

Recommendations of the SEC (Neurology & Psychiatry) made in its 07th/24 meeting held on 13.06.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/58/24 Online Submission (42915) PF-07899801 (Rimegepant)	M/s. Pfizer	The firm presented Phase III clinical study protocol No. C4951013 amendment 1 dated 19.03.2024. After detailed deliberation, the committee opined that justification to be submitted for following for further review by the committee: 1. Standard of care should be defined for both the arms. 2. Use of adult 75 mg dose in adolescents 12 to less than 18 years of age.
Medical Device Division			
2.	IMP/MD/2023/85599 Liquid Embolic System	M/s. India Medtronic Pvt. Ltd.	The proposal for import of product Onyx liquid Embolic System for marketing in the country has deliberated before the committee. The firm presented the case before the expert committee. After detailed deliberation, the committee observed that the predicate device available in the market is substantially equivalent with the applied device with respect to its material of construction, mechanism of action, intended use, indication of use, etc, As the applied product is substantially equivalent to predicate device, therefore the committee recommended for consideration of their proposal on the basis of the licence issued for predicate device under the Medical Device Rules, 2017.
SND Division			
3.	SND/MA/22/000053 Nicotine Ditartarate Dihydrate SNUS pouch 2 mg & 4 mg	M/s. Harsh Nutricare	Under Discussion.
4.	SND/IMP/24/000019 Nicotine Oromucosal Powder in Pouch	M/s. Fertin India Private Limited	

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	2 mg & 4 mg		
5.	SND/MA/23/000312 Nicotine Polacrilex pouches 2mg & 4mg	M/s. Lyrus Lifesciences Pvt. Ltd.	
6.	SND/IMP/24/000005 Risdiplam Powder for oral solution 0.75mg/ml (Additional indication)	M/s. Roche Products (India) Private Limited	<p>The firm presented their proposal for import & marketing of Risdiplam Powder for Oral Solution 0.75 mg/ml (additional indication) for the treatment of spinal muscular atrophy (SMA) in paediatric and adult patients along with interim results of clinical trial conducted other than India before the committee.</p> <p>Firm has informed that the Risdiplam Powder for Oral Solution 0.75 mg/ml already approved by CDSCO on 16.10.2020 for the treatment of spinal muscular atrophy (SMA) in patients 2 months and older.</p> <p>After detailed deliberation, the committee opined that the firm should submit casualty assessment data of 16 days to 2 months and real world scenario data of less than 16 days to CDSCO for further review by the Committee.</p>
7.	SND/CT/23/000015 Buprenorphine sustained release Injection 100mg	M/s. Rusan Pharma Ltd.	<p>In light of earlier SEC recommendation dated 08.11.2023 & 09.11.2023. Now, the firm presented revised protocol (Protocol No. 01/23 Version: 03 dated 09.02.2024) to conduct pharmacokinetic, safety and tolerability study of Buprenorphine sustained release Injection 100mg before the committee.</p> <p>After detailed deliberation, the committee recommended to conduct Pharmacokinetics, safety and tolerability study as per revised protocol as presented by the firm, subject to following conditions:</p> <ol style="list-style-type: none"> 1. The firm should increase sample size from 16 to 32 healthy volunteers. 2. Firm should include pharmacologist in the study as a PI.
New Drugs Division			
8.	ND/CT/23/000084 Lavender Oil 80 mg	M/s. JSS Medical Research	The firm has presented their proposal to conduct Phase III Clinical trial before the committee.

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	soft gelatin capsules		<p>After detailed deliberation, the committee observed that</p> <ul style="list-style-type: none"> • There is huge variation in the range of individual constituents of Lavender Oil. • There is no justification for the individual constituents having specific biological activity. <p>Hence, the committee opined that the applied drug product Lavender Oil 80mg soft gelatin capsule does not fall under definition of Phytopharmaceutical drug as per the New Drugs and Clinical Trials Rules, 2019.</p>
9.	ND/MA/23/000190 Pimavenserin Capsules 34mg	M/s. Bajaj Healthcare Ltd.	<p>The firm has presented the Phase III Clinical trial protocol before the committee.</p> <p>After detailed deliberation the committee recommended to submit the BE Protocol and revised Phase III CT protocol with the justification for sample size.</p>
FDC Division			
10.	FDC/MA/24/000003 Gabapentin IP (ER) tablet 600mg/300mg + Duloxetine Hydrochloride IP eq. to Duloxetine (as delayed release) tablets 20mg/20mg film coated tablet	M/s. Ravenbhel Healthcare Pvt. Ltd.	<p>In light of earlier SEC recommendation dated 18.01.2024 & 19.01.2024, the firm presented the proposal along with BE study report before the committee.</p> <p>After detailed deliberation, the committee opined that the firm should submit individual subject source data of the BE study report.</p> <p>Accordingly, the firm should submit individual subject source data of BE study report to CDSCO for review by the committee and taking decision on the Phase III Clinical trial protocol.</p>