

Recommendations of the SEC (Neurology & Psychiatry) made in its 80th meeting held on 12.05.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/IMP/22/000021 Perampanel tablets 2mg/4mg/6mg/8mg/10mg/12mg	M/s Eisai Pharma	<p>The firm presented their proposal before the committee for approval of the proposed additional indication for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients 4 years of age and older with epilepsy.</p> <p>After detailed deliberation, the committee felt that the proposal is based on approvals in the US and EU from extrapolated safety and efficacy data from studies where Perampanel was used as an adjuvant AED and recommended that the firm should submit the additional clinical study data (first line/monotherapy) in support of the proposed additional indication before the committee for further review.</p>
2.	SND/IMP/22/000019 Paliperidone Palmitate Prolonged Release Suspension for Intramuscular Injection 700mg & 1000mg	M/s Johnson & Johnson	<p>The firm presented their proposal for import & marketing of Paliperidone Palmitate Prolonged Release Suspension for Intramuscular Injection 700mg & 1000mg (6 months injection, (PP6M)) for the treatment of schizophrenia in adult patients who have been adequately treated with the 1 month Paliperidone palmitate injectable product for atleast 4 months.</p> <p>After detailed deliberation, the committee noted that there is no unmet need and the firm should provide following data:</p> <ol style="list-style-type: none"> 1. Data of Global & ethnic Indian (or Indian origin) patients on comparative efficacy of PP6M Vs PP3M and PP6M Vs PP1M. 2. The name of the countries where 6 months injection (PP6M), has approved without approval of 3 months injection (PP3M).
FDC Division			
3.	FDC/MA/21/000277 Alpha Lipoic acid USP 200mg + Mecobalamin IP	M/s. Pure & Cure Healthcare Pvt.Ltd.	The firm didn't turn up for presentation.

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	1500mcg + Myo- inositol 100mg + Folic acid IP 1.5mg + Pyridoxine Hydrochloride IP 3mg Chromium Picolinate eq. to Chromium USP 200mg + Benfotiamine 200mg tablets		
GCT Division			
4.	CT/175/21 Online Submission (29672) Remibrutinib (LOU064)	M/s. Novartis	In light of earlier SEC recommendation dated 10.03.2022, the firm presented their supportive clinical trial data before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study.
5.	CT/176/21 Online Submission (29674) Remibrutinib (LOU064)	M/s. Novartis	In light of earlier SEC recommendation dated on 10.03.2022, the firm presented their supportive clinical trial data before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study.
6.	CT/122/20 Online Submission (15385) Galcanezumab	M/s. Eli Lilly	The firm presented protocol amendments I5Q-MC-CGAS(g) dated 01.10.2021 before the committee . After detailed deliberation, the committee recommended for approval of the proposed protocol amendments.
7.	CT/123/20 Online Submission (15384) Galcanezumab	M/s. Eli Lilly	The firm presented protocol amendments I5Q-MC-CGTA(e) dated 01.10.2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendments. The committee also suggested that the size of needle for dose administration for age group between 6-12 years should be modified to minimize injection related injuries/side effects.
8.	CT/27/22 Online Submission (31174) K127	M/s. CBCC	The firm presented the proposed Phase III clinical trial protocol no. K127-301/122, version: 2.0 dated 03.Mar.2022 before the committee.

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	(Pyridostigmine Bromide SR tablets)		<p>After detailed deliberation, the committee opined that the firm should revise the study protocol as below:</p> <ol style="list-style-type: none"> 1. The protocol title should be revised by including comparator product. 2. Myasthenic crisis and cholinergic crisis are to be detailed and included as SAEs under the secondary objectives. 3. Under exclusion criteria, the firm should specify the names of immunosuppressant drugs which are prohibited for administration. 4. Safety management plan, rescue, and withdrawal criteria and the management and follow up plans and the detailed study statistical analysis plan should be submitted. 5. The firm should include more clinical trial sites including Govt. sites. <p>Accordingly, the firm should submit revised protocol for further consideration by the committee.</p>
BA/BE Division			
9.	12-09/2022/BA-BE/MISC-09/DC Galantamine Benzoate Delayed released Tablets 4.25mg/ 8.5mg/12.75mg	M/s. Vimta Labs Limited	<p>The firm presented the study protocol of Galantamine Benzoate Delayed released Tablets 4.25mg/ 8.5mg/12.75mg before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study subject to submission of the pre-clinical study data of Galantamine Benzoate by oral route of administration as per regulatory requirements.</p>