Recommendations of the SEC (Ophthalmology) made in its 71st meeting held on 23.11.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2023/38544 Brolucizumab Solution for Injection (r-DNA origin) 120 mg/ml	M/s. Sandoz Private Limited	The firm presented their proposal for grant of permission to conduct Phase IV Clinical Trial vide Protocol No. CRTH258BIN01 Version number: 00, Dated 02.05.2023 titled as 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). After detailed deliberation, the committee recommended for approval of the study protocol with following changes in the protocol: 1. Subjects should be discontinued from the study when there is any worsening condition/adverse event in the treatment eye. Subsequently, the patients should be provided with standard of care. 2. Treatment of other eye as per standard of care should be included in the protocol. 3. Study design should be changed with the objective of the phase IV study i.e., non-interventional design shall be changed to interventional. Accordingly, firm should submit the revised protocol to CDSCO for further review by the Committee.
2.	BIO/CT04/FF/2023/38367 Ranibizumab	M/s. Sun Pharma	The firm presented their proposal for grant of permission to conduct Phase IV Clinical Trial vide Protocol No. ICR/23/004, Version No. 1.0 dated 03.07.2023 titled as "A Prospective, Multi-center, Single-arm, Phase IV Study to Assess the Safety, Efficacy and Immunogenicity of Ranibizumab Solution for Injection 10 mg/mL (r-DNA Origin) for the Treatment of Neovascular Age-related Macular Degeneration". After detailed deliberation, the committee recommended for approval of the study protocol with following changes in the protocol:

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			1. Subjects should be discontinued from the study when there is any worsening condition/adverse event in the treatment eye. Subsequently, the patients should be provided with standard of care. 2. Treatment of other eye as per standard of care should be included in the protocol. Accordingly, firm should submit the revised protocol to CDSCO for further review by the Committee.
3.	BIO/CT21/FF/2023/39537 Ranibizumab Solution for injection 10mg/mL	M/s. Lupin Limited	The firm presented their proposal for grant of permission for extrapolation of approved indications to the following additional indications: 1. The treatment of proliferative diabetic retinopathy (PDR). 2. Indicated in preterm infants 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 additional indication of Proliferative Diabetic Retinopathy (PDR). Further, for the indication Retinopathy of prematurity (ROP) with zone I (stage 1+, 2+, 3 or 3+), zone II (stage 3+) or AP-ROP (aggressive posterior ROP) disease in pre-term infants,thecommittee opined that firm shall submit detailed Phase IV Clinical Trial Protocol in the target population for evaluation of the protocol and consideration of the proposal for the approval of additional indication in pre-term infants.
GCT Division			
4.	CT/101/23 Online Submission (39075) OPT-302	M/s. InVentiv	The firm has presented phase III clinical study Protocol no. OPT-302-1004. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by firm with condition that the firm should add the phrase “for the duration of the study" for all sections saying standard of care

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			should be provided.
5.	CT/103/23 Online Submission (39140) OPT-302	M/s. InVentiv	The firm has presented phase III clinical study Protocol no. OPT-302-1004. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by firm with condition that the firm should add the phrase “for the duration of the study" for all sections saying standard of care should be provided.
6.	CT/104/23 Online Submission (39114) CBT-001 (Nintedanib), CBT-001 (Nintedanib	M/s. IQVIA RDS	The firm has presented phase III clinical study Protocol no. CBT-CS301. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by firm with condition that six monthly status report shall be submitted for review by the committee.
SND Division			
7.	SND/MA/23/000248 Forskolin 0.15% Eye drop	M/s. Sami-Sabina	The firm presented their proposal for manufacturing and marketing of Forskolin 0.15% Opthalmic Solution for the treatment of Glaucoma. Firm has presented the Phase III Clinical Trial Report entitled “A Randomized, Double blind and multicenter study to compare the efficacy and safety of topical Forskolin (0.15%) and topical Timolol (0.15%) in patients with ocular hypertension or open angle glaucoma”. After detailed deliberation, the committee opined that this is a non – inferiority trial and recommended for grant of permission to manufacture and market of topical Forskolin (0.15%) for the treatment in patients with ocular hypertension or primary open angle glaucoma subject to condition that firm should conduct Phase-IV clinical trial. However, the firm should fulfil the requirements of CMC data. Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within 03 months of approval of the drug for further review by the Committee.

SEC (Ophthalmology) meeting dated 23.11.2023