Recommendations of the SEC (Ophthalmology) made in its 08th/24 meeting held on 22.08.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/89/24 Online Submission (43937) OTX-TKI (Axitinib Implant)	M/s. Fortrea Development India Private Limited	The firm presented Phase III clinical trial protocol no. OTX-TKI-2023-AMD-301, version 2, dated 08 December 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial with the condition that the firm should submit safety data of first 20 Indian subjects to CDSCO for review by the committee before enrollment of remaining subjects.
Biological Division			
2.	BIO/CT04/FF/2024/ 44244 Bevacizumab Injection 1.25mg	M/s. Gennova Biopharmaceuticals Limited	The firm presented the protocol to conduct Phase III clinical study of Bevacizumab injection 1.25mg in patients with neovascular age-related macular degeneration titled "A Phase III Prospective, Randomized, Open-labelled, Blinded endpoint (PROBE), Multi-centric, Parallel Group, Non-inferiority Study to compare the Efficacy and Safety of GBL1204 with Ranibizumab in Patients with Wet Age-Related Macular Degeneration" vide Protocol no. GBL1204/2024/01 Version 1.0 dated 10.07.2024 along with results of the Phase I study conducted by firm. After detailed deliberation, the committee recommended for conduct of proposed Phase III study with a condition that firm should submit complete safety and efficacy data for initial 50 patients (25 in each arm) before the committee for evaluation. The continuity of the study shall be allowed after satisfactory evaluation of the safety and efficacy results of the first 50 patients by the committee. Accordingly, firm should submit the revised protocol to CDSCO for evaluation.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Devices Division			
3.	CI/MD/2024/116257 Synthetic Keratoprosthesis Implantation Kit (Brand Name: CorNeat KPro Implantation Kit)	M/s. Nextvel Consulting LLP	The firm presented the proposal for grant of permission for conduct of Pilot clinical investigation on applied device Synthetic Keratoprosthesis Implantation Kit (Brand Name: CorNeat KPro Implantation Kit) in the country as a part of global clinical study on Indian population before the committee. After detailed deliberation of the Clinical Investigation Plan, the expert committee recommended for the grant of permission to conduct said study on Indian population. The report of the study shall be submitted for the review and necessary action before approval of device for its commercialization in India.