

Recommendations of the SEC (Neurology & Psychiatry) made in its 16th/24 meeting held on 29.10.2024 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	GCT/CT04/FF/2024/45269 Online Submission (45269) Lumateperone (ITI-007)	M/s IQVIA	The firm presented phase 3 clinical study Protocol no ITI-007-452, Amendment 1 dated 03 Jul 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the firm should submit separate protocol for pharmacokinetic study in statistically significant Indian subjects.
2.	GCT/CT04/FF/2024/42915 Online Submission (42915) PF-07899801 (Rimegepant)	M/s Pfizer	In light of earlier SEC Recommendation dated 13.06.2024, now the firm presented Phase III clinical study protocol no. C4951013 amendment 1 dated 19.03.2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the paediatric subjects at least 40kg weight should be enrolled.
3.	GCT/CT04/FF/2024/43367 Online Submission (43367) GZ402671/Venglustat	M/s Sanofi	In light of earlier SEC recommendation dated 18.07.2024, now the firm presented Phase III clinical study protocol no. EFC17045, amended protocol 04, version number 01, dated 06 Oct 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
4.	GCT/Post Appr/2024/33297 Online Submission (33297) Milvexian	M/s IQVIA	The applicant unable to present the proposal before SEC due to technical issue at their end. Hence, the proposal will be deliberated in next SEC meeting.
New Drugs Division			
5.	ND/MA/24/000029 Pitolisant Tablets 4.45mg & 17.8mg	M/s MSN Laboratories Private Limited	The firm presented BE study report and justification of Phase-III local clinical trial waiver before the committee. The firm presented literature data on prevalence of disease. The committee noted that there is limited information of disease prevalence in

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			<p>Indian population.</p> <p>Further, the drug has novel mechanism of action as compared to the drugs approved for Narcolepsy and there is unmet need.</p> <p>After detailed deliberation, the committee recommended that in the prescribing information of product, firm should include CYP2D6 Genotype determination before initiation of treatment for dose titration.</p> <p>After detailed deliberation, the committee recommended for the grant of market authorization with the condition to conduct Phase-IV Clinical Trial. The firm is required to submit Phase-IV study protocol to the CDSCO within the period of three months of grant of Market Authorization for further evaluation by the committee.</p>
6.	<p>ND/MA/24/000038</p> <p>Siponimod tablets 0.25 mg, 1 mg and 2 mg</p>	<p>M/s Dr. Reddy's Laboratories Limited</p>	<p>In light of earlier recommendation dated 24.06.2024 firm presented BE study result and data on prevalence of disease Secondary Progressive Multiple Sclerosis (SPMS) in the Indian scenario and concluded the drug can be considered under Orphan drug category.</p> <p>After detailed deliberation, the committee recommended that in the prescribing information of product, firm should include CYP2C9 Genotype determination before initiation of treatment.</p> <p>The committee recommended for the grant of market authorization with the condition to conduct Phase-IV Clinical trial. The firm is required to submit Phase-IV study protocol to CDSCO within the period of three months of grant of Market Authorization for further evaluation by the committee.</p>
FDC Division			
7.	<p>FDC/MA/23/000287</p> <p>Gabapentin IP (SR) + Methylcobalamin IP + Nortriptyline Hydrochloride eq. to Nortriptyline IP (600mg+1500mcg+10</p>	<p>M/s. Ravenbhel Healthcare Pvt. Ltd.</p>	<p>In light of earlier SEC recommendation dated 12.03.2024, the firm presented the proposal along with Phase III clinical trial report before the committee.</p> <p>After detailed deliberation, the committee opined that the firm should submit following to CDSCO for further review</p>

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	mg/ 300mg+1500mcg+ 10mg) film coated bilayered tablet		by the committee: 1. Source data of the Phase III clinical trial report. 2. Justification for test product in Arm A and Arm B as there is no statistically significant difference observed in efficacy in both the arm.
8.	FDC/MA/24/000014 Gabapentin IP 100mg/200mg/300mg /400mg/400mg + Duloxetine Hydrochloride IP eq. to Duloxetine (As enteric coated pellets) 20mg/20mg/20mg/20 mg/30mg hard gelatin capsule	M/s. Torrent Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 15.02.2024, the firm presented the proposal along with BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. Accordingly, firm should submit BE study report along with Phase III CT protocol to CDSCO for review by the committee.