Recommendations of the SEC (Ophthalmology) made in its 06th/24 meeting held on 19.06.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/101/23 Online Submission (33059) OPT-302, Sozinibercept	M/s. InVentiv International Pharma Services Pvt. Ltd.	The firm presented protocol amendment 1 version 02 dated 19 December 2023 protocol No. OPT-302-1004. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/103/23 Online Submission (33072) OPT-302, Sozinibercept	M/s. InVentiv International Pharma Services Pvt. Ltd.	The firm presented protocol amendment 1 version 2.0 dated 19 December 2023 protocol No. OPT-302-1005. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
SND Division			
3.	SND/MA/24/000089 Atropine Sulphate Ophthalmic Solution USP 0.05% w/v	M/s. Entod Pharmaceuticals Limited	The firm presented the proposal for grant of permission to manufacture and marketing of Atropine Sulfate ophthalmic solution USP 0.05% w/v along with Phase-III clinical study report before the committee. After detailed deliberation, the committee noted that the proposed drug formulation Atropine Sulfate ophthalmic solution USP 0.05% w/v is not yet approved in anywhere in the world. Further, firm has stated that various clinical trials were under taken on proposed higher strength and published data are available on proposed higher strength of formulation. Therefore, the committee opined that the firm should submit current filing status of proposed formulation in any other countries along with details comparison of safety and efficacy of their own clinical trial data vis a vis published clinical trials of proposed higher strength formulation to CDSCO for further review by the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Device Division			
4.	CI/MD/2024/114688 Femtosecond Ophthalmic solid-state laser system (Brand Name: WaveLight UV-Femtosecond Laser System, Model 1026 (UV fs-Laser) with accompanying WaveLight Disposable-Set UV fs-Laser Patient Interface, Model no.1507). Protocol No. RFO268-C004, Version 2.0 dated 15.12.2023.	M/s.Alcon Laboratories (India) Private Limited	The firm presented the proposal for grant of permission for conduct of Pilot clinical investigation on applied device Femtosecond ophthalmic solid-state laser system in the country on Indian population before the committee. After detailed deliberation, the committee recommended that firm should submit following: 1. Copy of detailed reports with outcome of previously generated clinical study data on applied device. 2. Copy of approvals obtained from competent authorities for conduct of previous studies particularly in India. 3. It is suggested that the firm should include any Government institute as one of the Clinical study site in India. 4. The clinical investigation Plan should include mitigation strategy/rescue procedure of subjects if outcome of procedure are sub-optimal. Accordingly, the firm should submit above mentioned documents for taking necessary action in the matter.