

Recommendations of the SEC (Ophthalmology) made in its 07th/24 meeting held on 24.07.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/40/23 Online Submission (33466)	M/s. Roche Products	The firm presented protocol amendment version 2 dated 19.04.2023 protocol No. GR44278. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm with condition that paediatric population shall not be enrolled into the clinical trial.
Biological Division			
2.	BIO/CT04/FF/2023/ 38544 Brolucizumab Solution for Injection (r-DNA origin) 120 mg/ml	M/s. Sandoz	In light of the SEC recommendations dated 23.11.2023, the firm presented the revised protocol for conduct of Phase IV study titled “A prospective, multi-center, open-label, phase IV study to evaluate the safety and effectiveness of intravitreal injections (IVI) of Brolucizumab in patients with Diabetic Macular Edema (DME)” vide protocol CRTH258BIN01 version 01 dated 22.05.2024. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV study as per the revised protocol presented by the firm.
3.	BIO/CT-4/FF/2024/ 41868 Ranibizumab Injection 10mg/mL Single use vial (r-DNA origin)	M/s. Enzene	The firm presented the Phase IV study protocol titled “A Phase IV, open label, single-arm, multi-centre clinical study to evaluate the safety and efficacy of Biosimilar Ranibizumab (ENZ105) in patients with Neovascular (Wet) Age related Macular Degeneration (AMD)” vide protocol No. ALK34/ENZ105-RANI2, Version 1.0, Protocol dated 08.01.2024. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV study as per the protocol presented by the firm.
Medical Devices Division			
4.	CI/MD/2024/114688 Femtosecond Ophthalmic solid- state laser system (Brand Name:	M/s. Alcon Laboratories (India) Pvt. Ltd.	The firm re-deliberated the proposal for grant of permission for conduct of clinical investigation on applied device Femtosecond Ophthalmic solid-state laser system in the country on Indian

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	WaveLight UV-- Femtosecond Laser System, Model 1026 (UV fs-Laser) with accompanying WaveLight Disposable-Set UV fs-Laser Patient Interface, Model no.1507)		<p>population before the committee.</p> <p>After detailed deliberation, the committee recommended that firm should submit following:</p> <ol style="list-style-type: none"> 1. Considering large & diverse Indian population and the clinical study being a Nomogram Study, the firm should include at least one more clinical site in India addressing the above mentioned concern. 2. Further, the firm need to submit the copy of regulatory approval obtained from the National Regulatory Authority of countries viz. Australia, Germany, Greece for the conduct of said study 3. Firm shall submit an undertaking stating that they shall commercialize the product for Indian population. <p>Accordingly, firm should submit above mentioned documents for taking necessary action in the matter.</p>
SND Division			
5.	SND/MA/24/000089 Atropine Sulfate Ophthalmic solution USP 0.05% w/v	M/s. Entod Pharmaceuticals Limited	<p>In light of earlier SEC recommendations dated 19.06.2024, the firm presented the proposal for manufacture and marketing of Atropine Sulfate Ophthalmic Solution USP 0.05% w/v along with the current filing status and comparison of safety and efficacy of their clinical trial data vis a vis published clinical trials of proposed higher strength formulation.</p> <p>After detailed deliberation, the Committee recommended for grant of permission for manufacturing and marketing of Atropine Sulfate Ophthalmic Solution USP 0.05% w/v for the indication slowing down progression of myopia in children of age 6 years to 12 years subject to condition that the firm should conduct Phase IV clinical trial.</p> <p>Accordingly, the firm should submit Phase IV clinical trial study protocol to CDSCO within 03 months from date of approval of the drug product for further review by the committee.</p>