Recommendations of the SEC (Neurology & Psychiatry) made in its 83rd meeting held on 23.08.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/20/000124 Vigabatrin powder solution 500mg	M/s. MSN Lab	The firm didn't turn up for presentation.
SND Division			
2.	SND/MA/22/000052 Midazolam Nasal Spray 0.5% w/v & 1.25 % w/v	M/s. Savi Health	The firm presented their proposal of manufacture and marketing of Midazolam Nasal Spray 0.5% w/v & 1.25 % w/v indicated for preoperative sedation for conscious sedation prior to short diagnostic or endoscopic procedure and for indication of general anesthesia prior to administration of another anesthetic with bioavailability and local clinical trial waiver before the committee. After detailed deliberation, the committee recommended that the firm should submit proper justification and peer reviewed published data available in scientific database in support of bioavailability and local clinical trial waiver for further review by the committee.
3.	SND/CT/22/000052 Pregabalin Gel 8 % w/w	M/s. Lyka Labs	The firm presented the proposal for conduct of Phase III clinical trial for Pregabalin Gel 8 % w/w in patients with neuropathic pain before the committee. After detailed deliberation, the committee recommended that the firm should submit proper justification and peer reviewed published data, pharmacokinetic P_K-P_D data from experimental study in animal model to suggest that Pregabalin has peripheral mode of action and rationale for proposed new dosage form for further review by the committee.
FDC Division			
4.	FDC/MA/21/000277 Alpha Lipoic acid USP 200mg + Mecobalamin IP 1500mcg + Myo-inositol 100mg + Folic acid IP 1.5mg +	M/s. Pure & Cure Healthcare Pvt. Ltd.	In light of earlier SEC recommendation meeting held on 21.06.2022, firm presented their proposal along with justification for clinical trial and bioequivalence study waiver. After detailed deliberation, the committee noted that the similar FDCs

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	Pyridoxine Hydrochloride IP 3mg Chromium Picolinate eq. to Chromium USP 200mg + Benfotiamine 200mg tablets		have already been approved by this office. Accordingly, the committee recommended for grant of permission to manufacture and market the proposed FDC for the treatment of diabetic neuropathy with condition to conduct the active post marketing surveillance study.
GCT Division			
5.	CT/179/21 Online Submission (16918) SAR442168 Telebrutinib	M/s. Sanofi HealthCare	The applicant has presented protocol amendment 3.0 dated 30/11/2020, protocol amendment 4 dated 26/07/2021 and protocol amendment 5 dated 21/12/2021 before the committee. After detailed deliberation, the committee recommended for approval of protocol amendments as presented. (Dr. MV Padma did not participate during the deliberation).
6.	CT/116/21 Online Submission (19010) OAV101	M/s. Novartis	The applicant has presented protocol amendment version 01 dated 11/04/2022. After detailed deliberation, the committee recommended for approval of protocol amendment version 01 dated 11/04/2022 with condition that the applicant should adhere to guideline for gene therapy product in India. (Dr. Sunil Narayan did not participate during the deliberation).
7.	CT/86/19 Online Submission (17845) Evenamide	M/s. CliniRx	The applicant has presented protocol amendment 8 version 9.0 dated 03/05/2022 (increase in sample size- 30 subjects globally and 45 subjects from India) before the committee. The committee noted that the CTNOC was approved with total of up-to 120 subjects from India out of 150 subjects globally and applicant has already randomized 129 subjects from India, and opined that detailed site wise/ date wise enrolment of subjects from India should be submitted for further review in forthcoming meeting. After detailed deliberation, the committee did not recommend for approval of proposed protocol amendment and opined that the applicant should present the

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			detailed justification/rationale for proposed increase in global and Indian sample size in forthcoming meeting.
SND Division			
8.	SND/MA/22/000021 Perampanel Tablets 2mg/4mg/6mg/8mg/10mg/12mg (Additional Indication)	M/s. Eisai Pharmaceuticals India Pvt. Ltd	In light of earlier SEC recommendation dated 12.05.2022, the firm presented international approval status, approved package Insert (PI) and global clinical Study report of the applied drug product for proposed additional indication before the committee. After detailed deliberation, the committee recommended for grant of import and marketing permission of Perampanel Tablets 2mg/4mg/6mg/8mg/10mg/12mg for additional indication as "Perampanel is indicated for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 12 years of age and older" subject to following condition The firm should submit cognitive effects of the drug products in Indian population (specially school going children) within one year of the issuance of marketing approval of the applied drug product for proposed additional indication.