Recommendations of the SEC (Neurology & Psychiatry) made in its 84th meeting held on 15.09.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	4-29/Gennova/PAC-R-Tenecteplase/2022-BD Tenecteplase	M/s. Gennova Biopharmaceuticals Limited	The firm presented Interim Safety Report of the Active PMS study of IV Tenecteplase in Acute Ischemic Stroke for adult patients within 3 hours of stroke onset and the proposal to extend administration time of drug for Acute ischemic stroke up to 4.5 hours from stroke onset on the basis of published global studies and literature references. After detailed deliberations, the committee accepted the presented interim safety data of active PMS study and recommended for grant of approval to extend administration time of drug up to 4.5 hours of stroke onset on the condition that the firm should generate and present data on thrombolysis with the modified PMS protocol i.e upto 4.5 hours of stroke onset from the remaining number of subjects in the PMS and submit the data to CDSCO for further review by the committee.
SND Division			
2.	SND/IMP/22/000019 Paliperidone Palmitate Prolonged Release Suspension for intramuscular injection 700 mg & 1000 mg (6 months injection (PP6M)	M/s. Johnson & Johnson	In light of earlier SEC recommendation dated 12-05-2022, the firm represented comparative efficacy/safety data of PP6M Vs PP3M and PP6M vs PP1M of global clinical trial in global and ethnic Indian (or Indian Origin) patients. The committee noted that there is no country where PP6M (6 months injection) is marketed without the approval of PP3M (3 months injection). Also the committee opined that the patients recruited from India in global clinical trial are less in number. After detailed deliberation, the committee recommended for conduct of Phase III clinical trial in India. Accordingly, Phase III clinical trial protocol should be submitted for review by the committee.
3.	SND/CT/21/000081	M/s. BDR Pharmaceuticals	The firm didn't turn up for presentation.

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	Edaravone Oral Suspension 150 mg (30 mg/ml)		
FDC Division			
4.	FDC/MA/22/000082 Clonazepam 0.25mg + Desvenlafaxine 50mg (Extended Release) Tablets	M/s. Pure & Cure Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 20.04.2022, the firm presented the BE study results before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC.
GCT Division			
5.	CT/58/20 Online Submission (17877) Evobrutinib	M/s. IQVIA	The firm presented the proposed protocol amendment 4.0 dated 03-Apr-2022 under the Evolution RMS1 Phase III study protocol no. MS200527_0080 to re-open the trial recruitment in the country. After detailed deliberation, the committee recommended for the re-opening of the trial recruitment in the country with the proposed protocol amendment.
6.	CT/65/22 Online Submission (33077) Brilaroxazine (RP5063)	M/s. PRA	The firm presented the Phase III protocol no. RVP-30-001, version 4.0 (Amendment 3) dated 29-Mar-2022 (RECOVER) before the committee. After detailed deliberation, the committee recommended for grant of approval to conduct the study.
SND Division			
7.	SND/MA/20/000368 Midazolam Nasal Spray 0.5% w/v & 1.25%w/v	M/s. Biodeal Pharmaceuticals	The firm presented their proposal with justification alongwith published literature before the committee. After detailed deliberation, the committee opined that in light of the applied indications, the proposal should be deliberated in presence of Anesthetists.
8.	SND/MA/22/0002227 Edaravone Powder for Oral Suspension 105 mg in sachet (1.5 gm)	M/s. BDR Pharmaceuticals	The firm presented their proposal to manufacture and market Edaravone Powder 105 mg in Sachet (1.5gm) Oral Suspension "Indicated for the treatment of Amyotrophic Lateral Sclerosis (ALS)" alongwith BA/BE study protocol before the committee. After detailed deliberation, the

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			committee recommended for grant of permission to conduct the BA/BE study of this Edaravone suspension as per protocol presented.