Recommendations of the SEC (Analgesic & Rheumatology) made in its 06th/24 meeting held on 12.06.2024 & 13.06.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/75/24 Online Submission (43476) VAY736 (Ianalumab)	M/s. Novartis Healthcare Private Limited	The firm presented Phase II clinical study protocol no. CVAY736S12201 version 00 dated 06.3.2024, After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/69/23 Online Submission (32913) Anifrolumab	M/s. AstraZeneca Pharma India Limited	The firm presented protocol amendment version 3.0 dated 07. 3. 2024 protocol no. D3460C00002. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/55/23 Online Submission (33002) EKS-001	M/s. InVentiv International Pharma Services Private Limited	The firm presented protocol amendment 1 version 4.0 dated 29.1.2024 protocol no. ESK-001-010. After detailed deliberation, the committee opined that the firm should submit changes made in (tabular form) with earlier protocol with rationale for further review by the committee.
Biological Division			
4.	BIO/CT18/FF/2022/ 30484 Secukinumab 150mg/mL solution for injection	M/s. Novartis Healthcare Pvt. Ltd.	In light of the earlier SEC recommendation dated 29.04.2022, the firm presented the justification for usage of dose up to 300 mg based on clinical response for the product Secukinumab 150mg/mL solution for injection in Pre filled pen along with the request for waiver of requirement to generate PMS data in the country for the indications of psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis. After detailed deliberation, the committee recommended the following- 1. The committee recommended the usage of dose up to 300mg only in patients who continues to have active Psoriatic Arthritis and active ankylosing spondylitis in line with

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			USFDA approved PI. 2. The committee reiterated the earlier recommendation for generating the PMS data in the country to assess patient safety for the indications of psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondylo arthritis.
5.	BIO/CT04/FF/2021/ 29805 Rituximab Injection	M/s. Cliantha Research Limited	The firm presented the proposal for conduct of Phase- I/III clinical trial titled "A Randomized, Double-Blind, Multicenter, Parallel-Group, Active-Controlled Study to Evaluate Pharmacokinetics, Pharmacodynamics, Efficacy and Safety of Ipca's Rituximab (IPB004) Compared to Reference Biologic (MabThera®) in Subjects with Moderate to Severe Active Rheumatoid Arthritis" vide Protocol No C2A01733, Version no. 01 dated 22.12.2021. After detailed deliberation, the committee recommended for approval to conduct the study with the following changes in the protocol- 1. The study protocol should include the tests for immunoglobulins IgG and IgA in addition to IgM at baseline and at 3 months interval of the study. 2. The number of evaluable subjects should not be less than 100 in test arm. Accordingly, the firm should submit the revised protocol to CDSCO for further evaluation.
6.	r-DNA-11011(18)/ 75/2024-eoffice Denosumab 60mg/ml solution for injection	M/s. DRL	In light of earlier SEC recommendation dated 08th & 09th Nov 2023, the firm presented the justification for removal of warning statement i.e. "Risk of flare up of latent infection/ latent tuberculosis" in the PI of the product Denosumab (Prolia) 60 mg/ml Subcutaneous Injection. After detailed deliberation, the committee agreed for removal of warning statement of "Risk of flare up of latent infection/ latent tuberculosis" in the PI. However, the committee recommended to include the following statement under the section

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			of 'Special Warnings and Precautions for use' in the package insert of Denosumab (Prolia) 60 mg/ml Subcutaneous Injection. "Patients receiving denosumab therapy can have high risks of infections. However, the longer the duration of denosumab treatment, the lower the risk patients had of developing infections. Denosumab therapy is associated with a higher infection risk at the early periods of treatment. Nevertheless, the risk attenuates significantly after the 2nd year of therapy. Clinicians should closely monitor infection status in patients with osteoporosis during the initial stages of denosumab therapy". Accordingly, the firm should submit the revised PI to CDSCO for further evaluation.
7.	BIO/CT04/FF/2024/ 41613 Tocilizumab	M/s. Reliance Life Sciences	The firm presented the proposal for the conduct of Phase I clinical trial titled "A randomized, double-blinded, two-arms, single-dose, parallel comparative assessment of pharmacokinetics, pharmacodynamics, safety and immunogenicity of R-TPR-055 (Tocilizumab) and RoActemra®/ ACTEMRA®(Tocilizumab) administered by the intravenous route in normal healthy adult male subjects as per protocol no. RLS/IMM/2023/06 version 1.0 dated 11. 1. 2024. After detailed deliberation, the committee recommended for approval to conduct the study as per the protocol presented by the firm with the condition that firm should recalculate and justify the volume of blood sample drawn from the subjects for clinical tests. Accordingly, the revised protocol after recalculation of blood volume shall be submitted to CDSCO for further evaluation.
8.	E-2415 and E-36322 Golimumab	M/s. Reliance Life Sciences	The firm presented the proposal for update in Package Insert Version September 2023 for the drug product Golimumab solution for injection

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			50mg/0.5mL and 100mg/mL PFS (r-DNA origin). The committee noted that the changes are proposed in 'Therapeutic indication and Special warnings and precaution for use' that are related to additional indications which are not yet approved by CDSCO. After detailed deliberation, the committee recommended the firm to submit the updated PI with proposed changes after the approval of additional indications by CDSCO.
9.	BIO/CT04/FF/2024/ 42477 Abatacept	M/s. Ecron Acunova Limited	The firm presented the proposal for the conduct of Phase I clinical trial titled "A randomized, Open label, Three-arm, parallel group, single dose comparative pharmacokinetic, pharmacodynamic, safety and immunogenicity study comparing KSHB002 (Abatacept) pre-filled syringe of 125 mg/mL with US-licensed ORENCIA 125 mg/mL and EU-approved ORENCIA 125 mg/mL administered through subcutaneous route in healthy adult human subjects" vide Protocol no. 043-24 Version no. 1, Dated 15.03.2024. After detailed deliberation, the committee recommended the firm to submit the justification for number of healthy adult subjects proposed for conduct of the trial to CDSCO for further evaluation by the committee.
SND Division			
10	SND/MA/23/000303 Flurbiprofen Lozenges 8.75mg	M/s. Unique Pharma Laboratories (A division of JB chemicals & Pharma Limited)	The firm presented their proposal manufacture and marketing of Flurbiprofen Lozenges 8.75mg (Additional Dosage form & Indication) along with Bioequivalence study protocol and justification for waiver of Phase III clinical trial before the committee. After detailed deliberation, the committee recommended to conduct Bioequivalence study as presented by the firm and submit BE study report to CDSCO for further consideration of clinical trial waiver by the committee.

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New Drugs Division			
11	ND/CT/23/000061 Polmacoxib 2mg	M/s. Hetero Labs Limited	The firm presented Phase IV CT protocol with Title "A Phase IV, Post- Marketing, Prospective, Multi-centric, Single Arm, Non- Comparative Study to Evaluate the Safety and Efficacy of Polmacoxib 2mg in Adult Patient with Osteoarthritis of Hip/Knee" before the committee. After detailed deliberation, the committee recommended for Phase IV study subject to the condition that 1. Indian version of WOMAC- OA index to be used for valid assessment of efficacy. 2. Serum NT Pro BNP test at screening and 6 weeks for Cardiovascular safety assessment.
12	ND/CT/24/000027 Remifentanil Hydrochloride 1mg/2mg for Injection	M/s. Themis Medicare Ltd.	The firm presented Phase IV CT protocol Title "A Prospective, Multi-Centre, Open Label, Single-Arm, Non-interventional Observational Focused Pharmacovigilance Study to assess the safety of Remifentanil HCl injection in Indian patients" before the committee. After detailed deliberation, the committee recommended for Phase IV study subject to the condition that the firm shall submit revised protocol to CDSCO after including the following: "The attending anesthetist should administer suitable analgesic before discontinuation of Remifentanil infusion".
13	12-1/24-DC (Pt-77) Dexmedetomidine	Sir Ganga Ram Hospital (SGRH), India.	The applicant presented his academic trial protocol title: "Effect of use of Dexmedetomidine on Propofol requirement and recovery characteristics in TCI-propofol based TIVA in pediatric infra umbilical daycare surgeries" before the committee. After detailed deliberation, the committee recommended for conduct of trial subject to the condition to register the trial in CTRI after approval from IEC.