Recommendations of the SEC (Analgesic & Rheumatology) made in its 83rd meeting held on 29.04.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2022/30484 Secukinumab150mg/ml solution for injection in a pre-filled pen	M/s. Novartis Healthcare Pvt. Ltd.	The firm presented the proposal for addition of new indication namely, psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis for prefilled pen of the drug. After detailed deliberation, the committee recommended for grant of approval for the proposed indications in only those patients whose maximum prescribed dose is not more than 150 mg per dose. Further, the firm should generate PMS data in the country to assess patient safety and satisfaction.
SND Division			
2.	SND/MA/22/000010 Teriperatide Injection, Solution for injection in a pre-filled pen600mcg/2.4ml	M/s. Sun Pharma	The firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial as per the protocol presented subject to the following conditions: • Age of the post menopausal women should be revised to 45 to 85 years. • Both Frax score and BMD should be estimated and it should be done with the same equipment throughout the period of study.
3.	SND/MA/22/000079 Tofacitinib SR Tablets 11 mg	M/s. Mascot Health	The firm presented the proposal for manufacturing and marketing of Tofacitinib SR Tablets 11 mg along with the BE study protocol. After detailed deliberation, the committee recommended for grant of permission for conduct of the BE study as per the protocol presented.
4.	SND/CT/22/000018 Drotaverine Hydrochloride Extended Release Tablets 240 mg	M/s. Martin and Harris	The firm presented the BE study protocol before the committee for approval. After detailed deliberation, the committee recommended for grant of permission for conduct of the BE study as per the

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
			protocol presented.
FDC Division			
5.	FDC/MA/22/000070 Dicyclomine Hydrochloride + Paracetamol +Tramadol Hydrochloride (50mg+10mg+325mg) capsules	M/s. Akums Drugs	The firm didn't turn up for presentation.
GCT Division			
6.	CT/67/21 Secukinumab	M/s. Novartis	The firm presented their proposal for protocol amendment, protocol number CAIN457A02001B version 1.0 dated 22-Jul-2021. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment except the revision at section 4.6 and 5.1 of the protocol.
7.	CT/35/21 VIB7734	M/s. PPD	The firm presented their proposal for protocol amendment, protocol number VIB7734.P2.S1, version 2.0, amendment 1.0 dated 10-Feb-2022. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
Medical Device Division			
8.	CI/MD/2021/49121 Nanocomposite Fibrous scaffold (NANOTEX BONE Graft)	M/s. Amrita Vishwa Vidyapeetham	In light of earlier SEC recommendation dated 12.01.2022 & 13.01.2022, the firm presented their proposal for pilot clinical investigation of the proposed product before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the pilot clinical investigation of the proposed product in the country.