Recommendations of the SEC (Analgesic and Rheumatology) made in its 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	The firm presented phase 3 clinical study protocol no. ID-064A302(OPUS-2) final version 2.0 dated 06 December 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the study with the conditions that the protocol shall be amended to include: 1. Comprehensive eye examination and its record (slit lamp exam, visual acuity test, tonometry, dilated fundoscopic exam by direct ophthalmoscopy) to rule out macular disorders and uveitis at the time of screening the participants. 2. ECG with long leads for all screened patients to rule out cardiac events, during screening and all visits. 3. Serum NT proBNP or BNP, and High-sensitivity cardiac troponin I (hs-cTnI) or hs-cTnT as screening tests for severe cardiovascular disease for determining eligibility of participation in the study.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			4. Stool occult blood test to screen for pre-existing GI bleeding. Further, the committee opined that the adverse events or reactions noted during the follow-up period shall be submitted CDSCO for further review by the committee.
2.	CT/134/24 Online Submission (46317) Cenerimod (ACT-334441)	M/s MYLAN PHARMACEUTICALS PRIVATE LIMITED	The firm presented phase 3 clinical study protocol no. ID-064A301 (OPUS-1) final version: 2.0, dated 4 December 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the study with the conditions that the protocol shall be amended to include: 1. Comprehensive eye examination and its record (slit lamp exam, visual acuity test, tonometry, dilated fundoscopic exam by direct ophthalmoscopy) to rule out macular disorders and uveitis at the time of screening the participants. 2. Serum NT proBNP or BNP, and High-sensitivity cardiac troponin I (hs-cTnI) or hs-cTnT as screening tests for severe cardiovascular disease for determining eligibility of participation in the study.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			3. Stool occult blood test to screen for pre-existing GI bleeding. Further, the committee opined that the adverse events or reactions noted during the follow-up period shall be submitted CDSCO for further review by the committee.