

Recommendations of the SEC (Neurology & Psychiatry) made in its 02nd/25 meeting held on 25.02.2025. at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/36/23 Online Submission (33297) Milvexian	M/s IQVIA RDS	In light of earlier SEC Recommendation dated 19.11.2024, now the firm presented protocol amendment 2 dated 10 April 2024 protocol no. 70033093STR3001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm subject to following condition: <ol style="list-style-type: none"> 1. Monitoring of urine protein by creatinine ratio shall be carried out on every visit of enrolled patients. 2. India specific amendment with respect to frequent monitoring of urine protein by creatinine ratio shall be submitted for further review by the committee before enrolling new patients.
2.	CT/130/20 Online Submission (32645) Fenebrutinib	M/s Roche Products (India) Private Limited	Under discussion.
BA/BE Division			
3.	BABE/CT05/FF/2022 /31205 Meloxicam/ Rizatriptan tablets 20/ 10 mg	M/s Apotex Research Private Limited.	The firm presented the BA/BE study Protocol No. 4412US-IMTB-MRZ1070-FA, version 00, dated 08.03.22 & 4412US-IMTB-MRZ1071-FE, version 00, dated 08.03.22 for export purpose only. After detailed deliberation, the committee recommended for grant of permission to conduct the BABE study for export purpose only, subject to condition that all the participating subjects should be screened for sulfa drug allergy test before enrolling into the study.

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			Accordingly, revised protocol should be submitted to CDSCO for approval.
SND Division			
4.	SND/MA/23/000314 Pregabalin Gel 8% w/w	M/s. Lyka Labs Limited	The firm presented active PMS study protocol No. SCR/001/PGB/2024, version No. 1.0 dated 23.12.2024 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the active PMS study as presented by the firm with following condition: 1. The number of subjects shall be increased to 500. 2. More number of Geographically distributed sites including proportional Government sites shall be included in the study.
5.	SND/MA/24/000090 Ketorolac Tromethamine Sublingual Tablets 30mg	M/s. Troikaa Pharmaceuticals Limited	In light of earlier SEC recommendations dated 26.11.2024 & 27.11.2024, the firm presented Prescribing Information of Ketorolac Tromethamine Sublingual Tablets 30mg for the treatment of migraine headache in adults only. After detailed deliberation, the committee considered the Prescribing Information of Ketorolac Tromethamine Sublingual Tablets 30mg.
6.	SND/MA/22/000238 Caroverine HCL Capsules 40 mg	M/s Lincoln Pharmaceuticals Ltd	In light of earlier recommendation dated 12.12.2023 & 13.12.2023, firm presented therapeutic justification and clinical relevance of higher strength of Caroverine HCL Capsules 40 mg along with Phase III Clinical Trial Protocol before Committee. After detailed deliberation, Committee did not satisfy with the Single-arm, Non-comparative design of Phase III Clinical Trial Protocol and recommended to revise the Phase III CT protocol as Randomised, Double Blind, Placebo Controlled design for establishing safety and efficacy of Caroverine HCL Capsules 40 mg in Tinnitus. Also, Committee recommended to submit the justification for higher 120 mg & 160 mg dosage in applied

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			indication with relevant data/ literature.
New Drug Division			
7.	ND/IMP/20/000073 Risdiplam Powder for Oral Solution 0.75 mg/ml	M/s Roche Products (India) Pvt. Ltd.	In light of earlier SEC recommendation dated 18.01.2022 for import & marketing permission granted to the firm in Form CT-20 dated 16.10.2020, the firm presented interim clinical study report on 15 patients for Risdiplam Powder for Oral Solution 0.75 mg/ml before the committee. After detailed deliberation, the committee observed that as per protocol no. ML43557, the firm was supposed to recruit patients from 20-25 centres for the PMS study for 3 years. The committee recommended that firm should continue to actively recruit patients and submit report as per the conditions of CT-20 for further review by the committee. The firm is also requested to comply with the other conditions to submit clinical trial data on safety and efficacy of drug before the committee.
8.	ND/IMP/20/000073 Risdiplam Powder for Oral Solution 0.75 mg/ml	M/s Roche Products (India) Pvt. Ltd.	The firm presented the proposal for amendment in the warning statement of permission granted to import and market Risdiplam Powder for Oral Solution 0.75 mg/ml before the committee. After detailed deliberation, the committee did not recommend for the amendment in warning statement from 'To be sold by retail only under the prescription of Neurologist/Pediatric Neurologist' to 'To be sold by retail on the prescription of a Neurologist/Pediatric Neurologist or Medical Geneticist ' and opined that the firm's proposal may be deferred to be deliberated with the experts from rare disease cell/ Centre of Excellence.
FDC Division			
9.	FDC/MA/23/000131 Pregabalin ER	M/s Hetero Labs Limited	In light of earlier SEC recommendation dated 26.09.2024, firm presented the proposal along with revised Phase III

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	82.5mg I.P. + Polmacoxib 2mg Tablet		<p>clinical trial protocol.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III clinical trial.</p> <p>Accordingly, the firm should submit Phase III clinical trial report to CDSCO for further review by the committee.</p>