Recommendations of the SEC (Analgesic & Rheumatology) made in its 86th meeting held on 27.07.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT21/FF/2021/24679 Denosumab	M/s. Reliance	In light of SEC recommendation dated 16.11.2021, the firm presented revised Phase III clinical study report before the committee with justification for approval of the drug in India. After detailed deliberation, the committee opined that the firm should relook into the clinical data and use appropriate statistical tool to evaluate the statistical significance for expressing the number of percentage change. Accordingly, the firm should submit the revised data to the committee for further deliberation.
2.	BIO/CT/19/000047 Tocilizumab	M/s. DRL	The firm presented the proposal for the amendment in Phase I clinical trial protocol TC-01-001 version 2.1 dated 27.04.2022. After detailed deliberation, the committee recommended for proposed amendment in the protocol.
SND Division			
3.	SND/MA/22/000190 Naproxen Sodium Tablets 275/550 mg	M/s. RPG Life Science	The firm presented their proposal for grant of manufacture and market of Naproxen Sodium Tablets 275mg & 550mg as additional strengths with BE protocol and request for local CT waiver before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct said BE study as per the protocol presented subject to following conditions: (1). COVID test of the subjects should be done during screening. (2). To establish healthy status of the volunteers all required tests and examination should be performed during screening.
FDC Division			

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
4.	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.
5.	FDC/MA/22/000179 Combikit of Esomeprazole Magnesium Trihydrate 20 mg/ 20 mg/20 mg + Naproxen Sodium 500 mg/375 mg/250 mg (immediate release) Tablets	M/s. Ravenbhel Healthcare Pvt. Ltd.	The firm didn't turn up for presentation.
Medical Device Division			
6.	CI/MD/2022/58199 Arthroscopy Implants-Bioabsorbable Ligament Anchor (BIO-VIM®)	M/s. ChetanMeditech Pvt Ltd	The firm presented their protocol for grant of permission to conduct Post Marketing Clinical Investigation before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct the proposed study in India.
7.	IMP/MD/2021/45460 GENTA-COLL® resorb and GENTA-PROTEC® (Resorbable collagen for Hemostasis), GENTA-FOIL resorb®(Resorbable collagen for Hemostasis)	M/s Morulaa Health Tech Pvt. Ltd.	The firm presented their proposal before the committee. After detailed deliberation, the committee recommended for the grant of import permission for the productsGENTA-COLL resorb and GENTA-PROTEC and GENTA-FOIL resorb for marketing in the country with the condition that monitoring of kidney function test should be mentioned in the IFU.
8.	IMP/MD/2020/23772 Biodegradable, implantable balloon	M/s Stryker India Private Limited	The firm didn't turn up for presentation.
9.	IMP/MD/2021/41354 Bioinductive Implant (REGENET)	M/s. Smith & Nephew Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 12.01.2022 & 13.01.2022, the firm presented their proposal before the committee. After detailed deliberation, the committee recommended for the grant of import & marketing permission for the medical device Bioinductive Implant (REGENET)

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Additional Proposal –SND Division			
10.	12-199/2008-DC (Pt-Troikaa-SND) Paracetamol Injection 500mg/2ml (IM Route)	M/s Troikaa Pharmaceuticals	The firm presented their proposal for grant of manufacture and market of Paracetamol Intramuscular Injection 500mg/2ml with clinical trial and bioavailability data before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Paracetamol Intramuscular Injection 500mg/2ml for the applied indication subject to the condition that the Package Insert,(PI) of the product should clearly mention the Warning that the product is for Intramuscular use only and not for Intravenous use.