Recommendations of the SEC (Neurology & Psychiatry) made in its 91st meeting held on 18.04.2023 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 tablets, Sodium Valproate I.P. + Valproic Acid I.P 133mg/58mg, 200mg/87mg, 333mg/145mg Sodium Valproate I.P Oral Solution 200mg/5ml	M/s. Sanofi Healthcare India Private limited	The firm presented the updation in prescribing information of Sodium Valproate tablets 200mg /500mg tablets, Sodium Valproate I.P. + Valproic Acid I.P 133mg/58mg, 200mg/87mg, 333mg/145mg and Sodium Valproate I.P Oral Solution 200mg/5ml. After detailed deliberation, the committee recommended for proposed updation in prescribing information.
SND Division			
2.	SND/MA/22/000164 Perampanel oral suspension 0.5mg/ml	M/s. Alkem Laboratories Ltd	The firm presented its proposal for manufacturing and marketing of Perampanel oral suspension 0.5mg/ml along with BA/BE study results and justification of Phase III clinical trial waiver, before the committee. The committee noted that Perampanel oral suspension 0.5mg/ml is already approved in USA under brand name "FYCOMPA" and marketed by M/s. Eisai Inc. After detailed deliberation, the committee recommended that based on BA/BE study results, the waiver for local Phase III clinical trial and grant of permission for manufacture and marketing of Perampanel oral suspension 0.5mg/ml for already approved indication could be considered.
3.	SND/MA/22/000275 Perampanel oral suspension 0.5mg/ml	M/s. Akums Drugs and Pharmaceuticals Limited	The firm presented the proposal for manufacturing and marketing of Perampanel oral suspension 0.5mg/ml along with BA/BE study results and justification of Phase III clinical trial waiver, before the committee. The committee noted that Perampanel

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			oral suspension 0.5mg/ml is already approved in USA under brand name "FYCOMPA" and marketed by M/s. Eisai Inc. After detailed deliberation, the committee recommended that based on BA/BE study results the waiver for local Phase III clinical trial and grant of permission for manufacture and marketing of Perampanel oral suspension 0.5mg/ml for already approved indication could be considered.
4.	SND/CT/22/000052 Pregabalin Gel 8% w/w	M/s.Lyka	In light of SEC recommendation dated 18-11-2022, the firm presented the revised clinical trial protocol. After detailed deliberation, the committee recommended that Clinical trial protocol should be revised with respect to following points: 1. Design of clinical trial should be double blind, double dummy, placebo controlled trial. 2. There should be one primary end point. 3. Sample size should be recalculated. Accordingly, the firm should submit revised clinical trial protocol for further review by the committee.
5.	SND/IMP/22/000019 Paliperidone Palmitate Prolonged Release Suspension for intramuscular injection 700mg/1000mg	M/s. Johnson & Johnson Pvt. Ltd.	In light of earlier recommendation dated 15-09-2022, the firm presented the proposal for import and marketing of Paliperidone Palmitate Prolonged Release Suspension for Intramuscular Injection 700mg/1000mg (6 months injection i.e PP6M). Committee noted that the firm has not presented additional data. After detailed deliberation, the committee reiterated the previous SEC recommendation i.e the recommendation of SEC meeting held on 15-09-2022.
6.	SND/IMP/22/000068 Ketamine Hydrochloride Injection 50 mg/ml	M/s Themis Medicare Ltd.	In light of earlier recommendation of SEC held on 15.02.2023, the firm presented the revised protocol for Phase-III clinical trial w.r.t study design, study period and safety endpoint before the committee.

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			After detailed deliberation, the committee recommended that firm should modify the presented protocol as discussed during the meeting and the relevant publication in peer reviewed journal for particular indication should be submitted for further review by the committee.
FDC Division			
7.	FDC/MA/20/000190 Nortriptyline HCl eq to Nortriptyline10mg/10 mg + Gabapentin 100mg/200mg film coated tablet	M/s. Synokem Pharmaceuticals Ltd.	The firm presented the proposal along with Phase IV Clinical study protocol. After detailed deliberation, the committee recommended to conduct Phase IV Clinical study with the condition to include more Govt. sites which should be geographically distributed.
GCT Division			
8.	CT/62/21 Online Submission (20679) Varespladib-methyl	M/s. Premier Research	The firm presented the proposal to increase patient number in India from 50 to 83 before the committee. The firm informed the committee that globally there are 96 patients in the ongoing trial and there was no safety issue (no SAE) so far with the study drug and the trial DMSB has recommended for continuation of the study. After detailed deliberation, the committee recommended to increase the patient number in India from 50 to 83.
9.	CT/24/23 Online Submission (36610) AMZ002	M/s. Tech observer	Firm did not turn up for presentation.
10.	CT/179/21 Online Submission (21248) SAR442168	M/s. Sanofi	The firm presented the proposal of protocol amendment no. 06 version 01 dated 23rd May 2022 and protocol amendment no. 07 version 01 dated 13-Sep-2022 to protocol no. EFC16645 before the committee. After detailed deliberation, the committee recommended that the firm should submit safety data in support of proposed protocol amendments for further review by the committee.

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11.	CT/115/22 Online Submission (34193) Fenebrutinib Compared with Ocrelizumab	M/s. Roche	Firm did not turn up for presentation.
Medical Device Division			
12.	IMP/MD/2023/79104 DuraSeal Dural Sealant System &DuraSealXact Sealant System	M/s. Dr. Reddys Laboratories Limited	The proposal was deferred for next meeting.
GCT Division			
13.	CT/03/20 Online Submission (22774) Evenamide	M/s. CliniRx	The firm presented India specific protocol amendment 4.2 dated 08-07-2022 before the committee. After detailed deliberation, the committee did not recommend for approval of proposed protocol amendment and recommended that the firm should submit consolidated interim analysis report along with DMSB recommendations for further review by the committee.
14.	CT/12/23 Online Submission (36044) Basimglurant 1.5 to 3.5 mg	M/s. CliniRx	The firm presented Phase II/III clinical trial protocol no NOE-TGN-201, version 2.0 dated 26-12-2022 before the committee. After detailed deliberation, the committee did not recommend for grant of permission to conduct of the study at this stage for the following reasons: 1. There is no rationale for dose selection for the proposed study. 2. There is no sufficient safety data available with study drug. 3. There is no rationale for using placebo as comparator in the proposed study. 4. There is no rationale for 52 weeks open label extension phase without doing interim analysis in the proposed study.