Recommendations of the SEC (Ophthalmology) made in its 05th/24 meeting held on 22.05.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/54/24 Online Submission (42516) BAY3283142 5mg, 10 mg tablets or matching Placebo	M/s. Bayer	The firm presented Phase II clinical study protocol No. 22046 version 1.0 dated 18.12.2023 After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. (Dr. Somesh aggrawal didn't participate in the deliberation).
Biological Division			
2.	E-25674 Bevacizumab Injection, 25 mg/mL	M/s. Reliance Life Science	The firm presented the clinical study report for Phase I clinical trial vide protocol No. RLS/OPT/2022/05; Version 2.0, Dated: 20.04.2023 for drug Bevacizumab (R-TPR-023) to evaluate the safety in patients with neovascular (wet) age-related macular degeneration. After detailed deliberation, the committee noted the result of Phase I study. (Dr. Somesh aggrawal didn't participate in the deliberation).
3.	r-DNA-11011(18)/32/2024-eoffice Aflibercept Solution for Intervitreal Injection 40mg/mL	M/s. Bayer Life Sciences	The firm presented the proposal for update in the package insert with respect to introduction of more flexible treatment regimen with Aflibercept for Diabetic Macular Edema (DME) patients allowing for individualization of dosing within the first year of treatment. The committee noted that proposed revision in the package insert has been approved in 56 countries including European Union, UK, Australia, Brazil etc. After detailed deliberation, the committee recommended for revision in the package insert vide version number EY_2023-01 dated 07.09.2023 inline with EMA approved PI. Accordingly the firm shall submit approved PI of EMA to CDSCO.

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			(Dr. Somesh aggrawal didn't participate in the deliberation).
4.	BIO/CT04/FF/2023/38367 Ranibizumab Solution for Injection 10 mg/mL	M/s. Sun Pharma	The firm presented the proposal for permission to conduct Phase IV study titled as "A prospective, multi-center, single-arm, Phase IV study to assess the safety, efficacy and immunogenicity of Ranibizumab solution for injection 10 mg/mL (r-DNA Origin) vide protocol No. ICR/23/004, version No. 2.0 dated 05.04.2024. After detailed deliberation, the committee recommended to incorporate the sample size proportionate with each indication in the study. Accordingly, the firm should submit the revised protocol to CDSCO for further deliberation by the committee.
5.	BIO/CT04/FF/2021/23940 Bevacizumab injection, 25 mg/mL	M/s. Intas Pharmaceuticals Ltd	In light of earlier recommendation of SEC meeting dated 31.10.2019, dated 23.02.2021 & 24.02.2021 & 25.06.2021 and dated 20.07.2023, the firm presented the justification for not conducting the initial Phase of clinical studies before carrying out Phase III clinical trial as the drug is approved by EMA for the proposed indication. After detailed deliberation, the committee reiterated its earlier recommendation and the same is reproduced as below: "The firm should demonstrate the safety and adequacy of the dose through initial phase clinical studies before carrying out Phase III clinical trial."
6.	4-93/Intas/PAC-R-Ranibizumab/2021-BD-Ranibizumab Ranibizumab solution for injection 10mg/ml	M/s. Intas Pharmaceuticals Ltd	The firm granted permission for additional indication with condition to submit Phase IV study report within one year, the same was not submitted. Hence, the firm was asked to submit interim study report. The firm did not present the interim study report to the committee and stated that the study is ongoing. However the firm has committed to submit the CSR within two

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			months. After detailed deliberation the committee recommended the firm to submit the complete study report within two months' time period.
SND Division			
7.	SND-11011(13)/1/2024-e-office Atropine Sulfate Ophthalmic Solution USP 0.01 % w/v	M/s. Entod Pharmaceuticals Limited	The firm presented the proposal for waiver Phase-IV clinical trial as per the condition of MA permission along with justification including established safety profile of Atropine sulfate ophthalmic solution 0.01% w/v before the committee. After detailed deliberation, the committee opined that the justification provided by the firm is not found adequate. The committee reiterated its earlier recommendation to conduct Phase-IV clinical trial for which firm should submit Phase-IV clinical trial protocol to CDSCO for further review by the committee.