Recommendations of the SEC (Analgesic & Rheumatology) made in its 97th meeting held on 07.06.2023 at CDSCO HQ New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2022/ 32816 Anifrolumab concentrate for solution for infusion 150 mg/ml	M/s. AstraZeneca Pharma India Limited	In light of earlier SEC recommendation dated 14.12.2022, the firm presented the proposal for grant of permission for import and marketing the drug along with request for local Phase III clinical trial waiver with a commitment to conduct Phase IV clinical trial study. After detailed deliberation the committee reiterated its earlier recommendation dated 14.12.2022.
2.	BIO/CT18/FF/2022/ 35426 Guselkumab Solution for Injection 100 mg/ml in Single-use Pre-filled syringe and Prefilled Pen	M/s. Johnson & Johnson Pvt. Ltd.	The firm didn't turn up for presentation.
SND Division			
3.	SND/CT/23/000001 Nimesulide Granules for oral suspension 100mg	M/s. Dr. Reddy's Laboratories Limited	The firm presented the proposal for grant of permission to conduct Phase IV clinical trial for Nimesulide Granules for oral suspension 100 mg indicated for the treatment of inflammatory conditions including joint disorders such as Rheumatoid Arthritis, post traumatic and post –operative painful conditions and fever. The detailed deliberation , the committee made the following recommendations that 1. The firm should mention the no. of study centers and where the study is to be conducted. 2. In Exclusion criteria it is mentioned that Patients detected with / suffering from any major organ system disorder as per physician's clinical discretion, hence it should be clearly specifiedwhich organ system or which condition they are excluding. Accordingly, the firm should submit the revised protocol to CDSCO for further review by the committee.

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4.	SND/MA/23/000001 Tofacitnib Oral Solution 1 mg/ml	M/s. MSN Laboratories Pvt. Ltd.	The firm presented the proposal for grant of permission for manufacturing and marketing of Tofacitinib Oral solution 1mg/ml for the treatment of juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older along with the results of clinical trial conducted in Indian and Asian patients by innovator and summary on safety data in pediatrics patients with request for local clinical trial and BA/BE study wavier. The committee noted that the Tofacitinib Oral solution 1mg/ml was already approved in USA on 06th Nov 2012, Europe on 22nd Mar 2017, for the treatment of juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the drug in the country subject to condition that the firm should conduct Phase IV clinical trial. Accordingly, firm should submit Phase IV clinical trial protocol within 3 months from the date of approval of the drug for further review by the committee.
FDC Division			
5.	FDC/MA/23/000132 Polmacoxib 2mg + Paracetamol 325mg tablets	M/s. Hetero Labs Limited.	The firm presented the proposal along with BE Study and Phase-III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the BE Study and conduct that trial subject to the condition to include following screening tools should be included to exclude patients of significant cardiovascular diseases: 1. History of angina, 2. History of myocardial infarction or stroke or TIA., 3. History of PTCA or CABG, 4.12-lead resting ECG, BP measurement at 2 separate occasions 30 minutes apart, ankle brachial blood pressure index, serum NT-pro-BNP level.
6.	FDC/MA/23/000144 Calcium Orotate 1120mg + Magnesium	M/s. Overseas Health Care Pvt. Ltd.	The firm presented the proposal before the committee along with request for BE study waiver and Phase-III clinical trial waiver. After detailed deliberation, the committee recommended for grant of

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	Hydroxide 180mg + Vitamin D31000IU Tablets		permission for manufacturing and marketing the FDC subject to condition that firm should conduct the active post marketing surveillance study. Accordingly, the firm should submit the Active PMS study protocol within three months from the date of approval of the drug for further review by the committee.
7.	FDC/MA/23/000134 Ferrous Fumarate 30mg + Niacinamide 10mg + Pyridoxine Hydrochloride 1mg + Folic Acid 250mcg + Riboflavin 1.2mg + Zinc Sulphate Monohydrate 20mg + Thiamine Mononitrate1.2mg + Cyanocobalamin (Vit B12) 2.5mcg + Ascorbic Acid (Coated) (Vit.C) 40mg Capsules	M/s. Hindustan Laboratories Limited	The firm presented the proposal before the committee along with request for BE study waiver and Phase-III clinical trial study waiver. The committee noted the following: 1. The doses of various ingredients are sub-optimal. 2. The firm could not present any rationale, safety and efficacy data w.r.t the proposed FDC. 3. The indication proposed by the firm i.e vitamins deficiency is not appropriate as FDC contains Vitamins alongwith Ferrous Fumarate. In view of above, after detailed deliberation, the committee recommended that, the firm should submit above mentioned data and the justification for the FDC to CDSCO and proposal should be reviewed in SEC (Endocrinology & Metabolism).
8.	FDC/MA/21/000176 Tramadol HCl IP 37.50mg + Acetaminophen IP 325mg tablets	M/s SciTech	In light of the earlier recommendations dated 16.05.2023, the firm presented the proposal before the committee along with request for Phase III clinical trial waiver. The committee considered the request for Phase III clinical trial waiver. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the FDC subject to condition that the firm should conduct Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol within three months from the date of approval of the drug for further review by the committee
GCT Division			
9.	CT/148/22 Online Submission	M/s. Novartis	In light of earlier SEC dated 15-03-2023, the firm presented justification before the

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	(34897) Ianalumab		committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the proposed study subject to condition that India specific protocol addendum is required to be submitted for including patients of overlap syndrome (patient satisfying criteria of >1 autoimmune rheumatic disease) in the study since the same is not mentioned in clinical study protocol (CSP) under inclusion criteria.
10.	CT/15/23 Online Submission (36161) BI 685509	M/s. IQVIA	The firm presented Phase II clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the proposed study.
11.	CT/124/21 Online Submission (25963) Tofacitinib	M/s. Pfizer	The firm presented the proposal for increase of number of subjects from 15 to 21 from India before the committee. After detailed deliberation, the committee recommended for approval for increase of the number of subjects from 15 to 21 from India.