Recommendations of the SEC (Analgesic & Rheumatology) made in its 89th meeting held on 12.10.2022 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	91/Phase IV/Johnson/18-BD Golimumab	M/s. Johnson & Johnson	The proposal was deferred as per request of the firm.
2.	BIO/CT18/FF/2022/ 30484 Secukinumab 150 mg/ml solution for injection in prefilled pen formulation	M/s. Novartis	The proposal was deferred as per request of the firm.
3.	BIO/CT04/FF/2022/ 33034 Tocilizumab	M/s. CuraTeq	The firm presented the Phase I/III protocol titled "A randomized, double blind, multicenter, parallel group study to compare efficacy, safety, immunogenicity, pharmacokinetics and pharmcodynamics of BP08(Tocilizumab) and RoActemra in patients with moderate to severe Rheumatoid Arthritis(RA) with inadequate response to Methotrexate" vide protocol no ICS/CUR/2022-006 Version no 2.0 dated 27.09.2022. After detailed deliberation, the committee recommended to grant permission to conduct the clinical trial as per presented protocol.
4.	BIO/MA/22/00053 Golimumab	M/s. Reliance Life Sciences Limited	The firm presented their proposal for manufacture and marketing of drug product Golimumab Injection 50mg/0.5ml and 100mg/ml in PFS before the committee along with results of Phase III clinical trial including pk-pd data conducted in India. After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of the proposed drug subject to the condition that the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of marketing approval.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
5.	SND/MA/22/000211 Tofacitinib Oral Solution 1mg/ml	M/s. Mascot Health	The firm did not turn up for presentation.
6.	SND/MA/21/000491 Nimesulide Granules for oral Suspension 100 mg	M/s. Dr. Reddy's Laboratories	The firm presented their proposal of manufacturing and market of Nimesulide Granules for Oral Suspension 100mg for "Short-term treatment of inflammatory conditions including joint disorders such as rheumatoid arthritis, post-operative painful conditions and fever" alongwith different measures taken by them for ensuring no misuse in children below 12 years of age before the committee. After detailed deliberation, the committee recommended for manufacture and marketing of the drug product with proposed indication subject to condition that "the drug product should be available only under prescription of a Registered Medical Practitioner. The prescription should contain clearly displayed Medical Council Registration No. of the Physician".
FDC Division			
7.	FDC/MA/21/000179 Pregabalin IP (as prolonged release) + Etoricoxib IP 60mg film coated bilayered tablets	M/s. Ajanta Pharma Ltd.	The firm presented their proposal of Phase IV CT protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase IV clinical trial.
8.	FDC/MA/21/000084 Alcohol IP 36.8% v/w + Ketoprofen IP 2.5%w/w Gel	M/s. Akums Drugs & Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 10.02.2022, the firm presented the Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial. The results of the study should be presented before the committee for further consideration.
9.	FDC/MA/22/000287 Camylofin Dihydrochloride 25mg + Paracetamol IP 300mg Film Coated tablet	M/s. Pure & Cure	The committee noted that the FDC is already under examination under 18 months policy decision. Hence the committee deferred the proposal.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Device Division			
10.	IMP/MD/2021/41651 INNOTERE 3D Scaffold	M/s. Avana Medical Devices Pvt. Ltd.	The firm did not turn up for presentation.