Recommendations of the SEC (Neurology & Psychiatry) made in its 07th/25 meeting held on 23.04.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/32/24 Online Submission (38351) SAR441344 /frexalimab	SANOFI HEALTHCARE INDIA PRIVATE LIMITED	The firm presented protocol amendment 04 version 01 dated 25 October 2025 protocol no. EFC17919. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/93/20 Online Submission (38408) Edoxaban	M/s CBCI Society For Medical Education	The firm didn't turn up for presentation.
3.	CT/154/24 Online Submission (46917) BHV-7000	M/s PPD Pharmaceutical Development India Private Limited	In light of earlier SEC Recommendation dated 28.01.2025, now the firm presented phase II/III clinical trial protocol no. BHV7000-303 version V3.1 APAC dated 15 November 2024. After detailed deliberation, the committee noted the following: (1) The present study is lesser duration and follow-up duration also less instead of 24 months. (2) Reason for black box warning for the similar molecule by USFDA is not provided. (3) Data regarding Asian descent is not provided. The committee has expressed reservation on the possibility of the ethnic difference on the adverse effects particularly with Asian descent on the present study. Therefore, the committee did not recommend the present study protocol in the present form presented by the firm.
4.	CT/162/24 Online Submission (47101) BHV-7000	M/s PPD Pharmaceutical Development India Private Limited	Under Discussion.
Biological Division			
5.	BIO/CT18/FF/2024/41384	M/s. Eisai Pharmaceuticals	In light of earlier SEC recommendation dated 12.03.2024, the firm presented

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	Lecanemab concentrated solution for infusion 100 mg/ml	Pvt. Ltd.	safety and efficacy data generated from Global clinical trial including Asian population along with justification for the waiver of local clinical trial. Also the firm has presented the clinical data of 295 subjects of Asian sub-group. The committee noted that drug is approved in 42 countries including USA, Japan, EU and UK. There is an unmet medical need in the country. After detailed deliberation, the committee recommended for grant of permission to import and market the drug Lecanemab concentrated solution for infusion 100 mg/ml with local clinical trial waiver with condition to conduct Phase-IV study. The Phase IV study should be conducted in not less than 25 subjects and the study subject should be monitered for the period of 2 Years. Accordingly, the firm should submit Phase IV study protocol to CDSCO within 03 months of approval
BA/BE Division			
6.	BABE/CT05/FF/2024/43000 Rizatriptan Nasal Spray 2.5 mg/spray, Rizatriptan Nasal Spray 5mg/spray, Rizatriptan Nasal Spray 7.5 mg/spray.	M/s Lupin Limited	In light of the earlier SEC recommendation dated 12.12.2024, the firm presented more elaborated justification for dose assumption for applied test product and 14 days repeated animal toxicity data on Swiss albino mice (36 males + 36 females) and Sprague Dawley Rats (36 males + 36 females) After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BABE study for export purpose only
SND Division			
7.	SND/MA/25/000032 Quetiapine Oral Suspension 20 mg/ml	M/s Intas Pharmaceuticals Ltd	Firm presented their Proposal for grant of permission for manufacture and marketing of Quetiapine Oral Suspension 20 mg/ml along with BE study Protocol 0431-23 ver. no. 2.0. dated 12-Mar-2025 and justification for CT waiver before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct BE study as per Protocol presented by the firm along with request

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			of CT waiver. Firm shall submit the BE study report to CDSCO for further review by the committee.
8.	SND/IMP/24/000018 Clostridium BotulinumNeurotoxin Type A 50 Units & 100Units	M/s. Clini Experts Services Private Limited	In light of the earlier SEC recommendation dated 12.12.2024, firm has presented the global clinical data before the committee. Firm has informed that Clostridium Botulinum Neurotoxin Type A 50 Units & 100Units is approved for the proposed indication in UK, Japan and Switzerland. After detailed deliberation, the committee recommended for grant of permission to manufacture & marketing of Clostridium Botulinum Neurotoxin Type A 50 Units & 100Units for Symptomatic Treatment in adults of spasticity of the lower limb with the condition that firm should conduct the Phase-IV clinical trial study. Accordingly, firm should submit Phase-IV clinical trial protocol to CDSCO within 03 months from date of approval of drug for further review by the committee.