Recommendations of the SEC (Neurology & Psychiatry) made in its 06th/24 meeting held on 15.05.2024 & 16.05.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/116/21 Online Submission (28551) OAV101	M/s. Novartis	In light of earlier SEC recommendation dated 18.01.2024 and 19.01.2024,the firm presented protocol amendment version 03 dated 02.06.2023 protocol No. COAV101B12301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/174/21 Online Submission (31863) SAR442168	M/s. Sanofi	The firm presented protocol amendment 10 version 01 dated 17.11.2023 and protocol amendment 11 version 01 dated 20.12.2023 protocol No. EFC16034 After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/55/24 Online Submission (42808) Cenobamate Adjunctive Therapy	M/s. GCT Pharma	The firm presented Phase III clinical study protocol No. YKP3089C025 version 4 dated 27.10.2022. After detailed deliberation, the committee opined that the firm should submit rationale for the number of subjects, proper safety data and justification for sites selection for further review by the committee in presence of a paediatric neurologist.
4.	CT/178/21 Online Submission (31999) SAR442168	M/s Sanofi	The firm presented protocol amendment 12 version 1 dated 28.09.2023 and protocol amendment 13 version 1 dated 20.11.2023 protocol No. EFC16035 After detailed deliberation, the committee opined that the firm should submit detail sample size justification with statistical significance for decrease in the study population in this study from 990 to 700 subjects and justification for change of primary end point for further review by the committee.
5.	CT/132/23 Online Submission (40198)	M/s. Sanofi	In light of earlier SEC recommendation dated 20.12.2023, the firm presented Phase III clinical study protocol No.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	SAR442168/ Totebrutinib, Tolebrutinib		LTS17043, amendment 1, version 1 dated 12.07.2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
6.	CT/143/23 Online Submission (40495) OAV101 Onasemnogene abeparvovec	M/s. Novartis	The firm didn't turn up for presentation.
Biological Division			
7.	BIO/CT/20/000036 Tenecteplase/ R-TPR-012 (0.25 mg/kg)	M/s. Reliance Life Science	The firm presented clinical study report (CSR) of stage 1 study of Phase II/III clinical trial of similar biologic – Tenecteplase (TPR-012(0.25 mg/kg) compared with Tenectase™ (0.20 mg/kg) in Acute Ischemic stroke vide protocol No. RLS/CNS/2020/01 version 4.0 dated 17.09.2021 along with request to initiate the stage 2 of study as per approved protocol. The committee noted the results of the stage 1 study of Phase II/III clinical trial. After detailed deliberation, the committee recommended for approval to initiate the stage 2 study as per approved protocol.
SND Division			
8.	SND/MA/23/000078 Aripiprazole Oral Solution 1mg/ml	M/s. Pulse Pharmaceuticals Private Limited	In light of the earlier SEC recommendation dated 12.12.2023 & 13.12.2023, the firm represented the justification for waiver of BE study before the committee. After detailed deliberation, the committee opined that the firm did not submit the required data to establish the drug is bioequivalent. Hence, the firm's request for biowaiver can not considered and firm shall conduct Bioequivalence study with the innovator product approved in EU/USA.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			Accordingly, the firm needs to submit BE study protocol for further review by the committee.
New Drugs Division			
9.	ND/MA/24/000038 Siponimod tablets 0.25mg, 1mg, and 2mg	M/s. Dr. Reddy's Laboratories Ltd.	Under Discussion