Recommendations of the SEC (Neurology & Psychiatry) made in its 75th meeting held on 16.12.2021 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/21/000489 Zolpidem Sublingual Spray 3.85% w/v	M/s. Troikaa Pharmaceuticals	The firm presented the proposal along with animal study and BE protocol. After detailed deliberation, the committee recommended for grant of permission for conduct of the bioavailability study as per the protocol presented.
2.	SND/MA/21/000370 Amitriptyline Hydrochloride Tablets 10/25/50/75 mg	M/s. Wockhardt Limited	The firm presented their proposal along with the therapeutic rationale and justification for the proposed additional indication for- 1. The treatment of neuropathic pain in adults. 2. The prophylactic treatment of chronic tension type headache (CCTH) in adults. 3. The prophylactic treatment of migraine in adults. 4. The treatment of nocturnal enuresis in children aged 6 years and above, only when organic pathology, including spina bifida and related disorders, have been excluded, and no response has been achieved to all other non-drug and drug treatments, including antispasmodics and vasopressin-related products. This medicinal product should only be prescribed by healthcare professional with expertise in the management of persistent enuresis. The committee noted that the above indication is already approved in UK. After detailed deliberation, the committee recommended for the grant of permission for manufacture and marketing of Amitriptyline hydrochloride tablets 10/25/50/75 mg for the proposed additional indications.
3.	SND/MA/21/000135 Nicotine Transdermal Patch 14.5mg (7mg/24 hr), 29mg (14mg/24 hr) and43.5mg (21mg/24 hr)	M/s. Rusan Pharma	The firm presented the proposal along with the BE study report. After detailed deliberation, the committee opined that the firm should present the detailed data on methodology adopted, adverse events, adhesion score, raw data (including data with respect to subjects

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			who dropped out of study) etc, for further review by the committee.
4.	SND/CT/21/000092 Amantadine Extended release Tablets 129 mg and 193 mg	M/s. Sun Pharma	The firm presented the proposal for Phase IV clinical trial of Amantadine ER tablets 129mg and 193mg for the treatment of Parkinson's disease and drug-induced extra pyramidal reactions in adult patients. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial of Amantadine ER tablets 129mg and 193mg subject to condition that- 1. Atleast 50% Government sites should be included. 2. The firm should provide the approximate time line for completion of the study.
FDC Division			
5.	FDC/MA/21/000267 Naloxone Hydrochloride eq. to Naloxone 0.25mg + Buprenorphine Hydrochloride eq. to Buprenorphine 1mg tablets	M/s. Rusan Pharma Ltd.	The firm presented the proposal for grant of permission for manufacturing and marketing the proposed intermediate strength. After detailed deliberation, the committee opined that- 1. The proposed strengths of individual ingredients in FDC are not approved. 2. The firm did not present any clinical evidence indicating the benefit of the proposed strength. In view of above, the committee recommended that the firm should submit adequate justification along with supportive documents on the above points for further deliberation by the committee.
BA/BE Division			
6.	12-09/2021/BA-BE/Misc-31/DC Dextromethorphan and Bupropion Extyended release Tablets 45/105mg	M/s. Alembic Pharmaceuticals Limited	The proposal was deferred to the next meeting.