Recommendations of the SEC (Ophthalmology) made in its 06th/26 meeting held on 17.06.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2026/55029 Aflibercept solution 114.3 mg/mL in vial for intravitreous injection. Each single-dose vial provides a usable amount to deliver a single dose of 70 microliters containing 8 mg aflibercept to adult patients	M/s. Bayer Pharmaceuticals Pvt. Ltd	The firm presented the proposal for grant of permission to import and market additional strength of Aflibercept solution 114.3 mg/mL in vial for intravitreous injection (Each single-dose vial provides a usable amount to deliver a single dose of 70 microliters containing 8 mg aflibercept to adult patients) for the treatment of adult patients in following indications: ·Neovascular (wet) age-related macular degeneration (nAMD) ·Diabetic macular edema (DME) The proposed additional strength is already approved in 60 countries including USA, United Kingdom, Japan, Australia, Canada, EU, Singapore and Switzerland. After detailed deliberation, the committee recommended for grant of permission to import and market additional strength of Aflibercept solution 114.3 mg/mL in vial for intravitreous injection (Each single-dose vial provides a usable amount to deliver a single dose of 70 microliters containing 8 mg aflibercept to adult patients) for the treatment of adult patients in following indications: ·Neovascular (wet) age-related macular degeneration (nAMD) ·Diabetic macular edema (DME) with waiver of local Phase III clinical trial under the provisions of Rule 101 of the New Drugs and Clinical Trials Rules, 2019, subject to the condition that the firm shall conduct a Phase IV clinical trial in the Indian population for the proposed indication(s). Accordingly, firm shall submit Phase IV Clinical Trial protocol to CDSCO within 03 months of grant of marketing authorization permission.
2.	BIO/CT21/BO/2026/54579	M/s. LUPIN LIMITED	The firm presented the proposal for grant of permission to manufacture and market

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	Aflibercept Drug Substance & Aflibercept Drug Product (40 mg/ml) Solution for intravitreal injection in vial (Each vial to deliver a single dose of 2mg/0.05mL).		Aflibercept Drug Substance & Aflibercept Drug Product (40 mg/ml) Solution for intravitreal injection in vial based on the results from Global Clinical Trial titled "Phase III, Prospective, Randomized, Parallel group, Double-blind, Multicentre Study to Compare the Efficacy, Safety, and Immunogenicity of Lupin's Aflibercept with Eylea® in Patients with Neovascular Age-Related Macular Degeneration". After detailed deliberation, the committee recommended for grant of permission to manufacture and market Aflibercept Drug Substance & Aflibercept Drug Product (40 mg/ml) Solution for intravitreal injection in vial for the indication of Neovascular (Wet) Age-Related Macular Degeneration (AMD) Further, the firm also presented proposal for approval of following additional indications by the way of extrapolation in line with indications approved for innovator product by USFDA and EMA. i. Visual impairment due to macular Oedema secondary to Retinal Vein Occlusion (branch RVO or central RVO) ii. Visual impairment due to Diabetic Macular Oedema (DME) iii. Visual impairment due to Diabetic Retinopathy (DR) iv. Visual impairment due to Myopic Choroidal Neovascularization (myopic CNV) After detailed deliberation, the committee recommended for approval of additional indications (i), (ii), (iii) and (iv) by way of extrapolation subject to the condition that the firm shall conduct a Phase IV study in India in all approved indications on statistically significant sample size. Accordingly, the protocol to conduct the Phase IV study shall be submitted to CDSCO within three months of grant of marketing authorization permission to manufacture and market the said drug product.

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Medical Devices Division			
3.	CI/MD/2025/165750 Sodium Hyaluronate 0.2% w/v Eye Drops 10ml (Evolve HA)	M/s. IR Innovate Research Private Limited.	The proposal for grant of permission to conduct Clinical investigation on the device viz. Sodium Hyaluronate 0.2% w/v Eye Drops 10ml (Evolve HA), manufactured by M/s Medicom Healthcare, UK was redeliberated before the Subject Expert Committee. The firm has produced the revised Clinical study protocol as per the recommendations of the previous SEC meeting. After detailed deliberation, the experts recommended for the permission to conduct Clinical investigation on the device with the following amendments in the protocol 1. Objective criteria for Dry Eye Disease should be included in the primary endpoint. 2. A robust randomized stratification system should be employed during the study.
SND Division			
4.	SND/CT21/FF/2026/54614 Timolol Eye Gel 0.1% w/w	M/s. Ajanta Pharma Limited	Firm presented proposal for manufacturing & marketing of Timolol Eye Gel 0.1% w/w for the applied indication along with the proposal for conduct of Phase-III clinical study before the committee. The committee noted that Timolol Eye Gel 0.1% w/w is approved in Belgium, The U.K and Ireland. After detailed deliberation, the committee recommended grant of permission to conduct Phase III Clinical Trial by the firm with the following changes in the protocol- 1. The follow-up period for patients must be at least 6 months. 2. Subjects with any contraindication to beta-blockers should be excluded from the study and same should be mentioned in exclusion criteria. Accordingly, firm should submit revised CT Protocol to CDSCO.