Recommendations of the SEC (Neurology & Psychiatry) made in its 77th meeting held on 16.02.2022 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.
Biological Division			
2.	BIO/CT/20/000036 Tenecteplase	M/s. Reliance Life Sciences Pvt. Ltd	The firm presented the proposal for amendment in the Phase II/III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
SND Division			
3.	SND/MA/22/00042 Glatiramer Acetate Injection 40mg/ml Pre-filled Syringes	M/s. Biocon	The firm presented the proposal along with justification for toxicity study, BE study and clinical trial waiver before the committee. After detailed deliberation, the committee opined that the firm should conduct a Phase III clinical trial and also submit the sub acute toxicity data generated with the proposed product for further consideration.
4.	SND/MA/22/00030 Clozapine ER Capsules 12.5/25/50/100 & 200 mg	M/s. Intas Pharmaceuticals.	The firm presented the proposal of modified release dosage form of the drug along with the results of BE study. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Clozapine ER Capsules 12.5/25/50/100 & 200 mg indicated for management of Schizophrenia in adult patients, subject to the condition that the firm should conduct Phase IV clinical trial. Accordingly, the firm should submit the protocol for conduct of Phase IV clinical trial to CDSCO within 3 months from the date of approval of the drug.
FDC Division			

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5.	FDC/MA/19/000079 Pregabalin IP (as prolonged release form) + Nortriptyline Hydrochloride IP eq. to Nortriptyline + Mecobalamin IP (75mg+ 10mg+1500mcg) film coated bilayered tablet	M/s. Synokem Pharmaceuticals Ltd.	The firm presented their proposal alongwith BE as well as Phase III CT study report before the committee. After detailed deliberation, the committee recommended that the firm should re-analyze the Phase III clinical trial study data w.r.t primary and secondary efficacy endpoints for repeated measures using appropriate statistical tool and present again before the committee.
6.	FDC/MA/21/000293 Etoricoxib 60mg/90mg/120mg + Pregabalin (As prolonged Release Form) 75mg/75mg/75mg tablets	M/s. Akums Drugs and Pharmaceutical Ltd.	The firm presented their proposal alongwith BE study protocol and requested for Phase III CT waiver before the committee. The committee noted that FDC of Etoricoxib 60 mg + PregabalinER 75 mg is approved by CDSCO. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study. Further committee also recommended that the firm is required to conduct Phase-III clinical trial for additional unapproved strengths. Accordingly the firm should submit the Phase III protocol for review by the committee.
GCT Division			
7.	CT/58/20 Online Submission (14339) Evobrutinib	M/s. IQVIA	The firm presented their protocol amendment version 3.0 dated 19 May 2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
8.	CT/167/21 Online Submission (29408) Satralizumab	M/s. Roche Products	The firm presented their Phase IIIB clinical trial proposal before the committee. **Assessment of risk vs. benefit to the** patients: the safety profile of the study drugs from preclinical toxicology, including repeat dose toxicity study justify the conduct of the trial. **Innovation vis-à-vis existing therapeutic option:** the purpose of the study is to describe the efficacy of Satralizumab in patients with AQP4 antibody seropositive NMOSD, either treatment naïve

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			or inadequate responders to previous treatment with RTX (or its biosimilar). **Unmet medical need in the country:** the test drug may be provided in pediatric patients with in neuromyelitisoptica spectrum disorder (nmosd) After detailed deliberation, the committee recommended for grant of permission to conduct the study (Protocol no. MN42928,amendment 1 ,dated 09 Jul 2021) with condition that the firm should increase the sample size in the country. Note: Dr. Debashish Chowdhury did not participate in the deliberation.
Medical Device Division			
9.	CI/MD/2021/39455 Magnetic Resonance Imaging Scanner	M/s. Voxelgrids Innovations Private Limited	The firm presented their proposal for clinical investigation of the proposed device before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical investigation of the proposed device in the country with the condition that only the volunteers who have not been implanted with any medical devices should be included in the study.