Prefilled Pen	M/s. Johnson & Johnson Pvt. Ltd.	The committee opined that the proposal should be deliberated in presence of Rheumatologist in upcoming SEC meeting.