Recommendations of the SEC (Analgesic & Rheumatology) made in its 09th/24 meeting held on 04.09.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2024/ 43671 Tocilizumab Injection 80mg, 200mg and 400mg in vial	M/s Reliance Life Sciences	The firm presented the proposal 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 number: RLS/IMM/2024/01 version 1.0, Dated 29 Apr 2024. After detailed deliberation, the committee recommended to revise the following in the protocol. 1.Disease duration of atleast six month before screening shall be included instead of three months. 2. Subjects on a stable dose between 20 to 25 mg/week methotrexate prior to screening shall be included instead of 10-25mg/week 3.Patients with uncontrolled hyperlipidemia shall be excluded. 4. The TB test such as QuantiFERON®-TB Gold test andTuberculin skin test/ Mantoux test shall be removed from the study schedule of week 24 and end of study 5. The stool occult blood test should be included in the screening test 6. ACR 50 and ACR 70 should be accessed in the efficacy parameter. Accordingly, the firm is required to submit revised protocol to CDSCO for further evaluation by the committee .
2.	E-42179 (Golimumab 50mg in PFS)	M/s Reliance Life Sciences	The firm presented the amendment in protocol for the conducting Phase IV clinical trial vide RLS/PMS/2023/04 version 3.0 dated 04 Mar 2024 by

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			including the additional indications of psoriatic arthritis and ulcerative colitis titled as "A prospective, multi-centre, open label, Phase IV study to evaluate safety and efficacy profile of GolimuRel® (Golimumab manufactured by Reliance Life Sciences Pvt. Ltd.) in rheumatoid arthritis, psoriatic arthritis and ulcerative colitis. After detailed deliberation, the committee recommended the firm to conduct the proposed Phase IV study with the following changes in the protocol Subjects on a stable dose between 20 to 25 mg/week methotrexate prior to screening shall be included instead of 15mg/week. Accordingly, the firm should submit revised protocol to CDSCO for further evaluation.
3.	BIO/CT04/FF/2024/ 43390 Abatacept 125mg/ml PFS	M/s DRL	In light of the earlier SEC recommendation dated 16.07.2024, the firm presented the comparative nonclinical study data, status of ongoing global clinical trials along with proposed Phase III protocol 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 severely active rheumatoid arthritis" vide Protocol number: AB-01-005 ,Version: 1.0 dated 07.02.2024. After detailed deliberation, the committee recommended the firm to conduct the proposed Phase III study with following changes in the protocol Subjects on a stable dose of Methotrexate between 20 to 25 mg/week prior to screening shall be included instead of 15mg/week dose.

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			Accordingly, the firm should submit revised protocol to CDSCO for further evaluation
Medical Devices Division			
4.	CI/MD/2022/75448 3-D scaffold matrix	M/s EffecMed Private Limited	The firm presented the revised clinical investigation plan for Pivotal study (EFFECMED/SCAFFOLD/ORTHO/001-2022) version 2.1 dated 29.04.2024 of product 3-D scaffold matrix before the committee. The applicant revised the clinical investigation plan with respect to change in enrolment, sample size, statistical analysis, screening period, imaging, imaging visits, inclusion criteria,clinical and laboratory investigations, addition of clinical investigation study sites and investigators, primary radiographic efficacy/ performance assessment, safety analysis. After detailed deliberation, the committee recommended for grant of permission for conduct of the said pivotal clinical investigation subjected to the condition that sample size of the study shall be atleast 100 subjects at 3:1 ratio (Test vs. Reference Product) as approved in the earlier clinical investigation plan, version 2.0.
New Drugs Division			
5.	12-01/24-DC(Pt-142) Morphine and Fentanyl combined with Hyperbaric Bupivacaine	M/s ICARE, Institute of Medical Sciences and Research	The firm did not turn up for presentation.
6.	12-01/24-DC(Pt-142) Part -1 Bupivacaine and Hyperbaric Buprenorphine	M/s ICARE, Institute of Medical Sciences and Research	The firm did not turn up for presentation.
7.	ND/31/2024-eoffice Remifentanil Hydrochloride	M/s Pondicherry Institute of Medical Sciences (PIMS)	The study investigator, Pondicherry Institute of Medical Sciences (PIMS) presented protocol for the conduct of academic clinical trial with drug

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	1mg/2mg for Injection		Remifentanil Hydrochloride. After detailed deliberation, the committee recommended for the grant of permission to conduct the academic clinical trial as per the protocol presented.