Recommendations of the SEC (Neurology & Psychiatry) made in its 02nd/24 SEC meeting held on 15.02.2024 at CDSCO (HQ) New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	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 for approval of protocol amendment as presented by the firm.
2.	CT/45/22 Online Submission (30345) Eteplirsen (AVI-4658)	M/s. PPD	The firm presented protocol amendment 10.0 version 11.0 dated 17 October 2023 protocol no. 4658-402. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm
3.	CT/20/000041 OnlineSubmission(30722) Lasmiditan Hemisuccinate	M/s. Eli Lilly And Company	The firm presented protocol amendment (c) dated 20 July 2023 protocol no. H8H-MC-LAHW After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm
4.	CT/23/000092 Online Submission(30891) BAY 2433334	M/s. Bayer Pharmaceuticals Pvt. Ltd.	The firm presented protocol amendment 1, version 2.0 dated 29November 2023 protocol no. 20604. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm with condition that all adverse events including minor shall be reported and DSMB review shall be conducted every 3 months.
Biological Division			
5.	4-38/Roche/PAC-R-Ocrelizumab/2023-BD(Diary no 5537) Ocrelizumab 300mg concentrate for solution for infusion	M/s. Roche	The firm did not turn up for presentation.
BA/BE Division			
6.	File No. 12-09/2024/BA-BE/MISC-09/DC	M/s. VerGo Pharma Research Pvt. Ltd., Goa -	The firm presented their proposal along with the Protocol (No.047-23 ver. 01 dated 12.08.2023) of the BE Study for

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	BABE/CT05/FF/2023/39230 Acamprosate Calcium 333 mg EC Tablets (Test Product -T1 and Test Product-T2)	403110	export purpose only. After detailed deliberation, the committee recommended for grant of permission to conduct the BE Study as presented by the firm.
SND Division			
7.	SND/MA/20/000351 Naltrexone Sustained Release Injection 190mg/ml	M/s. Rusan Pharma	In light of earlier SEC (Neurology & Psychiatry) meeting dated 10-03-2022, firm presented their study report for comparative Bioavailability study of Naltrexone Sustained Release Injection with Naltrexone Hydrochloride Tablets 50mg of Teva Canada Ltd in healthy adult human subjects. After detailed deliberation, the committee opined that the firm should conduct Phase III clinical trial. Accordingly, firm should submit Phase III Clinical study protocol to CDSCO for further deliberation by SEC.
New Drugs Division			
8.	ND/IMP/23/000072 Rimegepant ODT 75 mg	M/s. Pfizer Limited	The firm has presented its proposal for grant of permission to import and market Rimegepant ODT 75 mg, with a request for local Phase III clinical trial waiver, along with Clinical Trial reports of other countries for the Rimegepant ODT 75 mg. After detailed deliberation, the committee did not approve the firm's request for Clinical Trial waiver in India. The committee recommended that the firm should conduct the randomized controlled Phase III Clinical Trials in Indian population. Accordingly, the Phase III CT protocol should be submitted to CDSCO for review by SEC committee.
FDC Division			
9.	FDC/MA/21/000277 Alpha Lipoic acid	M/s. Pure & Cure Healthcare Pvt.	In light of the condition mentioned in permission in Form CT-23 dated

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	USP 200mg + Mecobalamin IP 1500mcg + Myo-inositol 100mg + Folic acid IP 1.5mg + Pyridoxine Hydrochloride IP 3mg Chromium Picolinate eq. to Chromium USP 200mg + Benfotiamine 200mg tablets	Ltd.	16.09.2022, the firm presented the Active PMS protocol before the committee. After detailed deliberation, the committee noted that the primary objective and secondary objective of the presented active PMS protocol is not inline with the already approved indication of the proposed FDC. Accordingly, the firm should submit the revised Active PMS protocol with adequate modification w.r.t to primary and secondary objective, exclusion criteria etc, to CDSCO for further review by the committee.
10.	FDC/MA/24/000014 Gabapentin IP 100mg/200mg/300mg /400mg/400mg + Duloxetine Hydrochloride IP eq. to Duloxetine (As enteric coated pellets) 20mg/20mg/20mg/20 mg/30mg hard gelatin capsule	M/s. Torrent Pharmaceuticals Ltd.	The firm presented their proposal along with request for BE study waiver & Phase III clinical trial protocol before the committee. After detailed deliberation, the committee did not consider the request of BE study waiver and recommended for conduct of BE study with the proposed FDC. Accordingly, the firm should submit the BE study protocol to CDSCO for review. Further, decision on the Phase III clinical trial protocol may be taken after review of BE study results.
11.	FDC/MA/24/000015 Gabapentin IP 100mg/200mg/300mg /400mg/400mg + Duloxetine Hydrochloride IP eq. to Duloxetine (As Enteric coated pellets) 20mg/20mg/20mg/20 mg/30mg + Methylcobalamin IP 1500mcg/1500mcg/15 00mcg/1500mcg/1500 mcg hard gelatin capsule	M/s. Torrent Pharmaceuticals Ltd.	The firm presented their proposal along With request for BE study waiver & Phase III clinical trial protocol before the committee. After detailed deliberation, the committee did not consider the request of BE study waiver and recommended for conduct of BE study with the proposed FDC. Accordingly, the firm should submit the BE study protocol to CDSCO for review. Further, decision on the Phase III clinical trial protocol may be taken after review of BE study results.