Recommendations of the SEC (Analgesic & Rheumatology) made in its 02nd/24 SEC meeting held on 06.02.2024 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/90/23 Online Submission (38667) Anifrolumab (MEDI-546)	M/s. AstraZeneca	The firm didn't turn up for presentation.
2.	CT/24/000008 Online Submission (41424) VAY736 (Ianalumab)	M/s. Novartis Healthcare Private Limited	The firm presented phase 3b clinical study protocol no. CVAY736A2301E1 version 00 dated 03 March 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/14/24 Online Submission (41450) Tildrakizumab Injection 100 mg/ ml	M/s. Sun Pharmaceutical Industries Limited	The firm presented phase 3 clinical study protocol no. TILD-21.01, amendment 2 dated 9th November 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm
4.	CT/107/23 Online Submission (31028) Abatacept biosimilar (DRL_AB) with Orencia®	M/s. Dr. Reddy's Laboratories	The firm presented protocol amendment version 2.0 dated 15 September 2023 protocol no. AB-01-004. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
5.	BIO/CT04/FF/2023/38250 Olokizumab 160mg	M/s. DRL	In light of the SEC recommendation dated 05.10.2023,the firm presented the revised protocol titled "A phase III, multicentre, single arm, clinical trial 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 2.0 dated 27 Nov 2023. After detailed deliberation, the committee recommended to include the immunogenicity study in the clinical trial protocol for collecting sample from all the study subjects for analysis.

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			Accordingly, the firm has to submit the revised protocol to CDSCO for further evaluation by the committee.
BA/BE Division			
6.	File No. 12-09/2024/BA-BE/MISC-05/DC BABE/CT05/FF/2023/38909 Apremilast MR 75 mg Tablet	M/s. Cipla Limited, Mumbai-400013	The firm presented protocol no. 0049-12-22, Version No. 2.0 dated 07-Jul-2023. After detailed deliberation, the committee did not recommend the proposed study as the applied product dosage form and strength is not approved anywhere in the world and the prototype of proposed formulation developed by Innovator is under review by the concerned regulatory authority (USFDA). The committee also noted that the data published by the Innovator in ClinicalTrail.gov may not be used to compare the test product as the published data is under review by the concerned regulatory authority.
SND Division			
7.	SND/MA/23/000272 Etoricoxib infusion 1.2mg/ml	M/s. Themis Medicare Ltd.	The firm didn't turn up for presentation
FDC Division			
8.	04-01/2022-DC (Misc. 2) (Pt.1) Ibuprofen 100mg + Paracetamol 162.5mg suspension and Ibuprofen 400mg + Paracetamol 325mg tablet	M/s. Sanofi India Limited	The firm presented the proposal for update prescribing information for the FDC changes based on the updated company core data sheet (CCDS) version 7 dated 02.03.2023 and version 8 dated 11.05.2023. After detailed deliberation, the committee recommended for grant of approval for the proposed update in prescribing information as presented by the firm.
9.	FDC/MA/23/000167 Ketorolac Tromethamine 10mg + Serratiopeptidase 15mg Capsules	M/s. Dr. Reddy's Laboratories Ltd.	In the light of earlier SEC recommendation dated 27.07.2023, the firm presented the medical rationale/justification along with Phase III clinical trial study protocol and request for BE study waiver before the committee.

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			The committee noted that: 1. The firm did not present the rationality of the combination and its significant benefits. 2. The proposed FDC is not approved anywhere in the world. 3. The PK is not matching with the FDC as Ketorolac Tromethamine should be taken post meal and Serratiopeptidase should be taken before meal. 4. There is no additional benefit of Serratiopeptidase in the FDC as the proposed duration of treatment is short for 3 to 5 days only. 5. In the proposed CT protocol, the firm has used single drug Ketorolac as the comparator product with the non-inferior study design. After detailed deliberation, the committee did not recommend for approval of the FDC.
10.	FDC/MA/23/000343 Aceclofenac IP 1.5% w/v + Linseed oil BP 3% w/v + Methyl Salicylate IP 10% w/v + Menthol IP 5% w/v Lotion	M/s. Lyka Labs Ltd.	The firm presented their proposal before the committee. After detailed deliberation, committee opined the following: 1. The firm did not present the rationality of the combination and its significant benefits. 2. The firm did not justified the need to include all the ingredients in the proposed FDC. 3. The firm did not present any data w.r.t efficacy of FDC in Lotion dosage form. 4. The product is not approved internationally. Accordingly, the firm should submit above data for further review by the committee.
11.	FDC/MA/24/000001 Mefenamic Acid IP 500mg + Paracetamol	M/s. Pure and Cure Healthcare Pvt. Ltd.	The firm presented their proposal before the committee.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	IP 325mg + Serratiopeptidase IP (As enteric coated granules 20,000 units) 10mg film coated tablet		After detailed deliberation, committee opined the following: 1. The firm did not present any rationality of the combination and its significant benefits. 2. There is pharmacokinetic mismatch. 3. The firm did not present rationality on use of Serratiopeptidase in the indicated group. After detailed deliberation, the committee did not recommend for approval of the FDC.