Recommendations of the SEC (Ophthalmology) made in its 12th meeting held on 19.12.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/11/24 Online Submission (36080) Dexamethasone Ophthalmic Suspension 1.5% (15mg/ml) (OCS-01)	M/s PRA	The firm presented protocol amendment version 3.1 dated 16 October 2024 and Increase in patients to be enrolled from 30 to 60 in India for protocol no. DX221. After detailed deliberation, the committee recommended for approval of protocol amendment and Increase in number of patients to be enrolled from 30 to 60 in India as presented by the firm with following conditions: 1. If Anti-VEGF is required, expenses towards it, shall be borne by the sponsor. 2. If Glaucoma is not manageable, expenses towards surgical intervention shall be borne by the sponsor. 3. IOL proposed to be used shall be monofocal or monofocal toric square edge hydrophobic yellow chromophore and expenses towards it, shall be borne by the sponsor.
2.	CT/15/24 Online Submission (36077) Dexamethasone Ophthalmic Suspension 1.5% (15mg/ml) (OCS-01)	M/s PRA	The firm presented protocol amendment version 6.1 dated 16 October 2024 for protocol no. DX219. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm with following conditions: 1. If Anti-VEGF is required, expenses towards it, shall be borne by the sponsor. 2. If Glaucoma is not manageable, expenses towards surgical intervention shall be borne by sponsor. 3. IOL proposed to be used shall be monofocal or monofocal toric

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			square edge hydrophobic yellow chromophore and expenses towards it, shall be borne by the sponsor.
Biological Division			
3.	BIO/CT04/FF/2024/45392 Aflibercept injection 40mg/mL	M/s Reliance Life Sciences Private Limited	The firm presented the proposal to conduct Phase III study titled "A Prospective, Multicenter, Randomized, Double-Blind, Parallel-Group, Two-Arm Comparative Clinical Study to Evaluate the Efficacy, Safety, Pharmacokinetics and Immunogenicity of R-TPR-051 (RLS-Aflibercept) and Eylea® administered by intravitreal injection in Patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD)" vide Protocol number: RLS/OPT/2024/04 Version 2.0, Dated 23 Sep 2024. After detailed deliberation, the committee recommended for approval to conduct the Phase III study as per the protocol presented by the firm.
4.	BIO/CT18/FF/2024/45055 Faricimab 6mg/0.05mL	M/s. Roche Products India Pvt. Ltd.	The firm presented the proposal for the additional indication of Macular edema secondary to retinal vein occlusion (RVO) for the drug product Faricimab 6 mg/0.05ml solution for Intravitreal injection (VABYSMO®) along with the request of Phase III clinical trial waiver. The committee noted that there is no published long term clinical safety data and there is no unmet need for the proposed indication. Further, the ongoing Global clinical trial in the proposed indication does not include India as one of the participating country. After detailed deliberation, the committee did not consider the firm's request for approval of additional indication of Macular edema secondary to retinal vein occlusion (RVO) with waiver of Phase III clinical trial and recommended the firm to conduct Phase III clinical trial for the proposed indication.
5.	File No. 46173 dated 22.7.2024	M/s Intas Pharmaceuticals Ltd.	The firm presented CSR of Phase IV study titled "A prospective, Interventional, Single arm, Multi-centre,

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	Ranibizumab 0.2mg solution for injection		Phase 4 study to assess the safety and efficacy of Ranibizumab in participants with Retinopathy of prematurity" conducted vide Protocol No. 0248-22, Version 1.0 dated 30.8.2022. After detailed deliberation, the committee noted the results of the Phase IV study presented by the firm.
6.	File No.: BIO/CT18/FF/2024/45784 Aflibercept Injection 8mg solution in vial for intravitreous injection	M/s Bayer Pharmaceuticals Pvt. Ltd	The firm presented the proposal for approval of additional strength of Aflibercept 8mg solution in vial for intravitreous injection along with clinical data generated from Global clinical studies with the request for the local clinical trial waiver. The committee noted that there is no clinical data available in India population for the proposed additional strength. After detailed deliberation, the committee did not recommend for the approval of proposed additional strength of the drug product Aflibercept 8mg solution in vial for intravitreous injection with waiver of Phase III clinical trial.
7.	F.No.: BIO/CT04/FF/2024/44147 Bevacizumab Injection 1.25mg	M/s. Reliance Life Sciences Pvt. Ltd	In light of earlier SEC recommendation dated 19.09.2024, the firm presented the revised protocol no. RLS/OPT/2024/03 Version 2.0, Dated 08 Oct 2024 for the conduct of Phase II/III clinical trial of Bevacizumab injection 1.25 mg with the inclusion of standard of care and sample size justification in the protocol. After detailed deliberation, the committee recommended for approval to conduct the Phase II/III clinical trial as per revised protocol presented by firm.
FDC Division			
8.	FDC/MA/22/000188 Tropicamide IP 0.2mg + Phenylephrine Hydrochloride IP 3.1mg + Lidocaine Hydrochloride IP 10mg per ml	M/s. Appasamy Ocular Devices Pvt. Ltd.	The firm did not turn up for the presentation.

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	Ophthalmic solution for Injection		