Recommendations of the SEC (Analgesic & Rheumatology) made in its 1st/24 meeting held on 16.01.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/90/23 Online Submission Anifrolumab (MEDI-546)	M/s. AstraZeneca	The firm didn't turn up for presentation.
2.	CT/157/23 Online Submission (40152) Abatacept (DRL_AB)	M/s Dr. Reddy's Laboratories Limited.	The firm presented Phase I clinical trial study protocol No. AB-01-001. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm with condition that the firm should include more geographically distributed Government sites.
3.	CT/15/23 Online Submission (27610) BI 685509	M/s IQVIA RDS	In light of the earlier recommendation dated 05.12.2023, wherein the protocol number 1366-0031, amendment version 3.0 dated 11 May 2023 was recommended for approval, however, the firm was asked to submit justification w.r.t. increase in number of subjects from 06 to 20, the firm presented justification before the committee. After detailed deliberation, the committee recommended for approval for increase in the number of subjects in India from 06 to 20 as presented by the firm.
4.	CT/179/22 Online Submission (35422) DRL Tocilizumab (DRL_TC)	M/s Dr. Reddy's Laboratories Limited	The firm presented Phase III clinical trial study protocol No. TC-01-003. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm with condition that atleast 30 percent subjects shall be enrolled from Government sites in India.
Biological Division			
5.	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	In continuation to earlier SEC deliberations dated 15.03.2023 & 08.08.2023, the firm presented safety data generated from global clinical trial study along with justification for proposal to import and market Guselkumab solution for injection 100 mg/ml indicated for Psoriatic Arthritis with local clinical trial

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			waiver. The committee noted that the drug is approved in USA, Japan, EU, Canada, Switzerland & Australia and having novel mechanism of action. The firm is conducting 04 Global Clinical Trials in other indications by including Indian subjects. The committee also noted that there is unmet need for the drug in Psoriatic Arthritis treatment. After detailed deliberation, the committee recommended for grant of permission to import and market Guselkumab solution for injection 100 mg/ml indicated for Psoriatic Arthritis with Phase-III clinical trial waiver subject to the following conditions – 1. The firm shall conduct Phase-IV clinical trial in India for the proposed indication with at least 100 patients. Accordingly, protocol to conduct phase-IV study shall be submitted to CDSCO within 3 months of grant of marketing authorization. 2. Patients shall be screened for QuantiFERON-TB Gold test before initiation of treatment and at regular intervals during the treatment. 3. Prescribing information of the drug product shall be submitted to CDSCO for further review.
6.	BIO/CT04/FF/2023/39220 Tocilizumab 20mg/ml	M/s Curateq	The firm presented their proposal to conduct Phase I clinical trial titled – "A randomized phase 1, double-blind, single dose, three-arm, parallel group comparative Pharmacokinetic, Pharmacodynamic, safety, and immunogenicity assessment of BP08 (Tocilizumab) versus US licensed Actemra® and EU approved RoActemra® administration through the intravenous infusion route in healthy adult male subjects" vide protocol No. BP08-101; version No.: 01; Dated: 16 Aug 2023. After detailed deliberation, the committee recommended for approval of the Phase I clinical trial protocol presented by the firm.

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BA/BE Division			
7.	File No. 12-09/2023/BA-BE/MISC-38/DC BABE/CT05/FF/2023/39352 Probenecid Oral Suspension 100mg/ml	M/s. Vayam Research Solutions Limited	The firm presented their proposal along with the protocol of the BA/BE study for export purpose only. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study (for export purpose only) with a condition to revise the protocol with exclusion criteria w.r.t. G6PD deficiency. Accordingly, the firm should submit the revised protocol to the CDSCO.
8.	File No. 12-09/2023/BA-BE/MISC-39/DC BABE/CT05/FF/2023/39346 Probenecid Oral Suspension 100mg/ml	M/s. Vayam Research Solutions Limited	The firm presented their proposal along with protocol of the BA/BE study for export purpose only. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study (for export purpose only) with a condition to revise the protocol with exclusion criteria w.r.t. G6PD deficiency. Accordingly the firm should submit the revised protocol to the CDSCO.
9.	File No. 12-09/2023/BA-BE/MISC-41/DC (BABE/CT05/FF/2023/39112) Tenoxicam IR + Thiocolchicoside SR Capsules 20 mg+8mg	M/s. Dr. Reddy's Laboratories Limited, Telangana.	The firm presented their proposal along with protocol of the BA/BE study for export purpose only. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study (for export purpose only) with a condition to revise the protocol with exclusion criteria w.r.t. G6PD deficiency, Lactose intolerance and abnormal LFT results, etc. Accordingly the firm should submit the revised protocol to the CDSCO.
SND Division			
10.	SND/MA/23/000243 19.09.2023 Ketorolac Tromethamine Sublingual Tablet 10mg	M/s. Troikaa Pharmaceuticals Ltd.	The firm presented their proposal for grant of permission to manufacture and marketing of Ketorolac Tromethamine sublingual tablet 10mg along with BE study protocol (Protocol No. 22-VIN-0433, version No.- 01, Dated 16.12.2023) before the committee. After detailed deliberation, the committee recommended for grant of permission to

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			conduct the bioequivalence study of Ketorolac Tromethamine sublingual tablet 10mg as per protocol presented by the firm.
FDC Division			
11.	FDC/MA/23/000341 Diclofenac Diethylamine IP 2.32 eq. to Diclofenac Sodium 2% w/w + Methyl Salicylate IP 10% w/v + Menthol 5% w/w topical nano dispersion	M/s. Pulse Pharmaceuticals Pvt. Ltd.	The firm presented their proposal before the committee. The committee noted that the proposed formulation include new technology of drug delivery by tropical nano dispersion. After detailed deliberation, the committee recommended to conduct comparative clinical or pharmacodynamic studies to prove equivalence of proposed FDC with already approved similar FDC. Accordingly, clinical trial protocol should be submitted to CDSCO for review.