Recommendations of the SEC (Ophthalmology) made in its 04th/25 meeting held on 16.04.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/11/24 Online Submission (38239) Dexamethasone Ophthalmic Suspension 1.5% (15mg/ml) (OCS-01)	M/s Pharmaceutical Research Associates India Pvt Ltd	The firm presented Protocol Amendment Version 4.0 dated 27 Feb 2025 Protocol no. DX221. After detailed deliberation, the committee recommended for approval of protocol amendment with the condition that only those subjects shall continue in the study who have transient rise in intraocular pressure i.e below 27mmHg and which can be easily controlled to normal range by administering single antiglaucoma medicine. Further the Subjects have intraocular pressure above 27 mmHg should be discontinued from the study.
Biological Division			
2.	E-73266 Ranibizumab injection) 2.3mg vial	M/s Reliance Life Sciences	The firm presented the CSR of Phase IV study titled "A prospective, multi-center, single arm, open label, study to evaluate safety and efficacy of RanizuRel® containing Ranibizumab for intra-vitreal injection, manufactured by Reliance Life Sciences, Pvt. Ltd.India in patients with neovascular (wet) age-related macular degeneration vide protocol no RLS/OPT/2020/03, version 2.0 dated 28.07.2023. After detailed deliberation, the committee noted the results of the Phase IV study presented by the firm
SND Division			
3.	SND/CT/25/000017 Pilocarpine Hydrochloride Ophthalmic Solution 1.25% w/v	M/s Entod Pharmaceuticals Ltd.	The firm has presented the proposal for the grant of permission to conduct Phase-IV clinical trial of Pilocarpine Hydrochloride Ophthalmic Solution USP 1.25% w/v for the treatment of presbyopia in adults. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase-IV clinical trial as per the protocol presented by the firm with the following changes in the protocol

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			1. Firm should quantify the eye contrast. 2. To exclude patients with Pathological myopias. 3. Treatment duration shall be up to 4 months and Safety follow up visit shall be after 30 days of end of the study visit. Accordingly, firm shall submit the revised protocol to the CDSCO.
4.	SND/MA/24/000241 Voriconazole powder for eye drops 1%w/v	M/s. Protech Telelinks	The firm presented the proposal for grant of permission to manufacture and market of Voriconazole powder for eye drops 1% w/v along with Phase-III clinical trial protocol. After detailed deliberation, the committee recommended for the grant of permission to conduct the Phase-III clinical trial as per the protocol presented by the firm with the following conditions/changes in the protocol. In the Inclusion criteria following to be added 1. If scraping is negative but culture is positive, then that patients can be included in the study. In the exclusion criteria following to be added 2. Patients with Dacrocystitis shall be diagnosed with standard investigations. 3. Deep stromal keratitis is present Accordingly, firm shall submit the revised protocol to the CDSCO
FDC Division			
5.	FDC/MA/22/000188 Tropicamide IP 0.2mg + Phenylephrine Hydrochloride IP 3.1mg + Lidocaine Hydrochloride IP 10mg per ml Ophthalmic solution	M/s. Appasamy Ocular Devices Pvt. Ltd.	In light of earlier SEC recommendation dated 18.10.2023 and as per condition of Form CT-23 dated 24.04.2023, the firm presented Phase IV clinical trial report before the committee. After detailed deliberation, the committee observed that firm did not present the Phase IV report satisfactorily.

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	for Injection		Accordingly, firm should re-present the phase IV report along with safety and efficacy with proper endpoints to CDSCO for further review by the committee