Recommendations of the SEC (Analgesics, Anesthetics and Orthopedics) made in its 7th/26 meeting held on 28.07.2026 at CDSCO HQ New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT21/BO/2025/54027 Abatacept (DRL_AB) 250mg/Vial Lyophilized powder for concentrate for solution for intravenous infusion	M/s. Dr. Reddy's Laboratories Limited.	The firm presented the proposal for the grant of permission to manufacture and market the drug product Abatacept 250mg/Vial Lyophilized powder for concentrate for solution for intravenous infusion. The Committee noted that the firm has conducted a global phase-3 study to compare the efficacy, safety & immunogenicity of DRL_AB with the reference drug product (EU approved Orencia) administered by the IV route as an add-on to methotrexate in the treatment of moderate to severe rheumatoid arthritis. The committee further noted that the firm has applied for the extrapolation of the indications as per the Biosimilar guideline of CDSCO. After detailed deliberation, the committee recommended for the grant of permission to the firm to manufacture and market Abatacept (DRL_AB) 250mg/Vial Lyophilized powder for concentrate for solution for intravenous infusion for the below-mentioned indications (in line with EMA), with a condition to conduct a Phase IV study in the country for the approved indications. Rheumatoid arthritis: Abatacept, in combination with methotrexate, is indicated for: • the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate (MTX) or a tumour necrosis factor (TNF)-alpha inhibitor. • the treatment of highly active and progressive disease in adult patients

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			with rheumatoid arthritis not previously treated with methotrexate Psoriatic arthritis: Abatacept, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients when the response to previous DMARD therapy including MTX has been inadequate, and for whom additional systemic therapy for psoriatic skin lesions is not required. Accordingly, the protocol to conduct the Phase IV study shall be submitted to CDSCO within 3 months of grant of marketing authorization permission to manufacture and market the drug product.
2.	BIO/CT04/FF/2026/54979 Tocilizumab 162mg/0.9ml (180mg/ml) solution for injection in PFS	M/s. Reliance Life Sciences Pvt. Ltd.	The firm presented a proposal to conduct a Phase-1/3 clinical trial titled, "A prospective, multi-center, randomized, double-blind, two-arm, parallel group, comparative clinical study to evaluate efficacy, safety, pharmacokinetics and immunogenicity of R-TPR-055 (RLS-Tocilizumab) with RoActemra®/ Actemra® administered by subcutaneous injection in patients with moderately to severely active rheumatoid arthritis on a stable dose of methotrexate vide protocol no. RLS/IMM/2025/06; Version 1.0, Dated: 03 Nov 2025. After detailed deliberation, the committee recommended the following changes in the study protocol: 1. Reference product shall be specified in the study protocol instead of mentioning either of the brands as RoActemra®/Actemra®. 2. Comparative Analytical & functional similarity data shall be submitted for the clinical trial batches. 3. Mantoux test shall be removed from the screening tests. 4. The stool occult blood test should be included in the screening tests. 5. Subjects on stable dose between 20 to 25mg/week methotrexate prior to screening shall be included instead of

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			10-25mg/week. 6. Clinical trial sites shall be geographically distributed. 7. Justification for the appropriateness of the overall sample size and the statistical margins used in the subject Phase-1/3 study. Accordingly, the firm shall submit the revised protocol to the CDSCO for further evaluation by the committee.
3.	BIO/CT04/FF/2026/55354 Rituximab concentrate for solution for infusion 100mg/10 ml & 500mg/50ml in vials (r-DNA origin)	M/s. Reliance Life Sciences Pvt. Ltd.	The firm presented a proposal to conduct a Phase-1 clinical trial titled, "A Prospective, Multicenter, Randomized, Double-Blind, Parallel-Group, Two-Arm Clinical Study to Evaluate the Pharmacokinetic Similarity, Comparative Pharmacodynamics, and Safety of R-TPR-017 (RLS-Rituximab) with reference MabThera®/ Ristova®in Patients with Moderately to Severely Active Rheumatoid Arthritis vide Protocol no. RLS/IMM/2026/04; Ver 1.0, Dated: 17 Feb 2026. After detailed deliberation, the committee recommended the grant of permission to conduct the Phase I clinical trial meant for export purpose subject to the following changes in the study protocol: 1. Reference product shall be specified in the study protocol instead of mentioning either of the brands as MabThera®/Ristova®. 2. Testing for anti-HBc shall be included in the screening procedures in addition to HBsAg testing. 3. Pre-medication detailsshall be specified during screening of patients. 4. Effective contraception should be maintained for 12 months after treatment 5. Clinical trial sites shall be geographically distributed Accordingly, the firm shall submit the revised protocol to the CDSCO for further evaluation.

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4.	E-receipt no. 149426 Secukinumab 150 mg/mL solution for injection in pre filled pen	M/s. Novartis Healthcare Private Limited	The firm presented a proposal to conduct a PMS study titled, "A prospective, observational, multicentre study to assess the safety of subcutaneous Secukinumab 150 mg solution for treatment in adult Indian participants with Axial Spondyloarthritis (axSpA), Ankylosing Spondylitis (AS), and Non-Radiographic Axial Spondyloarthritis (nr-axSpA) over a period of 16 weeks vide Protocol No. v00 dated 30.04.2026" After detailed deliberation, the committee recommended for grant of permission to conduct PMS study as per the protocol presented by the firm.
FDC Division			
5.	FDC/MA/25/000225 Caffeine 100 mg + Ibuprofen 400 mg Granules	M/s. AET Laboratories Pvt. Ltd.	The firm presented their proposal along withBE study report conducted for export purpose and justification for Phase III CT waiver before the committee. The committee noted that the said FDC is already approved in Europe. However, no clinical safety and efficacy data was presented by the firm in Indian population. After detailed deliberation, the committee considered BE study report conducted for export purpose. As regard to Phase III CT waiver was not considered at this stage. Accordingly, the firm should submit safety and efficacy data on Indian population as stated by the firm to CDSCO for further review by the committee.