Recommendations of the SEC (Neurology & Psychiatry) made in its 87th meeting held on 16.12.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/20/000078 Pimavanserin Capsules	M/s. Sun Pharma	The firm was granted permission on 28.01.2022 to conduct Phase III clinical trial for new drug Pimavanserin Capsules 34mg. The firm presented their proposal to amend existing protocol no. ICR/21/012 version no. 2.0 dated 27.12.2021 before the committee. After detailed deliberation, the committee agreed for amendments in existing protocol proposed by the firm subject to the condition that the firm should keep point no. 1 of inclusion criteria, of previously approved protocol as it is i.e. patients of either gender, aged ≥ 40 years, with a documented clinical diagnosis of idiopathic Parkinson's Disease (PD) (as per UK PD Society Brain Bank Clinical Diagnostic Criteria) of duration ≥5.5 years, and Hoehn & Yahr stage ≤3 of previously approved protocol. Accordingly, the firm should submit correct version of protocol no. ICR/21/012 version no. 3.0 dated 25.11.2022 to CDSCO.
SND Division			
2.	SND/MA/22/000068 Ketamine Hydrochloride Injection 50 mg/ml	M/s. Themis Medicare	The firm presented their proposal for Phase III CT protocol titled "A Phase III, randomized, double-blind, placebo controlled, parallel group, comparative, multi-centre clinical study to evaluate the efficacy and safety of Ketamine Subcutaneous Injection in patients with treatment-resistant depression (TRD) and major depressive disorder (MDD) with the acute depressive episode" before the committee. After detailed deliberation, the committee recommended that the firm should submit revised Phase III CT Protocol w.r.t study design, study period and safety endpoint for further review by the committee.

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Biological Division			
3.	BIO/CT18/FF/2022/ 33535 Ocrelizumab concentrate for solution for infusion	M/s. Roche Products (India) Private Limited	The proposal was deferred for next meeting.
FDC Division			
4.	4-91/2017-DC Gabapentin USP 6.0%w/w + Lidocaine HCl IP eq. to Lidocaine 5.0%w/w Gel	M/s. Akums Drugs & Pharmaceuticals	In light of the last SEC recommendation dated 16.02.2021, the firm presented the proposal along with justification and Phase III CT protocol before Committee. After detailed deliberation, the committee recommended that firm should submit the revised Phase III CT protocol as suggested by experts w.r.t exclusion criteria, sample size, rescue medication, etc. Accordingly, revised Protocol should be presented before SEC for further review.
GCT Division			
5.	CT/123/20 Online Submission (19011) Galcanezumab	M/s. Eli Lilly	The proposal was deferred for next meeting.
6.	CT/120/22 Online Submission (34243) Carbidopa +Levodopa	M/s. Cliantha	The proposal was deferred for next meeting.
7.	CT/135/22 Online Submission (34017) Crovalimab	M/s. Roche	The proposal was deferred for next meeting.
8.	CT/57/20 Online Submission (17881) Evobrutinib	M/s. IQVIA	The proposal was deferred for next meeting.
SND Division			
9.	SND/MA/20/000368 Midazolam Nasal Spray 0.5% w/v	M/s. Biodeal Pharmaceuticals	In light of earlier SEC recommendation dated 14.10.2022, the firm presented their proposal of Midazolam Nasal Spray 0.5%w/v and 1.25%w/v with request of

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	1.25%w/v		BA/BE study waiver based on BCS classification alongwith justification and clinical trial data before the committee. After detailed deliberation,the committee recommended that the BA/BE study waiver based on BCS classification may be consider. However, the firm needs to present results of in-vitro studies performed with their drug product showing comparable release pattern with innovator product.