

Recommendations of the SEC (Neurology & Psychiatry) made in its 78th meeting held on 10.03.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/20/000124 Vigabatrin Powder for oral solution 500 mg	M/s. MSN Laboratories Ltd	The firm didn't turn up for presentation.
2.	ND/IMP/20/000073 Risdiplam for Oral Solution	M/s. Roche Products (India) Pvt. Ltd.	<p>The firm presented their request for modification in inclusion criteria for pilot study on first 15 patients to enroll younger patients having body wt less than 20 kg as mentioned in first two levels of dosing recommendations mentioned in the prescribing information i.e. for 02 months to less than 2 years of age-- 0.20 mg/kg and ≥ 2 years of age (< 20 kg) -- 0.25mg/kg and change in prescribing specialists from Neurologist to Neurologist/Pediatrician/Pulmonologist/Clinical Geneticist before the committee.</p> <p>After detailed deliberation, the committee recommended for approval of the proposed amendment in inclusion criteria as above and revision of warning as "the drug should be sold on the prescription of Neurologist/Pediatric Neurologist".</p>
SND Division			
3.	SND/MA/19/000135 Nicotine Transdermal Patch 14.5mg (7mg/24 hr), 29mg (14mg/24 hr) and 43.5mg (21mg/24 hr)	M/s. Rusan Pharma	<p>In light of recommendations of the earlier SEC meeting dated 16.12.2021, the firm presented the methodology adopted and other data as requested in the earlier meeting.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Nicotine Transdermal Patch 14.5mg (7mg/24 hr), 29mg (14mg/24 hr) and 43.5mg (21mg/24 hr) indicated "to relieve and/or prevent craving and nicotine withdrawal symptoms associated with tobacco dependence.</p>
4.	SND/MA/20/000351 NaltrexoneDecanoate Sustained Release Injection 190mg/ml	M/s. Rusan Pharma	<p>In light of the recommendations of the earlier SEC meeting dated 18.01.2022, the firm presented the justification for not including the Vivitrol (Reference product) in the proposed PK study.</p> <p>After detailed deliberation, the committee</p>

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			recommended for grant of permission for conduct of the Phase II CT study of the test product in comparison with the Naltrexone HCl tablets 50mg as per the protocol presented by the firm subject to condition that the site of injection should be monitored with CT scan and an ultrasound testing and the results should be submitted to CDSCO for further review by the committee.
FDC Division			
5.	FDC/MA/19/000079 Pregabalin IP (as prolonged release form) 75mg+Nortriptyline Hydrochloride IP eq. to Nortriptyline 10mg +Mecobalamin IP 1500mcg film coated bilayered tablet	M/s. Synokem Pharmaceuticals Ltd	In light of earlier recommendation dated 16.02.2022, the firm presented their proposal before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC.
6.	FDC/MA/20/000184 Nortriptyline HCl eq to Nortriptyline 10mg + Pregabalin 50mg Film coated tablet	M/s. Synokem Pharmaceuticals Ltd	In light of earlier SEC recommendation dated 16.04.2021, the firm presented BE report and Active PMS study report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC.
GCT Division			
7.	CT/175/21 Online Submission (29672) Remibrutinib (LOU064)	M/s. Novartis	The firm presented Phase III clinical trial Protocol No- CLOU064C12301, version No.02 dated 18-Jan-2022. After detailed deliberation, the committee opined that the firm should first present Phase II study results before the committee to take further decision on the proposed Phase III clinical trial protocol.
8.	CT/42/19 Online Submission (15546) dated 31/01/22 K0706	M/s. Sun Pharma	The firm presented protocol amendment version no. 05, dated 20 th July 2021 before the committee. After detailed deliberation, the committee recommended for grant of approval for the proposed protocol amendment.
9.	CT/176/21 Online Submission (29674)	M/s. Novartis	The firm presented Phase III clinical trial protocol no.CLOU064C12302, version

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	dated 28/12/21 Remibrutinib (LOU064)		no.02 dated 18-Jan-2022. After detailed deliberation, the committee opined that the firm should first present Phase II study results before the committee to take further decision on the proposed Phase III clinical trial protocol.