Recommendations of the SEC (Neurology & Psychiatry) made in its 10th/24 meeting held on 24.07.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/92/23 Online Submission (32935) Asundexian (BAY 2433334)	M/s. Bayer Pharmaceuticals Pvt. Ltd.	The firm presented protocol amendment 2 version 3.0dated 18.04.2024 and Increase in number of 20 patients for India protocol No. 20604. After detailed deliberation, the committee recommended for protocol amendment and increase in number of subjects (additional 20 subjects) as presented by the firm with the condition that EQ-5D questionnaire scale (verbal or non-verbal shall be video recorded).
2.	CT/36/23 Online Submission (33297) Milvexian	M/s. IQVIA RDS	The firm presented protocol amendment 2 dated 10.04.2024 protocol No. 70033093STR3001. After detailed deliberation, the committee opined that the firm shall submit interim analysis report and proposal shall be deliberated in presence of Nephrologist.
Medical Devices Division			
3.	CI/MD/2023/100848 Gravity Supernova Revascularization Device	M/s. Gurutva Medical Technology	The firm presented the clinical investigation protocol along with the comparative statement of the proposed device (i.e. Supernova Revascularization Device) with respect to predicate devices available in India and the proposed device shown substantial equivalence with predicate device. However, the proposed device is not approved by any of the Stringent Regulatory Authority. After detailed deliberation, the committee opined that since the proposed device is substantially equivalent to the predicate devices available in the Indian market the firm may carry out the study with the approval of Ethics Committee with CTRI registry requirements and the data generated on Indian population may be produced as a clinical evidence for obtaining regulatory approval for commercialization of the product in the country.

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BA/BE Division			
4.	BABE/CT05/FF/2024 /42310 Brivaracetam 250 mg extended release tablets	M/s. Veeda Clinical Research Limited	The firm presented the Protocol No. 24-VIN-0071 Version 01 dated 26.2.2024 before the committee. After detailed deliberation, the committee opined that the firm should provide and present copies of published research articles of studies conducted with higher dose (i.e. more than 200mg) of the drug for further deliberation before the committee.
SND Division			
5.	SND/MA/22/000052 Midazolam Nasal Spray 0.5% w/v & 1.25 % w/v (Additional Dosage Form)	M/s. Savi Healthcare Private Limited	In light of earlier SEC recommendation dated 23.02.2024, the firm presented the study protocol SB-IND-CT-082 ver. 1.0 dated 09.05.2024 along with justification before the committee. The committee noted that the multiple dose spray of Midazolam nasal spray 0.5w/v & 1.25%w/v is not approved anywhere in the world and there is chance of drug abuse in the country. USFDA has approved Nayzilam single dose nasal spray containing Midazolam 5 mg/0.1 ml. Therefore, the committee opined that the dose for Midazolam nasal spray 1.25% w/v (multidose) should be limited to a maximum of 4 actuations (2 actuations per Nostril) and shall not be increased beyond 5mg/ vial. Further, Midazolam IP 0.5 mg/0.1 ml dosage formulation (Test product: T1) shall not be considered in clinical trial due to its large volume administration in nostrils. After detailed deliberation, the committee recommended for grant of permission to conduct clinical trial with Midazolam Nasal Spray 1.25%w/v in 04 Actuations (02 in each nostril) for the subjects with seizure clusters with following conditions: 1. The firm is required to submit revised Phase III clinical trial protocol for

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			Midazolam Nasal Spray 1.25%w/v. 2. The firm should also fulfil the requirements of CMC data.
6.	SND/MA/23/000314 Pregabalin Gel 8%w/w	M/s. Lyka Labs Limited	In light of earlier SEC recommendations dated 13.06.2023, the firm presented the proposal for manufacture and marketing of Pregabalin Gel 8% w/w along with Phase III clinical trial results data before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of Pregabalin Gel 8% w/w indicated for Diabetic neuropathic pain subject to condition that the firm should conduct Active PMS study. Accordingly, the firm should submit Active PMS study protocol to CDSCO within 03 months from date of approval of the drug product for further review by the committee.
New Drugs Division			
7.	ND/MA/22/000125 Lisdexamfetamine Dimesylate Capsules 10mg/20mg/30mg/40 mg/50mg/60mg/70mg	M/s. Ind-Swift Ltd.	In light of earlier SEC recommendations dated 18.04.2024, the firm submitted the published safety and efficacy data along with justification for Phase III CT waiver before the committee. After detailed deliberation, the committee noted that there is no sufficient data submitted by the firm for establishing safety and efficacy of drug product. Hence, the committee recommended that the firm should conduct comparative randomized Phase III Clinical Trial on Indian population. Accordingly, the firm should submit the Phase III CT Protocol to CDSCO for further review by the committee.
8.	ND/MA/23/000209 Nusinersen Solution for Injection 2.4 mg/ml (12mg/5ml)	M/s. Jodas Expoim Pvt. Ltd.	In earlier SEC meeting dated 18.04.2024, the committee noted that the innovator formulation is approved for SMA patients in other countries like USA and EU. However, the firm has not provided any in vivo study data/ patient safety/ efficacy data for the applied drug product. Therefore, the committee recommended

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			to conduct Phase III clinical trial in India. In light of above mentioned earlier SEC recommendations, the firm presented preclinical animal toxicity, immunogenicity data and requested for Phase III clinical trial waiver before the committee. After detailed deliberation, the committee noted that there is no safety data on Indian population and safety & efficacy data needs to be established on Indian patients. Further, committee opined that the firm should submit Phase III CT protocol for further review by the committee.