Recommendations of the SEC (Neurology & Psychiatry) made in its 89th meeting held on 15.02.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/22/000066 Lasmiditan 50mg and 100mg tablets	M/s. Eli Lilly and Company (India) Pvt. Ltd.	The firm presented its proposal to import and marketing of Lasmiditan 50mg and 100mg tablets along with global Phase III clinical trial report before the committee. The committee noted that Lasmiditan Tablets 50mg/100mg is approved in countries like U.S.A., Japan and European union etc. The global clinical trial data demonstrate the efficacy and safety of drug for acute treatment of migraine with and without aura. After detailed deliberation, the committee recommended for grant of permission to import and marketing of Lasmiditan 50mg and 100mg tablets subject to the conditions that the firm should conduct Phase IV clinical trial in the country for which protocol should be submitted to CDSCO within two months of approval of the drug for further review by the committee.
2.	ND/MA/22/000151 Lasmiditan Tablets 50mg/100mg/200mg	M/s Pure & Cure Healthcare Pvt. Ltd.	The firm presented its proposal for manufacturing and marketing of Lasmiditan Tablets 50mg/100mg along with justification for clinical trial waiver for Phase III. The committee noted that the Lasmiditan Tablets 50mg/100mg is approved in countries like U.S.A., Japan and European union etc. The global clinical trial data demonstrate the efficacy and safety of drug for acute treatment of migraine with and without aura. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Lasmiditan Tablets 50mg/100mg subject to the conditions that the firm should conduct Phase IV clinical trial in the country for which protocol should be submitted to CDSCO within two months of approval of the drug for further review by the

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			committee.
SND Division			
3.	SND/MA/22/000238 Caroverine Capsule 40 mg	M/s Lincoln Pharmaceuticals	The firm presented the proposal to manufacture and marketing permission of Caroverine Capsule 40mg (additional strength) for already approved indication alongwith BE protocol and clinical trial waiver before the committee. In India Caroverine capsule 20mg and injection 40mg/2ml are already approved on 23/08/06 for abdominal pain and tinnitus in adult. The firm had also obtained manufacture and marketing permission of Caroverine Hydrochloride injection 40mg/2ml (160mg/8ml) on 19.01.2010 with same indication. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study as per the protocol presented by the firm.
4.	SND/MA/22/000314 Brivaracetam Sustained Release Tablets 50mg/100mg/150mg	M/s. Ravenbhel Healthcare	The firm presented the proposal to manufacture and marketing permission of Brivaracetam sustained release tablets 50mg/100mg/150mg (additional dosage form) for already approved indication alongwith BE and Clinical Trial waiver justification, before the committee. In India, Brivaracetam film coated tablets 25mg, Brivaracetam injection 50mg/5ml (10mg/ml), Brivaracetam Oral Solution 10mg/ml, Brivaracetam SR Tablets 200mg are already approved for the indication as mentioned below: ***As adjunctive therapy in the treatment of partial onset seizures in patients 16 years of age and older with epilepsy.*** The firm had conducted bioequivalence study at higher strength i.e. Brivaracetam SR Tablets 200mg and subsequently obtained manufacture and marketing permission of Brivaracetam sustained release tablets 200mg on 12.12.2022 for same indication. In view of above the committee considered the BE waiver for lower strengths of the approved drug product and recommended for grant of permission

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			to manufacture and market Brivaracetam sustained release tablets 50mg/100mg/150mg for already approved indication.
FDC Division			
5.	FDC/MA/22/000359 Lacosamide 50mg/50mg+Brivaracetam 50mg/100mg tablets	M/s. Hetero Labs Ltd.	The firm presented its proposal along with BE & Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended that : 1. There is no unmet need of proposed FDC. 2. The product is not approved internationally. 3. There is no scientific literature available from good indexed journal/peer reviewed journal in support of proposed FDC. 4. The firm could not justify the scientific rationale. 5. The firm did not inform adverse effect profile. Therefore, the firm should submit the justification to CDSCO for further review by the committee.
6.	FDC/MA/22/000417 Bupropion HCl (As extended release) 105mg + Dextromethorphan HBr 45mg tablets	M/s. Exemed	The firm presented its proposal along with BE and clinical trial protocol before the committee. The firm informed the committee that the product is already approved in USA. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study and Phase III clinical trial study with following conditions: 1. Patient with Dextromethorphan in any dosage form should be excluded from the study. 2. Long term safety data should be recorded.
7.	FDC/MA/22/000415 Pyridoxine HCl 3mg + Vitamin D3 (As stabilised form) 2000 IU+ Methylcobalamin (As Mecobalamin 5% in mannitol) 1500 mcg + Folic acid 5mg Mouth dissolving	M/s. Unison Pharmaceuticals Pvt. Ltd.	The firm presented its proposal along with justification for waiver of BE study and clinical trial study before the committee. The firm informed committee that the proposed FDC in Vitamin D3 1000IU strength is already approved by this office. After detailed deliberation, the committee recommended for grant of permission for

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	tablets		manufacturing and marketing of the product with condition to conduct the active post marketing surveillance study. Accordingly, the active post marketing surveillance protocol should be submitted to CDSCO for review by the committee.
GCT Division			
8.	CT/182/22 Online Submission (35385) Ocrelizumab	M/s. PPD	The proposal was deferred for next meeting.
9.	CT/115/22 Online Submission (34193) Fenebrutinib Compared with Ocrelizumab	M/s. Roche	The proposal was deferred for next meeting.
10.	CT/167/22 Online Submission (34987) EPX-100	M/s. GCT Pharma	The firm presented Phase II clinical trial protocol no. EPX-100-001 dated 18 July 2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase II trial subject to the following conditions: 1. Being a Phase II trial, safety should be co-primary end point. Accordingly, revised protocol should be submitted to CDSCO. 2. The applicant should submit interim analysis data along with IDMC recommendation to CDSCO for further review by the committee prior to commence of extension part of the study.
11.	CT/116/22 Online Submission (34287) Basimglurant Adjunctive	M/s. CliniRx Research	The proposal was deferred for next meeting.
12.	CT/144/20 Online Submission (21530) Evenamide	M/s. CliniRx	The proposal was deferred for next meeting.
13.	CT/175/22 Online Submission (35285)	M/s. Intas Pharmaceuticals Ltd.	The proposal was deferred for next meeting.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Endoxifen		
14.	CT/128/21 Online Submission (21801) IMU-838	M/s Bioinnovate Research	The proposal was deferred for next meeting.
15.	CT/130/21 Online Submission (21802) IMU-838	M/s Bioinnovate Research	The proposal was deferred for next meeting.
16.	CT/45/22 Online Submission (22587) Dated 16/12/2022 Eteplirsen Injection	M/s. PPD	The proposal was deferred for next meeting.
SND Division			
17.	SND/MA/22/000068 Ketamine Hydrochloride Injection 50 mg/ml	M/s Themis Medicare Ltd.	In light of earlier recommendation of SEC held on 16.12.2022, the firm presented its revised protocol w.r.t study design, study period and safety endpoint for Phase-III clinical trial study titled; "A Phase III, randomized, double-blind, placebo controlled, parallel group, comparative, multi-centre clinical study to evaluate the efficacy and safety of Ketamine subcutaneous injection in Patients with treatment-resistant depression (TRD) and major depressive disorder (MDD) with the acute depressive episode" before the committee. After detailed deliberation the committee recommended that revised protocol should be sent via mail to the committee members for review and comments/ recommendation.
18.	SND/MA/23/000002 Brivaracetam Mouth Dissolving Tablet 25 mg and 50 mg	M/s. Pure & Cure Healthcare Pvt. Ltd.	The firm presented the proposal to manufacture and marketing permission of (additional dosage form) for already approved indication alongwith BE and clinical trial waiver justification before the committee. In India, Brivaracetam film coated tablets 25mg, Brivaracetam injection 50mg/5ml (10mg/ml), Brivaracetam Oral Solution 10mg/ml, Brivaracetam SR Tablets 200mg are already approved for the indication as mentioned below: ***As adjunctive therapy in the treatment of partial onset seizers in patients 16 years***

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			of age and older with epilepsy. Brivaracetam mouth dissolving tablet 25 mg/50 mg is not approved in India as well as in any other country. After detailed deliberation, the committee opined that the firm did not present any rationality of the proposed dosage form of the Brivaracetam with respect to approved indication. In view of above, the committee recommended that the firm should come with proper rationality of the proposed dosage form alongwith supportive published clinical study data.
New Drug Division			
19.	ND/MA/22/000140 Cannabidiol Oral Solution 100mg/ml	M/s Zenara Pharma Pvt. Ltd.	In light of earlier SEC recommendations dated 14.10.2022, the expert opinion of two pediatric neurologists who are treating epilepsy was placed before the committee. The committee noted that the proposed drug is already approved in USA, Australia and Netherland as an Orphan drug designation. The committee opined that the drug is indicated for rare disease which is serious and life threatening and there is an unmet medical need in the country. After detailed deliberation, the committee noted that as per the current NDCT rules (2019), bioequivalence study would be needed for this formulation. However since the formulation is in solution form and does not have many additives, the bioequivalence study may be waived. In such a case, conduct of Phase 4 study becomes imperative. The committee thus recommended for grant of permission to manufacture and market of Cannabidiol Oral Solution, 100mg/mL with waiver of Phase-III clinical trial & bioequivalence study subject to following conditions: 1. The drug should be sold by retail under prescription of neurologist/ pediatrician/pediatric neurologist only.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			2. The firm should conduct Phase-IV clinical trial for which firm should submit Phase IV clinical trial protocol within 3 months of approval of the drug for review by the committee.