

Recommendations of the SEC (Analgesic & Rheumatology) made in its 07th/24 meeting held on 16.07.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/08/24 Online Submission (33646) VAY736 (Ianalumab)	M/s. Novartis Healthcare Private Limited	The firm presented protocol amendment version 01 dated 18.01.2024 protocol no. CVAY736A2301E1. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. Dr. Uma Kumar didn't participate in the discussion.
2.	CT/78/24 Online Submission (43727) VAY736 (Ianalumab)	M/s. Novartis Healthcare Private Limited	The firm presented Phase 3b clinical study protocol no. CVAY736F12301E1 version 01 dated 15.09.2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that all the study sites shall be included in this study.
3.	CT/77/24 Online Submission (43742) Anifrolumab (MEDI-546) Solution for injection	M/s. AstraZeneca Pharma India Limited	The firm presented Phase 3 clinical study protocol no. D3463C00003 version 3.0 dated 06.03.2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the CT Scan for tuberculosis screening shall not be mandatory and depend on discretion of investigator. Dr. Liza Rajasekhar didn't participate in the discussion.
Biological Division			
4.	BIO/CT04/FF/2024/ 43390 Abatacept 125mg/ml PFS	M/s. DRL	The firm presented the proposal to conduct Phase III clinical trial titled "A randomised, double-blind, multicentre study to compare the immunogenicity and safety of proposed Abatacept biosimilar (DRL_AB) with Reference abatacept (Orencia®) administered subcutaneously as an add-on to methotrexate in patients with moderately to

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			<p>severely active rheumatoid arthritis” vide Protocol number AB-01-005 Version 1.0 dated 07 Feb 2024.</p> <p>The committee noted that firm has conducted Phase I study in Netherlands and Hungary for Intravenous (IV) route.</p> <p>Further the firm is also conducting following global clinical trials for which India is also participating in the trials;</p> <ul style="list-style-type: none"> • Phase I study (AB-01-001) of the drug by Subcutaneous (SC) route (ongoing) • Phase III study (AB-01-004)by IV route(ongoing) <p>After detailed deliberation, the committee recommended that the firm has to present comparative nonclinical study data generated, status of ongoing global clinical trials along with proposed Phase III protocol for further evaluation by the committee.</p>
5.	<p>BIO/CT04/FF/2024/43387</p> <p>Adalimumab solution for injection 40 mg/0.4 ml</p>	<p>M/s. Shilpa Biologicals Private Limited</p>	<p>The firm presented the proposal to conduct Phase IV study titled “An Open label, Phase IV, Multi-Centric, Post-Marketing Study Evaluating the Safety and Efficacy of Adalimumab in patients with active Rheumatoid Arthritis” vide Protocol No. 24-AGCR-001, Version: 2.0, 05 Jul 2024.</p> <p>After detailed deliberation, the committee recommended the firm to conduct the proposed Phase IV study with the following changes in the protocol-</p> <ol style="list-style-type: none"> 1. The number of evaluable subjects should be at least 200. The number of study sites should be increased accordingly with more government sites. 2. Patients with latent TB (positive QuantiFERON-TB Gold test) should be included in the study provided that local treatment guidelines for TB to be followed. <p>Accordingly, firm should submit the revised protocol to CDSCO for evaluation.</p>
6.	<p>BIO/CT21/BO/2023/39673</p> <p>Adalimumab solution</p>	<p>M/s. Shilpa Biologicals Private Limited</p>	<p>In light of earlier SEC recommendations dated 03.04.2024, the firm presented the proposal for extrapolation to following additional indications in line with the innovator product -</p>

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	for injection 40 mg/0.4 ml		<p>1. Juvenile Idiopathic Arthritis (JIA) 2. Ankylosing spondylitis (AS) and axial spondyloarthritis without radiographic evidence of AS. 3. Psoriatic Arthritis (PsA)</p> <p>After detailed deliberation, the committee recommended that the firm should initiate Phase IV study (in RA indication) and submit the interim safety data for considering the approval of proposed additional indications by way of extrapolation.</p>
7.	BIO/CT04/FF/2024/ 42799 Tocilizumab 80 mg/4 mL, Concentrate for solution for Infusion	M/s. Hetero Biopharma Limited	<p>The firm presented the proposal for conduct of Phase I study titled “A double-blind, randomized, two arm, single dose, parallel study to compare the pharmacokinetics, pharmacodynamics and immunogenicity of intravenous injection of Tocilizumab (Hetero Biopharma Limited) and Reference Medicinal Product (Roche-Tocilizumab) in healthy, adult, human subjects” vide Protocol No. HCR/I/TOCIHV/11/2022 Version 1.0 dated 27.02.2024.</p> <p>After detailed deliberation, the committee recommended for the approval of the protocol presented by the firm.</p>
FDC Division			
8.	FDC/MA/22/000341 Paracetamol IP 325mg + Tapentadol Hydrochloride IP 50mg (as extended release) tablet	M/s. MSN Laboratories	<p>In light of earlier SEC recommendation dated 02.05.2024, the firm presented their proposal along with BE study protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. Accordingly, firm should submit BE study report along with Phase III CT protocol to CDSCO for review by the committee.</p>