Recommendations of the SEC (Ophthalmology) made in its 71st meeting held on 18.10.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biologics Division			
1.	BIO/CT04/FF/2023/38418 Faricimab 120mg/mL solution for injection	M/s. Roche Products	The firm presented their proposal to conduct Phase IV clinical trial protocol titled "A Phase IV, Multicenter, Open label, Single-Arm study in patients with Neo vascular age related macular degeneration or diabetic macular edema to evaluate the safety and effectiveness of the Faricimab Intravitreal injection in India (Vitreal study)" vide protocol No. ML45007 version 1.0 dated 10.07.2023. After detailed deliberation, the committee recommended for approval of the study protocol with following changes in the protocol; 1. The number of subjects should be minimum 100. 2. Subjects should be discontinued from the study when there is any worsening condition/adverse event in the treatment eye. Subsequently, the patients should be provided with standard of care. 3. Treatment of other eye as per standard of care should be included in the protocol. Accordingly, the firm should submit revised protocol to CDSCO. (N.B: Dr. Somesh Agarwal did not participate in the deliberation.)
2.	BIO/CT04/FF/2023/37966 Bevacizumab Injection 1.25mg	M/s. Gennova Biopharmaceuticals Limited	The firm presented their proposal to conduct to Phase I clinical trial titled "A prospective, multi-centre, open label, single-arm, phase I study to evaluate the safety of GBL1204 in patients with neovascular age-related macular degeneration" vide protocol No. GBL1204/2023/01, version No.: 1.0 dated 12.07.2023. After detailed deliberation, the committee recommended for approval of the study protocol with the following changes in the protocol. 1. Treatment of other eye as per standard of care should be included in the protocol.

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			Accordingly, the firm should submit revised protocol to CDSCO.
3.	BIO/CT21/FF/2023/37090 Adalimumab 100mg/mL	M/s. Enzene Biosciences	The firm presented the proposal for approval of additional indications for Adalimumab injection. The Adalimumab injection is earlier approved for the indication "Ankylosing Spondylitis''. The firm intend to extrapolate the additional indication of Paediatric Uveitis. After detailed deliberation, the committee noted that the firm is requesting extrapolation of indication to Adult Uveitis condition. Accordingly, the firm has to submit the application to CDSCO for further deliberation by the committee.
SND Division			
4.	SND/CT/22/000002 Cyclosporine Ophthalmic Solution 0.09%	M/s. Sun Pharma Limited	In light of earlier SEC recommendation dated 22.02.2022, the firm presented the revised Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial as per revised protocol (Protocol No. ICR/21/021, Version No. 2.0 Dated: 15.06.2023) presented by the firm.
FDC Division			
5.	FDC/MA/22/000188 Tropicamide IP 0.2mg + Phenylephrine Hydrochloride IP 3.1mg + Lidocaine Hydrochloride IP 10mg per ml Ophthalmic solution for Injection	M/s. Appasamy Ocular Devices Pvt. Ltd.	In light of the condition mentioned in permission in Form CT-23 dated 24.04.2023, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct of the Phase IV clinical trial. The firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.

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GCT Division			
6.	CT/34/22 Online Submission (26615) LUBT017 (Aflibercept)	M/s. Lupin Limited	In light of earlier recommendation, the firm presented their proposal for protocol no. LRP/LUBTI7/2021/003 version 1.0, dated 14 March 2022 to enroll additional 298 patients from India. After detailed deliberation, the committee recommended for approval for enrollment of additional 298 patients from India with the condition that firm should submit interim analysis results of the study in Russia & India after completion of enrollment of 300 subjects globally before the committee for further review by the committee.