Recommendations of the SEC (Neurology & Psychiatry) made in its 01st/24 SEC meeting held on 18.01.2024 & 19.01.2024 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/175/21 Online Submission (26712) LOU064 (Remibrutinib)	M/s. Novartis	The firm presented protocol amendment version 03 dated 20 February 2023 protocol no. CLOU064C12301. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
2.	CT/116/21 Online Submission (28551) OAV101	M/s. Novartis	The firm presented protocol amendment version 03 dated 02 June 2023 protocol no. COAV101B12301. After detailed deliberation, the committee recommended that safety data of 23 enrolled subjects in India and DSMB report shall be submitted for further review by the committee.
3.	CT/143/23 Online Submission (40495) OAV101/ Onasemnogeneabeparvovec	M/s. Novartis	The firm presented phase 3b clinical study protocol no. COAV101A12308 After detailed deliberation, the committee recommended that the safety data shall be submitted for further review by the committee.
4.	CT/59/21 Online Submission (29386) Ofatumumab (OMB157) Siponimod (BAF312)	M/s. Novartis	The firm presented protocol amendment version 01 dated 17July 2023 protocol no. CBAF312D2301 After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
5.	CT/84/20 Online Submission (29323) Inebilizumab	M/s. Medpace Clinical Research India Pvt. Ltd	The firm presented protocol amendment 7.0 dated 13 September 2023 protocol no. VIB0551.P3.S1 After detailed deliberation, the committee recommended that the safety data and major amendments in tabular form along with justification shall be submitted forfurther review by the committee.
6.	CT/45/22 Online Submission (30345)	M/s. PPD	The firm didn't turn up for presentation.

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	Eteplirsen (AVI-4658)		
7.	CT/116/22 Online Submission (30553) Basimglurant Adjunctive	M/s. CliniRx	The firm presented protocol amendment 5.0 dated 13 October 2022 protocol no. NOE-TSC-201 After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
Biological Division			
8.	BIO/IMP/20/000075 Satralizumab	M/s. Roche Products Pvt. Ltd.	The firm presented their proposal for waiver of condition i.e. "Firm should carryout global clinical study with India as one of the site as proposed by the firm in the 64th SEC (Neurology & Psychiatry) meeting held on 15.12.2020" as stipulated in the import and market permission of Satralizumab (r-DNA origin) solution for injection 120mg/mL PFS indicated as monotherapy or in combination with immunosuppressants for the treatment of adult and adolescent patients with neuromyelitisoptica spectrum disorders (NMOSD) with a justification that firm has discontinued the GCT study stating that it was infeasible to recruit in sufficient eligible patients. After detailed deliberation, the committee recommended that the firm should conduct an India specific trial to establish safety and efficacy of the drug in Indian patients. Accordingly, the firm should submit India specific clinical trial protocol to CDSCO for further evaluation by the committee.
9.	BIO/CT04/FF/2023/38428 Ocrelizumab 300 mg Concentrate for solution for infusion	M/s. Roche Products (India) Pvt. Ltd.	The firm presented the protocol to conduct Phase IV clinical trial for drug product Ocrelizumab 300 mg Concentrate for solution for infusion 300 mg/10 mL (30 mg/mL) in a single-dose vial titled "A Multi-Center, Open-Label, Single Arm Phase IV Study to assess the safety and effectiveness of Ocrelizumabin Multiple Sclerosis (RMS and PPMS) patients in India (Overture)" vide protocol ML45008, Version 1.0 dated 12 Jul 2023.

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			After detailed deliberation, the committee recommended for following changes in the protocol. 1. Follow up should be done for a minimum of 2 years. 2. The efficacy end point should be included as the co-primary objective of the study. 3. One Government independent site with a neurologist should evaluate the patients whether the patients is truly progressive for the PPMS before enrolment in the study. 4. Minimum of 10% of PPMS patients should be included in the study. 5. Number of evaluable patients in the study should be minimum 32. 6. The study sites should be geographically distributed. Accordingly, firm is required to submit revised protocol to CDSCO for further evaluation before the committee.
10	BIO/CT18/FF/2023/39263 Tenecteplase 0.25 mg/kg	M/s. Boehringer Ingelheim India Private Limited	The firm presented the proposal for approval of additional indications for the drug Metalyse 25 mg (tenecteplase 0.25 mg/kg) lyophilized powder for solution for injection based on the clinical data generated from the global clinical studies conducted for Acute Ischemic Stroke (AIS) with the request of local clinical trial waiver. The committee noted that a dose of 0.2mg/kg for the drug is approved in India for AIS indication for other manufacturer. The firm has proposed for a higher dose i.e. 0.25mg/kg for the drug which is not approved in India. After detailed deliberation, the committee did not consider the firm's request for waiver of local clinical trial and recommended the firm to conduct a Phase III study in Indian patients to establish safety and efficacy of the drug for AIS indication with the proposed dose of 0.25mg/kg.

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BA/BE Division			
11	File No. 12-09/2023/BA-BE/MISC-42/DC (BABE/CT05/FF/2023/38769) Carbidopa 70mg + Levodopa 280 mg Extended-Release Capsules	M/s. Lupin Limited, Mumbai-400055	The firm presented their proposal along with the Protocol of the BE study for export purpose only. After detailed deliberation the committee recommended for submission of animal toxicity study report as this dose is higher than the approved dose. Accordingly, the firm should submit the above data/document/information for re-deliberation by the SEC.
12	File No. 12-09/2024/BA-BE/MISC-02/DC BABE/CT05/FF/2023/39377 Doxepin HCl Buccal Film 1.6 mg Capsules	M/s. Lambda Therapeutic Research Limited, Ahmedabad – 382481	The firm presented their proposal along with the Protocol of the BE study for Export purpose only. After detailed deliberation the committee recommended for submission of the following documents: (1) The differences between the formulation of the Test product in the present BE study and previous BE study which did not meet the study objective. (2) Scientific justification for the changes in the Test formulation w.r.t. the previous study experience. (3) The BE Study report of the previous BE study along with safety assessment. Accordingly the firm should submit the above data/document/information for re-deliberation by the SEC.
FDC Division			
13	FDC/MA/23/000354 Cinnarizine IP 25mg + Piracetam IP 400mg capsule	M/s. G.C. Chemie Pharmie Ltd.	The firm presented their proposal before the committee. After detailed deliberation, the committee opined that: 1. The firm has not presented any scientific justification in proposed strength. 2. Combining the Cinnarizine and Piracetam involve the risk of adverse event and hazardous to

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			the patients. 3. The FDC is not rational in proposed strength. In view of above, the committee did not recommend for approval of the proposed FDC.
14	FDC/MA/23/000369 Mecobalamin IP 1500mcg + Nortriptyline Hydrochloride IP Eq. to Nortriptyline 10mg + Pregabalin IP 50mg Film Coated Tablets	M/s. Synokem Pharmaceuticals Ltd.	The firm presented their proposal along with BE and Phase III CT waiver before the committee. After detailed deliberation, the committee opined that: 1. The firm has not presented any scientific justification in proposed strength. 2. The firm has not presented any published scientific literature or peer reviewed journal regarding essentiality and desirability in lower strength. 3. The FDC is not rational in proposed strength. In view of above, the committee did not recommend for approval of the proposed FDC.
15	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.	The firm presented its proposal before the committee along with BE protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. Accordingly, the firm should submit the BE study report to CDSCO for review and taking decision on the Phase III clinical trial protocol.
16	FDC/MA/22/000228 Mecobalamine IP 1500mcg + Nortriptyline Hydrochloride IP eq. to Nortriptyline 10mg + Pregabalin IP (SR)	M/s. Savi health Science	In light of earlier SEC recommendation dated 12.10.2023, the firm presented their proposal along with BE study protocol before the committee. After detailed deliberation, the committee recommended for conducting the BE study with the condition that number of

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	75mg film coated bilayered tablet		subjects should be increased to 24 and pharmacokinetics parameters should be same for all drugs. Accordingly, the revised BE study protocol should be submitted to CDSCO for further review.
17	FDC/MA/22/000417 Bupropion Hydrochloride (ER) IP 105mg + Dextromethorphan Hydrobromide IP 45mg tablets	M/s. Exemed Pharmaceutical	In light of earlier SEC recommendation dated 15.02.2023, the firm presented BE study report and the Phase III clinical trial report before the committee. After detailed deliberation, the committee opined that: 1. Raw data for pharmacokinetic of each subject should be submitted. 2. Details safety data with causality assessment to be submitted. Accordingly, the firm should submit above data for further review by the committee.