

Recommendations of the SEC (Ophthalmology) made in its 05th/25 meeting held on 15.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/15/24 Online Submission (38504) Dexamethasone ophthalmic suspension 1.5% (15 mg/mL) (OCS-01)	M/s Pharmaceutical Research Associates India Private Limited	The firm presented protocol amendment version 7.0 dated 27 Feb 2025 protocol no. DX219. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
2.	BIO/CT21/FF/2025/47621 Ranibizumab solution for injection (r-DNA origin) 2.3 mg/ 0.23 mL (0.5 mg dose) and 1.38 mg/ 0.23 mL (0.3 mg dose)	M/s Reliance Life Sciences Pvt Ltd	The firm presented the proposal for the grant of permission for the additional indication of Retinopathy of prematurity (ROP) for the drug product Ranibizumab solution for injection (r-DNA origin) 2.3 mg/ 0.23 mL (0.5 mg dose) and 1.38 mg/ 0.23 mL (0.3 mg dose) by the way of extrapolation in line with the indications of innovator product. The proposed indication is “for the treatment of retinopathy of prematurity (ROP) with zone I (stage 1+, 2+, 3 or 3+), zone II (stage 3+) or AP-ROP (aggressive posterior ROP) disease.” After detailed deliberation, the committee recommended for approval of the proposed indication of ROP for the said drug product with dose of 0.2 mg in preterm infants in line with the recommended dose of innovator product approved by EMA for the said indication along with a condition that the firm should conduct Phase IV study in India in the proposed indication. Accordingly, the firm should submit protocol for conduct of Phase IV clinical trial within 3 months of approval of said indication.
3.	E-71842 Aflibercept intravitreal injection (Eylea)	M/s Bayer Pharmaceuticals Pvt Ltd,	The firm presented the final CSR of PMS study titled “Structured Post-marketing surveillance to collect the Safety data of intravitreal aflibercept injection (IVT-AFL) inpatients of wet age-related macular degeneration during real world

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			<p>clinical practice" vide Protocol no. 19140 version 2.1 dated 11.09.2017.</p> <p>After detailed deliberation, the committee noted the results of the PMS study presented by the firm.</p> <p>Note: Dr. Somesh Aggarwal didn't participate in the deliberation.</p>
4.	<p>BIO/CT21/BO/2024/47130</p> <p>Aflibercept 40 mg/ mL liquid solution for intravitreal solution</p>	M/s. Zydus Life Sciences Ltd	<p>The firm presented the proposal for grant of permission to manufacture and market the drug product Aflibercept 40 mg/ mL liquid solution for intravitreal solution based on the results of comparative Phase III clinical trial conducted in India to establish the efficacy, safety and immunogenicity of the drug product in patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD).</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market Aflibercept 40 mg/ mL liquid solution for intravitreal solution for the indication of Neovascular (Wet) Age-Related Macular Degeneration (AMD).</p> <p>Further, firm has 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.</p> <ol style="list-style-type: none"> i. 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) v. Retinopathy of Prematurity (ROP) <p>After detailed deliberation, the committee recommended for approval of additional indications (i), (ii), (iii) and (iv) only subject to the condition that firm shall conduct Phase IV study in India in these indications (RVO, DME, DR and CNV)</p>

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			with statistically significant sample size for each indication. Accordingly, the protocol to conduct the Phase IV study shall be submitted within three months of grant of marketing authorization permission to manufacture and market the said drug product.
SND Division			
5.	SND-16011(11)/49/2025-eoffice Moxifloxacin Hydrochloride Ophthalmic Solution 0.5 % w/v	M/s Novartis Healthcare Pvt. Ltd	The firm did not turn up for the presentation.
6.	SND/MA/23/000248 FORSKOLIN 0.150 % w/v Eye Drops	M/s Sami-Sabinsa Group Limited	In light of earlier SEC recommendation dated 23.11.2023, the firm presented the proposed Package insert for manufacturing and marketing of Forskolin 0.15% eye drops for the treatment of Open Angle Glaucoma before the committee. After detailed deliberation, the committee accepted the proposed Package insert as per presented by the firm.
FDC Division			
7.	FDC/CT/25/000029 Brimonidine Tartrate 2 mg + Brinzolamide 10 mg + Timolol 5 mg Ophthalmic Suspension	M/s Ajanta Pharma Limited	The firm did not turn up for the presentation.