Recommendations of the SEC (Ophthalmology) made in its 04th/26 meeting held on 21.04.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Devices Division			
1.	CI/MD/2025/165750 (Form MD-22) Sodium Hyaluronate 0.2 % w/v Eye Drops 10 ml (Evolve HA)	M/s.IR Innovate Research Private Limited	The firm presented the proposal for grant of permission to conduct Clinical investigation on the device viz. Sodium Hyaluronate 0.2 % w/v Eye Drops 10 ml (Evolve HA), manufactured by M/s Medicom Healthcare, UK. After detailed deliberation, the experts opined that the firm shall include the following points in the study protocol: 1. The study design should be comparative masked Randomized Controlled Trial (RCT) rather than single arm open label study. 2. Objective criteria for inclusion of Dry Eyes Disease. 3. Uniform geographical distribution of centers. 4. Proper justification for sample size according to the statistical calculation. 5. Study duration to be increased atleast up to six months follow up. Accordingly, a revised study protocol should be submitted for further deliberation.
Biological Division			
2.	BIO/CT04/FF/2025/53652 Aflibercept solution for injection (40 mg/ml)	M/s. Biocon Biologics Limited	The firm presented the proposal to conduct Phase IV clinical trial titled "A Phase IV, Multi-Center, Interventional Post-Approval Study to Evaluate the Safety of Intravitreal Biosimilar Aflibercept (Aflisite) in patients with myopic Choroidal Neovascularisation (mCNV), neovascular (wet) age-related macular degeneration (nAMD) and macular oedema secondary to Retinal Vein Occlusion (RVO)". Protocol No.: BIO-AFLIBE-402 Version No. 1.0 Dated 06-JAN-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial as per the presented protocol, subject to the

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			condition that firm shall strictly monitor the adverse events reported in Phase-III study especially in MACE events and conjunctival hemorrhage arising from injection procedures.
SND Division			
3.	File No. SND/CT/21/000021 Atropine Sulfate Ophthalmic Solution USP 0.01% w/v.	M/s. Sun Pharma Laboratories Limited	Firm has presented Phase IV clinical trial Report of Atropine Sulfate Ophthalmic Solution USP 0.01% w/v before the Committee. After detailed deliberation, the Committee recommended to accept the study report presented by the firm. Note: Dr Purvi Bhagat, being an investigator in the study, did not participate in the deliberation.