Recommendations of the SEC (Ophthalmology) made in its 55th meeting held on 07.04.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/MA/22/000030 Ranibizumab	M/s. Sun Pharma	The firm presented the proposal for marketing authorization for Ranibizumab solution for injection 10mg/ml along with the Phase III clinical study report. The committee observed that the firm has submitted head to head comparison, non clinical toxicity, immunogenicity and clinical efficacy data of the drug in comparison with the reference product for the indication under study. After detailed deliberation, the committee recommended for grant of permission for manufacture of the drug for the indication i.e. neovascular age-related macular degeneration (wet AMD) subject to the condition that the firm should carry out Phase IV clinical study as per the guidelines for similar biologics. Accordingly, the firm should submit protocol for conduct of Phase IV study within three months of obtaining the manufacturing license. With regard to the other indications applied, the committee recommended that the firm should make a separate proposal for consideration after grant of marketing authorization of the drug.
SND Division			
2.	SND/MA/21/000499 Atropine Sulfate Ophthalmic Solution 0.01% w/v StabilisedOxychloro complex 0.005%w/v (SOC) as preservative (Change in preservative)	M/s. Indiana Ophthalmic	The firm did not turn up for presentation.
3.	SND/MA/22/0000094 Loteprednol Etabonate Ophthalmic Suspension 1% w/v	M/s. Ajanta Pharma	The firm presented their proposal for manufacturing and marketing of Loteprednol Etabonate Ophthalmic Suspension 1% w/v before the committee along with the Phase III clinical trial protocol. After detailed deliberation, the committee

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			recommended for grant of permission to conduct the Phase III clinical trial with the condition that dosing regimen in arm B (reference drug Loteprednol Etabonate Ophthalmic Suspension 0.5% w/v) should be QID instead of TID and revised protocol should be submitted to CDSCO.
FDC Division			
4.	FDC/CT/22/000007 Brinzolamide + Timolol Ophthalmic Suspension (1% w/v + 0.5% w/v) ophthalmic Suspension	M/s. Sun Pharma	The firm presented their proposal before the committee along with Phase IV CT protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase IV CT study.
GCT Division			
5.	CT/156/21 Online Submission (29263) LL-BMT1	M/s. Ecron Acunova	The firm presented Phase IIb clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study subject to the condition that IOP measurement should be done during acclimation phase in similar manner as with medicated contact lens.
6.	CT/170/21 Online Submission (29616) AFIL-IJZ-3003 (Aflibercept)	M/s. Cliantha Research	The applicant presented Phase III clinical trial protocol before the committee. **Risk versus Benefit-** The test drug is bio-similar of already approved Aflibercept, clinical data of test drug may justify the conduct of the study. **Innovation vis-a-vis existing therapeutic option** -The purpose of the study is to evaluate ocular safety and effective administration of MYL-1701P pre-filled syringe in patients with conditions requiring Intravitreal Aflibercept. **Unmet medical need in the country-** The availability of bio-similar products in the market may reduce the cost and provide more alternative product to the patients. The applicant has informed that the proposed study will be conducted in USA & India and test product - AFIL-IJZ-3003

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			(Aflibercept) will be imported in India for the study. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III study.
7.	CT/08/22 Online Submission (30307) THR-687	M/s. Inventiv International Pharma Service	The applicant presented Phase II clinical trial protocol before the committee. After detailed deliberation, the committee opined the following: 1) The firm should include patients in which fellow eye have good vision (equal to or more than 20/40) 2) The firm should submit more data on cerebrovascular events on proposed IMP Accordingly, the firm should submit revised protocol & data for further review by the committee.
8.	CT/43/20 Online Submission (15976) SCD411	M/s. PPD	The applicant presented protocol amendment version 03 dated 24/01/2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
9.	CT/80/21 Online Submission (16032) ISTH0036	M/s. Cliantha Research	The applicant presented protocol amendment version 02 dated 26/01/2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment with a condition that use of Anti-VEGF drug(s) should be included under protocol title, aim and objective of the study.
Medical Device Division			
10.	CI/MD/2021/51828 CT ASPHINA 509M/MP (Intraocular Lens)	M/s. Clinexel Life Science Pvt. Ltd.	The firm presented their proposal before the committee. After detailed deliberation, the committee sought clarification on following points: 1. The objective of study and where will data generated be used. 2 Justification of sample size with supporting documents. 3. PMS data generated by the manufacturer since last 5 years. 4. Justification for selecting only two

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			sites in India.
11.	CI/MD/2021/52506 LISA tri 839 MP (Intraocular Lens)	M/s. Clinexel Life Science Pvt. Ltd.	The firm presented their proposal before the committee. After detailed deliberation, the committee sought clarification on following points: 1. The objective of study and where will data generated be used. 2 Justification of sample size with supporting documents. 3. PMS data generated by manufacturer since last 5 years. 4. Justification for selecting only one site in India.
BABE Division			
12.	12-09/2022/BA-BE/Misc-05/DC (Application No. BABE/CT05/FF/2022/30263) Bimatoprost 0.0095% Eye Drops Solutions	M/s. Veeda Clinical Research Limited, Ahmedabad-380015	The firm presented their proposed study protocol. After detailed deliberation, the committee recommended for conducting the study as per the proposed study design.