Recommendations of the SEC (Ophthalmology) made in its 68th meeting held on 20.07.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/MA/23/000034 Ranibizumab 10mg/mL solution for injection (2.3mg/0.23mL)	M/s. Enzene Biosciences Ltd.	The firm presented the proposal for grant of permission for manufacturing and marketing of Ranibizumab10mg/mL solution for intravitreal injection (2.3mg/0.23mL) for treatment of Neovascular Age related Macular degeneration based on the results of Phase III clinical trial. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the drug subject to the condition that firm should conduct Phase IV clinical trial. Accordingly, Phase IV clinical trial protocol should be submitted within 3 months of marketing approval.
2.	BIO/CT04/FF/2021/ 23940 Bevacizumab Solution for Injection 25 mg/mL (Vial 5.75 mg/0.23 mL)	M/s. Intas Pharmaceuticals Limited	In light of earlier recommendation of SEC meeting dated 31.10.2019, dated 23.02.2021 & 24.02.2021 and dated 25.06.2021, the firm presented their justification for not conducting the initial phase of clinical studies before carrying out Phase III clinical trial. After detailed deliberation, the committee reiterated the earlier recommendation of SEC meeting dated 25.06.2021 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."
SND Division			
3.	SND/MA/21/000499 Atropine Sulphate Ophthalmic solution 0.01 % w/v	M/s. Indiana Ophthalmics	In light of the earlier SEC recommendation, the firm presented the report of in vitro Neural Red Uptake (NRU) Cytotoxity Test of "Atropine Sulfate ophthalmic Solution USP 0.01 % w/v with stabilized Oxychloro Complex (SOC) as preservative by using 3T3 Cell Lines. After detailed deliberation, the committee did not accept the in vitro study data submitted by the firm and reiterated its earlier recommendation of SEC meeting

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			held on 01.09.2022 , that the firm should submit in vivo Ocular Toxicity Data for proposed formulation for further review by the committee.
GCT Division			
4.	CT/122/22 OnlineSubmission (24845) LLBMT1	M/s. CBCC	In light of earlier SEC dated 21.06.2023 the applicant presented the protocol version 4.0 dated 03.03.2023 in detailed before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment. (Dr. Purvi Bhagat did not participate in deliberation)