

Recommendations of the SEC (Neurology & Psychiatry) made in its 5th/24 meeting held on 18.04.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/33/24 Online Submission (42276) Frexalimab (SAR441344)	M/s. Sanofi	The firm presented Phase III clinical study protocol No. EFC17504. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/32/24 Online Submission (42067) Frexalimab (SAR441344) to Teriflunomide	M/s. Sanofi	The firm presented Phase III clinical study protocol No. EFC17919. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/179/21 Online Submission (31866) SAR442168	M/s. Sanofi	The firm presented protocol amendment 08, version number 1 dated 14 December 2022, protocol amendment 11, version number 1 dated 20 November 2023, protocol amendment 12, version number 1 dated 20 December 2023, protocol number EFC16645. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
4.	BIO/CT18/FF/2023/4 0718 Eculizumab Concentrate for solution for infusion 300 mg	M/s. AstraZeneca Pharma India Limited	The firm presented the proposal for grant of permission to import and market Eculizumab concentrate for solution for infusion 300 mg for the following indications “1. Refractory generalized myasthenia gravis (gMG) in patients who are anti-acetylcholine receptor (AChR) antibody-positive 2. Neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody-positive” along with request for local clinical trial waiver based on clinical data generated from Global clinical studies. The committee noted that clinical data of Indian subjects was not available. After detailed deliberation, the

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			committee did not approve the firm's request for waiver of local clinical trial for grant of permission to import and market Eculizumab Concentrate for solution for infusion.
5.	BIO/CT18/FF/2023/3 9263 Metalyse 25mg (Tenecteplase 0.25mg/kg)	M/s. Boehringer Ingelheim India Private Limited	<p>In light of earlier SEC recommendations dated 18.01.2024, the firm presented the proposal along with justification for grant of additional indication of the drug Metalyse 25 mg (Tenecteplase 0.25 mg/kg) lyophilized powder for solution for injection i.e. "Indicated in adults for the thrombolytic treatment of acute ischaemic stroke (AIS) within 4.5 hours from last known well and after exclusion of intracranial haemorrhage" along with local clinical trial waiver.</p> <p>The committee noted that the drug Tenecteplase 0.25 mg/kg is already approved and in the guidelines from Europe, US and Australia for the proposed indication.</p> <p>After detailed deliberation, the committee recommended for grant of approval for the proposed indication with waiver of local Phase III clinical trial with condition to conduct Phase IV clinical trial in India.</p> <p>Accordingly, Phase IV clinical trial protocol should be submitted by firm within 3 months from grant of marketing authorization.</p>
BA/BE Division			
6.	File No. 12-09/2024/ BA-BE/MISC-28/DC BABE/CT05/FF/ 2023/40552 Vinpocetine 30mg Extended-Release Tablets	M/s. Admerus Biosciences Private Limited, Telangana - 501401	<p>The firm presented the protocol No.: CS23111 ver 00 dated 17.08.2023, for BA/BE study for export purpose only.</p> <p>After detail deliberation, the committee opined that the firm is required to submit the following information / data / documents:</p> <p>(1) Safety & tolerability for 6 tablets of Vinpocetine 5 mg IR tablets (30 mg) given as single dose.</p>

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			<p>(2) Rational for giving 30 mg IR tablets as single dose in comparison with Vinpocetine 30mg extended-release tablets.</p> <p>(3) Qualitative & quantitative composition and drug delivery system of the proposed extended release formulation.</p> <p>Accordingly, the firm should submit the above information/data for re-deliberation by the SEC.</p>
7.	<p>File No. 12-09/2024/ BA-BE/MISC-2/DC</p> <p>BABE/CT05/FF/ 2023/39377</p> <p>Doxepin HCl Buccal Film 1.6 mg</p>	<p>M/s. Lambda Therapeutic Research Limited, Ahmedabad – 38 2481</p>	<p>In light of earlier SEC recommendation dated 18.01.2024 & 19.01.2024, the firm clarified that there are no differences in the formulation of earlier BE study and the proposed study. The firm also presented the safety assessment of the previous BE study.</p> <p>After detail deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study for export purpose only.</p>
SND Division			
8.	<p>SND/MA/20/000368</p> <p>Midazolam Nasal Spray 0.5w/v & 1.25% w/v</p>	<p>M/s. Biodeal Pharma Limited</p>	<p>In light of earlier SEC recommendation dated 23.02.2024, the firm presented published clinical trial data before the committee.</p> <p>The committee noted that the multiple dose spray of Midazolam nasal spray 0.5w/v & 1.25%w/v not yet approved anywhere and there is chance of drug abuse in the country.</p> <p>As per US FDA approval NYAZYLAM single dose nasal spray unit containing 5mg/0.1ml Midazolam is approved. Therefore, the committee opined that the dose for Midazolam nasal spray 1.25% w/v (MDI) should be limited to a maximum of 4 actuations (2 puff per Nostril) and shall not be increased beyond 5mg.</p>

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			<p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market Midazolam nasal spray 1.25% w/v in 4 Actuations for the acute treatment of episodes of prolonged or serial seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in adult patients with epilepsy, with local clinical trial waiver subject to following conditions:</p> <ol style="list-style-type: none"> 1. The firm should fulfill the requirements of CMC data 2. The firm should conduct Phase-IV clinical trial with 500 Patients and submit the Phase IV protocol to CDSCO for further review by the committee. 3. To be sold under the prescription of Neurologist/Psychiatrist/Emergency Medicine/ Trauma practitioner only. 4. A pack insert with warning advisory on the need for hospitalisation in case the patient's seizures are not controlled after a maximum of 4 actuations per event.
New Drugs Division			
9.	ND/MA/22/000125 Lisdexamfetamine Dimesylate Capsules 70mg	M/s. Ind-Swift	<p>In light of earlier SEC recommendations dated 18.11.2022, the firm presented BE study results before the committee.</p> <p>After detailed deliberation, the committee accepted the BE study results and opined to submit more safety & efficacy data before the committee w.r.t. the proposal on CT waiver.</p>
10.	ND/MA/20/000078 Pimavanserin Capsules 34 mg	M/s. Sun Pharma, Laboratories Limited	<p>The firm presented the Phase III clinical trial report of Pimavanserin 34mg capsules.</p> <p>After detailed deliberation, the committee recommended for the manufacturing and marketing of the proposed drug product in the country for the treatment of</p>

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			<p>Hallucination and Delusions associated with Parkinson's disease Psychosis subject to the conditions that</p> <ul style="list-style-type: none"> • The firm should submit the PMS data on minimum of 500 patients after the approval. • The drug should be sold by retail only under the prescription of Neurologist or Psychiatrist or MD (Geriatrics) only.
11.	<p>ND/MA/23/000209</p> <p>Nusinersen Solution for Injection 2.4 mg/ml (12mg/5ml)</p>	<p>M/s. Jodas Expoin Pvt. Ltd.</p>	<p>The firm presented the proposal for grant of permission to manufacture and market indigenously made Nusinersen biosimilar solution for Injection 2.4 mg/ml (12mg/5ml) along with waiver for Phase-III clinical trial in the country.</p> <p>After detailed deliberation, the committee noted that the innovator formulation is approved for SMA patients, in other countries like USA and EU. However, the firm has not provided any in vivo study data/ patient safety/ efficacy data for the applied drug product. Therefore, the committee recommended to conduct Phase-III clinical trial in India.</p>