Recommendations of the SEC (Analgesic & Rheumatology) made in its 85th meeting held on 23.06.2022 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/22/000073 Ibuprofen Sodium Dihydrate 256 mg & 512 mg Tablets	M/s. Lyrus Life Sciences	In light of earlier SEC (Analgesic and Rheumatology) recommendation dated 19.05.2022, the firm presented their proposal along with the BE Study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study subject to condition that the standard breakfast after drug administration should be included in protocol and the firm should conduct the BE study and submit the BE study results before the committee for further consideration.
Biological Division			
2.	BIO/CT21/BO/2022/31725 Adalimumab Injection (in PFS) 80 mg / 0.8 ml 40 mg/ 0.4 ml 20 mg/ 0.2 ml 10 mg/ 0.1 ml 40 mg/ 0.8 ml 20 mg/ 0.4 ml 10 mg/0.2 ml	M/s. Enzene Lifesciences	The firm presented the proposal for manufacturing and marketing of Adalimumab Injection along with the results of Phase III Clinical trial. After detailed deliberation the committee recommended for grant of permission of manufacture and marketing of Adalimumab Injection 100mg/ml (80 mg/0.8 ml, 40mg/0.4ml, 20mg/0.2ml, 10mg/0.1ml) in PFS for the indication of active Ankylosing Spondylitis(AS) subject to the condition that the firm should submit Phase IV protocol within three months from the date of approval.
3.	4-195/Johnson/ 13-BD (Part-I) Golimumab	M/s. Johnson & Johnson	The firm presented the proposal for inclusion of orthopedic in the prescribers for the product Golimumab.

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			After detailed deliberation the committee recommended for inclusion of orthopedician as the prescribers of the drug along with earlier approved prescribers.
4.	BIO/CT/21/000061 Adalimumab	M/s. Intas Pharma	In light of earlier SEC recommendation dated 12.01.2022 the firm presented the revised protocol. After detailed deliberation the committee recommended for grant of permission to conduct the Phase III clinical trial as per submitted protocol no 0881-19 version no 2.
SND Division			
5.	SND/MA/21/000533 Paracetamol Oral Solution	M/s. Pulse Pharmaceuticals Pvt. Ltd.	In light of earlier SEC (Analgesic and Rheumatology) recommendation dated 31.03.2022, the firm presented their proposal along with the BE Study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study as per the protocol presented.
FDC Division			
6.	FDC/MA/22/000070 Dicyclomine Hydrochloride + Paracetamol +Tramadol Hydrochloride (50mg+10mg+325mg) capsules	M/s AKUMS DRUGS	The firm did not turn up for the presentation.
7.	FDC/MA/22/000153	M/s. Lupin Ltd.	The firm presented their proposal before the committee along with BE study

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	Tranexamic Acid 750mg + Mefenamic acid 375mg tablets		protocol as well as requested for Phase III CT study waiver. After detailed deliberation,the committee opined that 1. Mefenamic Acid 375mg ER is not approved internationally. 2. Firm did not present any rational , published literature from peer reviewed journal for the FDC in proposed doses. In view of above, the committee did not recommend the FDC.
8.	04-01/2022-DC (Misc.) Pt.II 1. Diclofenac Diethylamide BP 4.64% w/v (Eq. to Diclofenac sodium IP) 4.00% w/v + Absolute Alcohol IP 10.00% v/v topical solution 2. Diclofenac Diethylamine BP 2.32 % w/v (Eq. to Diclofenac sodium IP) 2.00 w/v + methyl Salicylate IP 10.00 % w/v + Menthol 5.00% w/v + Absolute Alcohol IP 10.00%	M/s. Triokaa	The firm presented their proposal alongwith justification before the committee. After detailed deliberation, the committee recommended for amendment in the package insert by changing the dosing frequency from 4 times a day to 2-4 times of day.

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	v/v Topical Solution		
Medical Device Division			
9.	IMP/MD/2021/41651 NNOTERE 3D Scaffold	M/s. Avana Medical Devices Pvt Ltd.	In light of earlier SEC (Analgesic and Rheumatology) recommendations dated 16.11.2021, the firm presented their proposal before the committee. Committee observed that data the firm did not present satisfactorily data as requested by the SEC (Analgesic and Rheumatology) dated 16.11.2021 such as data generated from the device and post market surveillance data. After detailed deliberation, the committee recommended that the firm should submit the following: 1. Data generated from the device and published in high indexed peer reviewed journal in regard to biocompatibility, efficacy and safety. 2. Detailed post market surveillance data generated by the manufacturer in the countries where the proposed device is used.
10.	CI/MD/2022/36468 Malviya Dental implant	M/s. B.H.U	The applicant presented their proposal for clinical investigation of the proposed product before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct the clinical investigation of the proposed product in India.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
11.	IMP/MD/2020/23772 Biodegradable, implantable balloon	M/s Stryker India Private Limited	The firm did not turn up for presentation before the committee.