Recommendations of the SEC (Analgesic & Rheumatology) made in its 03rd/25 meeting held on 19.03.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/107/23 Online Submission (37601) Abatacept	M/s Dr. Reddys Laboratories Limited	The firm presented protocol amendment Version 3.0 dated 02 Sep 2024 protocol no. AB-01-004 After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/143/24 Online Submission (37754) ESK-001	M/s Synoes Health India Pvt. Ltd.	The firm presented for Increase in number of subjects from 40 to 57 (Protocol version 4.0 dated 29 January 2024 for Protocol Addendum no.1 dated 17 February 2025) protocol no.ESK-001-010. After detailed deliberation, the committee recommended for approval of Increase in number of subjects from India 40 to 57 as presented by the firm with condition that Post Trial Access, if required, shall be provided to patients.
3.	CT/58/23 Online Submission (37828) LY3871801	M/s Eli lily and Company	The firm presented for Increase in number of patients from India 37 to 57 for phase 2a study Protocol No.: J3P-MC-FTAF8. After detailed deliberation, the committee recommended for approval of Increase in number of patients from India 37 to 57 for phase 2a part of the study as presented by the firm.
Biological Division			
4.	F. No. BIO/CT/23/000103(E-62157) Ustekinumab Solution for Injection: 45mg/0.5ml & 90mg/ml, in PFS	M/s Reliance Life Sciences Pvt. Ltd	In light of earlier SEC recommendations dated 05.12.2023 and 13.12.2023, the firm presented the revised Phase IV clinical trial protocol vide Protocol No. RLS/PMS/2023/05, Version 3.0 dated 09.07.2024 after including the additional indications of Plaque psoriasis, Psoriatic arthritis, Ulcerative colitis and Crohn's disease in the study protocol. After detailed deliberation, the committee recommended to conduct the proposed

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			Phase IV clinical trial as per the protocol presented by the firm.
SND Division			
5.	SND/MA/24/000072 Paracetamol Oral Suspension IP 500 mg/5 ml	M/s PURE & CURE HEALTHCARE Pvt. Ltd	The firm presented their proposal for grant permission to manufacture and marketing of Paracetamol Oral Suspension 500mg/5ml along with BE study result of proposed test product with the approved reference formulation Paracetamol Oral Suspension 500mg/5ml Manufactured by Rosemont Pharmaceuticals Ltd (UK) before the committee. Firm has informed that, similar formulation is approved in the UK and the proposed formulation is bioequivalent with approved reference formulation. After detailed deliberation, the committee recommended to grant of permission to manufacture and marketing of paracetamol oral Suspension IP 500mg/5ml for the treatment of mild to moderate pain and treatment of fever for adult and adolescent over the age of 16 years.
6.	SND/MA/24/000059 Ropivacaine Injection IP 2mg/ml (200mg/100ml)	M/s Amneal Pharmaceuticals Private Limited	The firm presented their proposal for grant of permission to manufacture and marketing of Ropivacaine Injection IP 2mg/ml (200mg/100ml) Indicated for production of local or regional anesthesia for surgery and for acute pain

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			management before the committee. Firm has informed that, Ropivacaine HCL monohydrate solution for infusion 2 mg /ml (250 ml) ready to use formulation is already approved in India. and proposed generic drug product has been already approved & commercialized in US market with ANDA number # 216605 to Amneal Pharmaceuticals. After detailed deliberation, the committee recommended for grant of permission to manufacture and market of Ropivacaine Injection IP 2mg/ml (200mg/100ml) for applied indication.