Recommendations of the SEC (Analgesic & Rheumatology) made in its 103rd meeting held on 05.12.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT21/FF/2023/39520 Golimumab solution for Injection 50mg and 100mg	M/s. Reliance Life Sciences	The firm presented the proposal for approval of additional indications of Psoriatic Arthritis and Ankylosing Spondylitis for the drug Golimumab solution for injection 50mg and 100mgby the way of extrapolation in line with the approved indications of innovator drug. After detailed deliberation, the committee recommended for approval of proposed additional indication of Ankylosing Spondylitis by way of extrapolation in line with the approved indications of innovator drug. Further, for the indication of Psoriatic Arthritis, the committee recommended for approval by extrapolation with a condition to conduct Phase-IV study in Indian patients for the said indication. Accordingly, the firm should submit the Phase IV clinical trial protocol to CDSCO within three months of approval for the proposed indication of Psoriatic Arthritis.
2.	BIO/CT18/FF/2022/34526 Guselkumab Solution for Injection 100mg/ml in Single use pre-filled syringe and Prefilled Pen	M/s. Johnson & Johnson Pvt. Ltd.	The firm did not turn up for the presentation.
3.	BIO/CT04/FF/2023/39157 Golimumab solution for Injection 50mg/0.5ml in PFS	M/s. Reliance Life Sciences	The firm presented the protocol to conduct Phase IV clinical trial for the drug product Golimumab 50mg/0.5ml solution for injection in pre-filled syringe (PFS) titled “A prospective, multi-centre, open label, phase IV study to evaluate safety and efficacy profile of GolimuRel™ in patients with moderately to severely active rheumatoid arthritis on a stable dose of methotrexate” vide protocol RLS/PMS/2023/04 Version 2.0 dated 30.10.2023. After detailed deliberation, the committee recommended for approval of the

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			presented Phase IV clinical trial protocol.
4.	BIO/CT21/FF/2023/39464 Ustekinumab injection45mg/0.5ml and 90mg/Ml	M/s. Reliance Life Sciences	The firm presented the proposal for approval of indication of Psoriatic Arthritis for drug Ustekinumab solution for Injection (45 mg/0.5ml & 90 mg/ml in PFS) by way of extrapolation in line with the approved indications of innovator drug. After detailed deliberation, the committee recommended for the approval of the proposed indication of Psoriatic Arthritis by extrapolation with a condition to conduct Phase-IV study in Indian patients for the said indication. Accordingly, the firm should submit the Phase IV clinical trial protocol to CDSCO within three months of approval for the proposed indication of Psoriatic Arthritis.
SND Division			
5.	SND/CT/23/000001 Nimesulide granules for oral suspension 100mg	M/s. Dr. Reddy's Laboratories	In light of earlier SEC recommendation dated 07.06.2023, 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. After detailed deliberation, the committee recommended for approval of the Phase IV clinical trials in adults only. (Protocol Version 4.0 dated: 13 Oct 2023) Further, committee also suggested that firm should ensure that proposed formulation shall be marketed for adult population only.
GCT Division			
6.	CT/135/21 Online Submission (26389) Tofacitinib(CT-690,550)	M/s. Pfizer Limited	The firm presented the proposal for increase in the subject number in India from 15 to 22 vide Protocol no. A3921145 After detailed deliberation, the committee recommended for approval of increase in number of subjects in India from 15 to 22

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			as presented by the firm.
7.	CT/69/23 Online Submission (37948) Anifrolumab(MEDI-546) or Placebo 150 mg/mL (0.8 mL fill volume)	M/s. AstraZeneca	The firm presented Phase III clinical study Protocol No. D3460C00002. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm.
8.	CT/82/23 Online Submission (38165) Afimetoran,(BMS-986256)	M/s. Bristol-Myers	The firm presented PhaseII clinical study Protocol No. IM026-024. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm.
9.	CT/90/23 Online Submission (38667) Anifrolumab(MEDI-546)	M/s. AstraZeneca	The firm did not turn up for presentation.
10.	CT/15/23 Online Submission (27610) BI 685509	M/s. IQVIA	The firm presented protocol amendment version 3.0 dated 11 May 2023 Protocol no. 1366-0031. After detailed deliberation, the committee recommended for approval of the Protocol amendment as presented by the firm. However,Justification need to be submitted by the firm before the SEC for increasing the number of subjects from 06 to 20 in India.
11.	CT/107/23Online Submission (39435) Abatacept	M/s. Dr. Reddy's Laboratories	The firm presented Phase III clinical study Protocol No. AB-01-004. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm
12.	CT/120/23 Online Submission (39724) SAR441566 50 mg and 100 Tablets	M/s. Sanofi	The firm presented Phase II clinical study Protocol No. DR117821. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm subject to condition that inflammatory bowel diseases shall be taken as one of the exclusion criteria.The specific names of high potency opioids must be mentioned in the exclusion criteria of the study protocol.

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13.	CT/54/22 Online Submission (28256) Ianalumab	M/s. Novartis	The firm presented Protocol amendment version 01 dated 25 May 2023 clinical study Protocol No. CVAY736A2302. After detailed deliberation, the committee recommended for approval of the Protocol amendment as presented by the firm.
14.	CT/124/21 Online Submission (29558) Tofacitinib	M/s. Pfizer Limited	The firm presented Protocol amendment 08 dated 01 September 2023 clinical study Protocol No. A3921165. After detailed deliberation, the committee recommended for approval of the Protocol amendment as presented by the firm.