

Recommendations of the SEC (Ophthalmology) made in its 03rd/25 meeting held on 19.03.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/104/23 Online Submission (37703) CBT-001 (Nintedanib)	M/s IQVIA RDS India Private Limited	The firm presented protocol amendment 4.0 dated 26 November 2024 protocol no. CBT-CS301 and study status report in compliance to condition 1 of CT NOC. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
2.	BIO/CT04/FF/2024/46558 Ranibizumab Solution for Injection 10 mg/mL	M/s. Lupin Limited	In light of earlier SEC recommendations dated 23.11.2023, the firm presented the proposal to conduct Phase IV clinical trial titled “A multicentre, open label, prospective, single-arm, non-comparative, non-randomized phase IV study to evaluate safety and efficacy of Injection Ranibizumab (of Sponsor Lupin Limited) given as intravitreal injection in preterm infants with Retinopathy of Prematurity” vide Protocol No. 24-VIN-0299; Version No. 01; Dated: 05 th September, 2024. After detailed deliberation, the committee recommended to conduct the study with the following changes in the protocol:- 1. Proper detailed study methodology should be provided and SOP should be a part of study design. 2. Perkins tonometer should be used for measurement of IOP. If IOP is raised, then small parenthesis should be performed. 3. Study should include pre-term infants with Natural spontaneous breathing/normal breathing only. 4. Micro-ROPLAS test should be performed at screening to exclude congenital NLDO. 5. Echo test should be performed at screening if abnormality in ECG is suspected.

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			<p>6. If both the eyes are eligible for the study treatment as per the inclusion criteria, treatment should be provided simultaneously.</p> <p>Accordingly, the firm shall submit revised protocol to CDSCO for further evaluation.</p>
3.	E-59473 Brolucizumab Solution for Injection 120 mg/ml	M/s. Sandoz Pvt Ltd	<p>The firm presented the CSR of the Phase IV study titled “A real world, prospective, multi-center, open label, phase IV clinical study to evaluate the safety and effectiveness of intravitreal injections (IVI) of brolucizumab in patients with neovascular age-related macular degeneration (nAMD)” conducted in India as per Protocol No. CRTH258AIN01, Version No. 0.2, dated 06 May 2021.</p> <p>After detailed deliberation, the committee noted the results of the study conducted by the firm.</p>
SND Division			
4.	SND/MA/24/000039 Fenofibrate Tablets IP 160mg (Additional Indication)	M/s USV Pvt. Limited	<p>Firm presented their proposal for grant of permission to manufacture and marketing of Fenofibrate 160 mg tablets (additional indication) indicated for the reduction in the progression of diabetic retinopathy in patients with Type 2 diabetes and existing diabetic retinopathy along with justification for waiver of Clinical Trial study.</p> <p>Firm did not present BE study protocol during deliberation which was submitted to CDSCO.</p> <p>The committee noted that the presented safety data was not adequate in term of Long term safety of the applied product in proposed indication.</p> <p>After detailed deliberation, the committee did not recommend for Clinical Trial study waiver.</p>