Recommendations of the SEC (Neurology & Psychiatry) made in its 11th/24 meeting held on 07.08.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/84/24 Online Submission (44087) Lumateperone	M/s. IQVIA RDS (India) Private Limited	The firm presented Phase III clinical study protocol no. ITI-007-421, Amendment 1 dated 15 Mar 2024. After detailed deliberation, the committee opined that the firm shall submit revised protocol as mentioned below for further review of the committee: (i) Specifying the objective measures in the exclusion criteria related to Intellectual disability. Assessment of concomitant psycho social interventions at baseline and at every visit.
2.	CT/55/24 Online Submission (42808) Cenobamate	M/s. GCT Pharma Research (India) Pvt. Ltd.	In light of earlier SEC recommendation 15.05.2024 & 16.05.2024, the firm presented Phase III clinical study protocol no. YKP3089C025 Version 4 dated 27.10.2022. After detailed deliberation, the committee recommended for the grant of permission to conduct Phase III clinical trial as per the protocol presented subject to following conditions:- (i) The firm shall have India specific Independent data and safety monitoring board. More number of Government sites shall be included in the study.
Medical Devices Division			
3.	CI/MD/2024/118310 Nerve Electrical Stimulator (Brand Name: Nerivio). Protocol Number: DRL-NEU-003, Version 2.0, dated 02.02.2024	M/s. Dr. Reddy's Laboratories Limited	The firm presented the study protocol for conduct of Post Marketing Clinical Investigation on "Nerve Electrical Stimulator" on Indian population, to comply with one of the conditions of the permission granted under Form MD-26. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study on the Indian population subject to the condition that the inclusion criteria should be amended with the inclusion of patients with migraine needing Prophylaxis and had

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			failed the Prophylaxis with first line agent given in appropriate dose for atleast 03 months and the data generated shall be submitted to the Central Licensing Authority for further review and necessary action in the matter.
4.	CI/MD/2023/113858 Cochlear Implant System (Brand Name: HCLTech SUNO)	M/s. HCL Technologies Limited	The firm has presented the study protocol for conduct of Pivotal Study on Cochlear Implant System manufactured indigenously in the Indian population along with the report of Pilot Study generated on the Indian population. The report shows short term safety and functionality of the device in adults which have been encouraging. After detailed deliberation, the expert committee suggested that clinical investigation study may be considered subject to the condition that the study should include at least 50% of the subjects selected from prelingual paediatric population. The firm may carry out the proposed study with the approval of the Institute Human Ethics Committee of the respective site where the clinical study is proposed and the data generated on Indian population may be produced as a Clinical evidence for obtaining regulatory approval for its commercialization in the country.
BA/BE Division			
5.	BABE/CT05/FF/2024/42856 Tianeptine Extended Release Once Daily Tablets 37.5 mg	M/s. Lupin Limited	The firm presented the Protocol No.: LBC-P-024-24 Version No. 00 Protocol Date 05-APR-2024 for BA/BE study for export purpose only. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study for export purpose only.
6.	BABE/CT05/FF/2024/42540 Tianeptine Extended Release Once Daily	M/s. Lupin Limited	The firm presented the Protocol No.: LBC-P-006-24 Version No. 00 Protocol Date 19-MAR-2024 for BA/BE study for export purpose only.

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	Tablets 37.5 mg		After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study for export purpose only.
SND Division			
7.	SND/MA/24/000090 Ketorolac Tromethamine Sublingual Tablets 30mg	M/s. Troikaa Pharmaceuticals Limited	In light of earlier SEC recommendations dated 13.10.2020 & 14.10.2020, the firm presented Phase III Clinical trial study report before the committee. After detailed deliberation, the committee opined that the firm should submit the adequate data of the adverse events occurred in the initial one week of the trial especially in the group administered with placebo and effect of the drug product on kidney as it induces renal toxicity to CDSCO for further review by the committee.
8.	SND/MA/23/000078 Aripiprazole oral Solution 60ml and 150ml	M/s. Pulse Pharmaceutical Private Limited	In light of earlier SEC recommendations dated 15.05.2024 & 16.05.2024, the firm presented BE study protocol (Protocol No. TBS-06-24-828 Version No.1.0 dated 11.06.2024) before the committee. After detailed deliberation, the committee recommended the grant of permission to conduct Bioequivalent Study as per the protocol presented by the firm.
New Drugs Division			
9.	ND-11012(19)/13/ 2024-eoffice Zolpidem Tartrate ER Tablets 6.25mg/12.5 mg	M/s. Sanofi	The firm presented the proposal for amendment in Package Insert from Company Core data sheet (CCDS) Version 16 to CCDS Version 18 for drug Zolpidem Tartrate Extended Release Tablets 6.25mg and 12.5mg. After detailed deliberation, the committee recommended for approval of amendment in Package Insert from CCDS Version 16 to CCDS Version 18, for drug Zolpidem Tartrate Extended Release Tablets 6.25mg and 12.5mg.
10.	ND/MA/24/000013 Cenobamate Tablets 12.5mg, 25mg, 50mg, 100mg, 150mg,	M/s. Bajaj Healthcare Ltd.	The firm presented its proposal for manufacturing and marketing of the drug Cenobamate Tablets 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg and 200 mgalong

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	200mg		withPhase III Clinical Trial protocol and justification for BE study waiver before the committee. After detailed deliberation, the committee agreed for the waiver of BE study. Further, the committee opined that the firm should revise the Phase III Clinical Trial protocol with the following- 1. Revise the terminology from partial onset seizures to focal onset seizures 2. Inclusion of definition of the drug resistant focal onset seizures 3. The patient should have reached adequately tolerated dose of the first drug 4. Inclusion of more Govt. sites having drug resistant epilepsy clinics to be recruiting centers 5. Any SAEs which involve pregnant women or SUDEP (Sudden unexpected death in epilepsy), the firm should report immediately to CDSCO 6. The firm should have DSMB (Data Safety and Monitoring Board) Accordingly, the firm should submit revised protocol to CDSCO for further review by the committee.
FDC Division			
11.	FDC/MA/24/000123 Clonazepam IP 0.25mg/0.5mg + Venlafaxine Hydrochloride IP eq. to Venlafaxine (ER) 75mg/75mg uncoated bilayered tablet	M/s. Akums Drugs & Pharmaceuticals Ltd.	The firm presented the proposal before the committee. After detailed deliberation, the committee opined that: 1. The firm was unable to present any scientific rationality or justification of the combination and its significant benefits. 2. The firm was not able to present essentiality or desirability of the proposed FDC vis-a-vis approved individual drugs of FDC. 3. Using the proposed combination in women may put them in danger and jeopardise the pregnancy outcome. 4. Firm was not able to present

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			justification on dose titration along with dosing schedule. 5. Combining the Clonazepam and Venlafaxine may involve the risk of adverse event, include falls and its sequelae as complications and has the potential to lead the benzodiazepine dependency. 6. The product is not approved internationally. 7. There is no unmet need for proposed FDC. In view of above, the committee did not recommend for approval of the proposed FDC.