Recommendations of the SEC (Analgesic & Rheumatology) made in its 12th meeting held on 04.12.2024 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/134/24 Online Submission (46317) Cenerimod (ACT-334441)	M/s. Mylan Pharmaceuticals Private Limited	The firm did not turn up for the presentation.
Biological Division			
2.	BIO/CT04/FF/2024/43671 E-59263 Tocilizumab Injection80mg, 200mg and400mgin vial	M/s. Reliance Life Sciences Pvt. Ltd.	In light of earlier SEC recommendation dated 04.09.2024, the firm presented the revised protocol to conduct Phase III clinical trial titled "A prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative Phase III clinical study to evaluate efficacy, safety, pharmacodynamics and immunogenicity of R-TPR-055 (Tocilizumab) with RoActemra®/Actemra® in patients with moderately to severely active rheumatoid arthritis on a stable dose of methotrexate" vide Protocol No. RLS/IMM/2024/01 Version 2.0 Dated 30 Sep 2024. After detailed deliberation, the committee recommended for approval to conduct the Phase III study as per revised protocol presented by the firm.
3.	E-53911 Adalimumab Injection 20mg/0.2mL,40mg/0.4mL, 80mg/0.8mL	M/s. Enzene Biosciences Ltd.	The firm presented the final clinical study report (CSR) of Phase IV clinical trial titled "A prospective, multicenter, Open labelled, Phase IV study to evaluate safety & Efficacy of Biosimilar Adalimumab injection of Enzene Biosciences Ltd. in subjects with active Ankylosing spondylitis (AS)" conducted vide Protocol No.: ALK29/ENZ129-ADA2; Version:2.0 dated 07.08.2023. After detailed deliberation, the committee noted the results of the Phase IV clinical trial presented by the firm.
FDC Division			
4.	FDC/MA/24/000132 Esomeprazole MagnesiumTrihydrate	Zim Laboratories Limited	The firm presented the proposal along with BE study report carried out for export purpose for the FDC of Naproxen IP 500 mg + Esomeprazole Magnesium

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	20 &20(mg) + Naproxen 375 &500 (mg) (Capsules).		Trihydrate IP 20mg capsule with the internationally available innovator's FDC((VIMOVO 500 mg/20mg Modified Release Tablet) before the committee. Committee noted that central government vide gazette notification dated 12.08.2024 has restricted FDC of Naproxen IP 375mg + Esomeprazole Magnesium Trihydrate IP 20mg hard gelatin Capsules or Tablets under section 26A of Drugs and Cosmetics Act, 1940 for manufacture, sale and distribution subject to the following conditions, namely: (i) Naproxen is in an enteric coated form. (ii) The FDC is indicated in adults for the symptomatic treatment of osteoarthritis rheumatoid arthritis and ankylosing spondylitis, in patients who are at risk for developing non-steroidal anti-inflammatory drug (NSAID)-associated gastric and/or duodenal ulcers, to reduce the risk of developing gastric and duodenal ulcers and as per treatment guidelines. (iii) Demonstration of bioequivalence of the FDC with the internationally available innovator's FDC. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC
5.	FDC/MA/24/000261 Domperidone Maleate IP Eq. to Domperidone 10(mg) I.P.+ Naproxen IP (As Sustain Release Form) 750(mg) I.P (Tablet)	PURE & CURE HEALTHCARE Pvt. Ltd	The firm presented the proposal along with BE study protocol before the committee. Committee noted that proposed strength of the FDC is not yet approved by CDSCO. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study subject to the submission of Phase III CT Protocol. Accordingly, Phase III CT Protocol should be submitted to CDSCO for further review by the committee.

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BA/BE Division			
6.	BE/BE/CT05/FF2024 /45192 Methotrexate Tablets 10 mg	M/s. Cliantha Research Ltd.	The firm presented the protocol No. C1B04863, Version No. 01, Protocol Date 30-Aug-2024. After detailed deliberation, the committee recommended for grant of permission to conduct of the study for export purpose only subject to condition that the firm should include serum procalcitonin (to be tested within 48 hrs. prior to the dosing) in the screening tool for sepsis before the study drugs are administered to the participants. The firm should submit the amended protocol to CDSCO for review.