Recommendations of the SEC (Neurology & Psychiatry) made in its 90th meeting held on 16.03.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-01/2022-DC (Pt-267) Sodium Valproate Tablets 200mg/500mg, Sodium Valproate IP + Valproic Acid IP 133mg/58mg, 200mg/87mg, 330mg/145mg, & Sodium Valproate IP Oral Solution 200mg/5ml	M/s Sanofi Healthcare India Pvt Ltd.	The firm did not turn up for presentation.
SND Division			
2.	SND/MA/22/000164 Perampanel oral suspension 0.5mg/ml	M/s Alkem Laboratories ltd	The proposal was deferred for next meeting.
3.	SND/MA/22/000275 Perampanel oral suspension 0.5mg/ml	M/s Akums Drugs and Pharmaceuticals Limited	The proposal was deferred for next meeting.
4.	SND/CT/22/000052 Pregabalin Gel 8% w/w	M/s Lyka Labs Ltd.	The proposal was deferred for next meeting.
FDC Division			
5.	FDC/MA/20/000190 Nortriptyline HCl eq to Nortriptyline10mg/ 10mg+Gabapentin 100mg/200mg film coated tablet	M/s. Synokem Pharmaceuticals Ltd.	The proposal was deferred for next meeting.
GCT Division			
6.	CT/182/22 Online Submission (35385) Ocrelizumab(RO4964	M/s. PPD	The firm presented the proposed Phase 3 clinical trial protocol no. WN42086, version 2 (Operetta 2) before the committee. After detailed deliberation, the committee

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	913)		recommended for grant of permission to conduct the study with condition that before initiation of open label extension part of the study, the firm should submit primary analysis data of double blind part of study to CDSCO for further review by the committee.
7.	CT/115/22 Online Submission (34193) Fenebrutinib Compared with Ocrelizumab	M/s. Roche	The firm presented the proposed trial protocol no. GN41791, version 4, dated 15-Sep-2021 before the committee. After detailed deliberation, the committee recommended that the proposal might be deliberated in next meeting in presence of neurologist who is not proposed as Investigator in the study from India.
8.	CT/116/22 Online Submission (34287) Basimglurant Adjunctive	M/s. CliniRx Research	The firm presented the proposed Phase 2b trial protocol no. NOE-TSC-201, version 4.0 dated 28-Apr-2022 before the committee. After detailed deliberation, the committee recommended for the approval of the proposed study with the condition that the firm should submit the detailed safety report to CDSCO and SEC along with DSMB report after first 08 subjects complete the Part A of the study as per protocol. Once the data is reviewed by the CDSCO and SEC, the trial might be further continued for enrollment in the country.
9.	CT/144/20 Online Submission (21530) Evenamide	M/s. CliniRx	In light of SEC recommendations dated 17-01-2023, the firm presented the clarifications and the proposed protocol amendment 3.0 dated 19-Sep-2022 under the Phase 2/3 trial protocol no. NW-3509/008A/II/2020 before the committee. The committee noted that earlier there was no explicit approval granted for subject increase. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment with increase of 60 subjects from the initially approved number i.e. from 60 to 120 from the country.
10.	CT/130/21 Online Submission (21802)	M/s. Bioinnovate Research	The firm presented protocol amendment version 3.0 dated 22-09-2022 to protocol no. P3-IMU-838-RMS-02 (ENSURE-2) before the committee. After detailed deliberation, the committee

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	IMU-838		recommended for approval of the proposed protocol amendment.
11.	CT/128/21 Online Submission (21801) IMU-838	M/s. Bioinnovate Research	The firm presented protocol amendment version 3.1 dated 19-09-2022 to protocol no. P3-IMU-838-RMS-01 (ENSURE-1) before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
12.	CT/62/21 Online Submission (20679) Varespladib- methyl	M/s. Premier Research	The proposal was deferred for next meeting.
13.	CT/44/22 Online Submission (23713) SRP-4045 and SRP-4053	M/s. PPD	The firm presented protocol amendment version 13 (Amendment 12) dated 10-10-2022 to protocol no. 4045-301 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
14.	CT/22/000152 Online Submission (34942) Lumateperone (Caps)	M/s. IQVIA	The firm presented the proposed trial protocol no. ITI-007-501, amendment 2, dated 20-Aug-2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed study with condition that the HIV serology test to be performed at screening for all prospective trial subjects.
15.	CT/22/000162 Online Submission (35053) Lumateperone (Caps)	M/s. IQVIA	The firm presented the proposed trial protocol no. ITI-007-503, amendment 1, dated 23-Aug-2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed study as per the protocol.
16.	CT/45/22 Online Submission (24308) Eteplirsen (Injection)	M/s PPD	The firm has presented protocol amendment version 9 (Amendment 8) dated 10-06-2022 to protocol no. 4758-402 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment
17.	CT/175/22 Online Submission (35074) Endoxifen	M/s Intas	The firm presented Phase III clinical trial protocol no 72189812, version 02 dated 06-12-2022 before the committee. The committee noted that the study drug Endoxifen is already approved in India since 10-12-2019 for proposed indication.

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			After detailed deliberation, the committee recommended that the firm should submit approval letters from other participating countries and revise the protocol as below- 1. The treatment period should be at-least 4 weeks. 2. The study design should be 3:1 (Active: Placebo) rather than 1:1. 3. Sample size should be justified and to be re-calculated. Only 10% of global sample size should be proposed from the country. 4. eGFR test should be carried out at screening visit. 5. Additional pregnancy test should be carried out at the start of dosing in women of child bearing potential. 6. Safety management plan to be included in the protocol. Accordingly, revised protocol with revised no. of proposed samples size from the country should be submitted to CDSCO for further review by the committee.
SND Division			
18.	SND/CT/22/000068 Ketamine Hydrochloride Injection 50 mg/ml	M/s. Themis Medicare	The proposal was deferred for next meeting.