Recommendations of the SEC (Neurology & Psychiatry) made in its 19th meeting held on 12.12.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/84/24 44087 Online Submission (44087) Lumateperone	M/s IQVIA	In light of earlier SEC recommendation dated 07.08.2024, now the firm presented Phase III clinical study protocol no. ITI-007-421, Amendment 1 dated 15 Mar 2024 (India Amendment #1 dated 24 Oct 2024) After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/135/24 Online Submission (46277) Cladribine	M/s IQVIA	The firm presented phase III clinical study Protocol no.:MS700568_0183, version 2.0 dated 14 Mar2024. After detailed deliberation, the committee recommended that firm should submit the revised protocol with Active comparator rather than placebo against the study drug along with Safety data from previous study for further review by committee.
3.	CT/140/24 Online Submission (46533) Lumateperone (ITI-007)	M/s IQVIA	The firm presented phase III clinical study protocol no. ITI-007-321India original protocol dated 01Oct 2024. After detailed deliberation, the committee recommended for grant of Permission to conduct the trial as presented by the firm with following conditions: 1.Measures to assess the participants cognitive functions and school performance at baseline and end of treatment. 2.Instructions to be given to the participants and LAR regarding somnolence and suggesting safety measures.
BA/BE Division			
4.	BABE/CT05/FF/2024 /43000	M/s Lupin Limited	The firm presented the protocol no. LBC-P-039-24 Version no.00 Dt 15-4-2024 for Bioavailability study for export

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	Rizatriptan Nasal Spray 2.5 mg/spray, Rizatriptan Nasal Spray 5mg/spray, Rizatriptan Nasal Spray 7.5 mg/spray		purpose only. After detailed deliberation ,the committee opined that firm is required to submit the following documents : (1) More elaborated justification for dose assumption (2) Animal toxicity data generated on sufficient number of experimental animals, as the submitted toxicity data was having very less sample size. Accordingly , the firm should submit the above information/ data for re-deliberation in the SEC
5.	BABE/CT05/FF/2023 /38769 Carbidopa and Levodopa ER Capsule 70mg/280mg	M/s Lupin Limited	The firm has withdrawn the application
SND Division			
6.	SND/IMP/24/000018 Clostridium Botulinum Neurotoxin Type A 50 Units & 100Units	M/s Cliniexpert services pvt ltd	Firm presented the proposal for import and marketing of Clostridium Botulinum Neurotoxin Type A 50 Units & 100Units for the additional indication of Symptomatic Treatment in adults of spasticity of the lower limb before the committee. After detailed deliberation, the Committee opined that firm has not present the adequate clinical data in the context of Phase-III clinical trial waiver. Therefore, the committee recommended to submit the global clinical data to consider the waiver of Phase-III clinical trial for the proposed indication.
7.	SND/CT/21/000092 Amantadine Extended Release Tablets 193 mg & 129 mg	M/s Sun Pharma Laboratories Limited	In light of earlier SEC recommendations dated 16.12.2021, the firm presented Phase-IV clinical trial report before the committee. After detailed deliberation, the Committee considered Phase-IV clinical trial report as deliberated by the firm.
New Drug Division			
8.	ND/MA/22/000079	M/s Sun Pharma Laboratories Ltd.	In light of earlier SEC recommendations dated 12.12.2023 & 13.12.2023 and as

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Etifoxine Hydrochloride Capsules 50mg		per the marketing authorization approval condition to 9 for new drug Etifoxine Hydrochloride Capsules 50mg granted to the firm, the firm presented active PMS study protocol with drug Etifoxine Hydrochloride Capsules 50mg before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct active PMS study with new drug Etifoxine Hydrochloride Capsules 50mg as per the protocol presented.