Recommendations of the SEC (Neurology & Psychiatry) made in its 17th/24 meeting held on 19.11.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	GCT/PostAppr/2024/33297 Online Submission (33297) Milvexian	M/s. IQVIA RDS	***Under Discussion.***
BA/BE Division			
2.	File No. BABE/CT05/FF/2024/41854 Brexpiprazole 15.3 mg for Extended Release Injection.	M/s CBCC Global Research LLP	In light of the earlier SEC recommendation dated 18.07.2024, the firm presented revised Protocol (No.: MW230026 ver. 6.0 dated 02.09.2024) with PANSS Score in inclusion criteria. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Bioavailability study for export purpose .
3.	File No. BABE/CT05/FF/2024/42310 Brivaracetam 250 mg extended release tablets	M/s Veeda Clinical Research Limited	In light of the earlier SEC recommendation dated 24.07.2024, the firm presented the published research article conducted with higher dose (i.e. more than 200 mg) of the drug. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study for export purpose only .
4.	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	The firm did not turn up for the presentation.
5.	BABE/CT05/FF/2024/43255 Rizatriptan injection 1.5mg/0.5mL, Rizatriptan injection 3.0 mg/0.5mL, Rizatriptan injection	M/s Lupin Limited	The firm did not turn up for the presentation.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	4.5mg/0.5mL		
6.	BABE/CT05/FF/2023/38769 Carbidopa and Levodopa ER Capsule 70mg/280mg	M/s Lupin Limited	The firm did not turn up for the presentation.
SND Division			
7.	SND/MA/24/000102 Chlordiazepoxide Tablets I.P. 15mg & 20 mg	M/s Abbott Healthcare Private Limited	In light of the earlier SEC recommendation dated 18.07.2024, firm presented the proposal for grant of permission to manufacture and marketing of Chlordiazepoxide tablets I.P. 15mg & 20mg (Intermediate strength) along with Bioequivalence study protocol (Protocol no.PR/BE/24/089 version no.00 dated 16.05.2024) and justification for waiver of Phase III clinical trial before the expert committee which includes expert from National Drug Dependence Treatment Centre (NDDTC), AIIMS, Delhi. After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study as per the protocol presented by the firm. Further, the firm should submit Bioequivalence report and get evaluated by the SEC committee for further consideration.
8.	SND/IMP/24/000005 Risdiplam Powder for Oral Solution 0.75.mg/ml	M/s.Roche Products (India) Private limited	In light of the earlier SEC recommendation dated 13.06.2024, firm has presented the casualty assessment data of 16 days to 2 months and real world scenario data of less than 16 days before the committee. Firm has informed that Risdiplam Powder for Oral solution 0.75mg/ml for the treatment of spinal muscular atrophy (SMA) in paediatric and adult patients is already approved in USA. After detailed deliberation, committee recommended for the grant of permission for import and marketing of Risdiplam Powder for Oral solution 0.75mg/ml for the treatment of spinal muscular atrophy (SMA) in paediatric and adult patients with subject to condition that firm should conduct PMS study.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			Accordingly, firm should submit PMS protocol within 03 months from the date of approval of drug to CDSCO for further review by the committee.
New Drug Division			
9.	ND/MA/23/000208 Lumateperone capsules 10.5, 21 and 42 mg	M/s. MSN Laboratories Private Limited	The firm presented BE study report of Lumateperone capsules 42 mg along with Justification for Phase-III Clinical Trial waiver before the committee. Committee considered BE study results. Further, Committee noted that there is no unmet medical need of applied product in the country, as the standard of care drugs are already available. Committee also noted that firm has not submitted any supporting data for Lumateperone capsules 10.5 and 21 mg. After detailed deliberation, the committee did not agree for waiver of Phase-III Clinical Trial. Accordingly, firm should submit Phase-III Clinical Trial protocol to CDSCO for further review by committee.