Recommendations of the SEC (Neurology & Psychiatry) meeting held on 12.09.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/IMP/24/000044 Eplontersen Solution for Injection 45 mg/0.8 ml	M/s AstraZeneca Pharma India Ltd	The firm presented the proposal for grant of permission to import and market of new drug Eplontersen Solution for Injection 45 mg/0.8 ml with the request for waiver of local clinical trial before the committee. After detailed deliberation, the committee noted that there was not enough evidence supporting the classification of polyneuropathy associated with hereditary transthyretin-mediated amyloidosis (ATTR) as a rare disease according to the rare disease list published by the government. The committee didn't recommend the firm's request for Phase III and Phase IV Clinical trial waiver in India. The committee opined that the firm is required to submit data on prevalence of the disease and rationale for considering the said disease as rare or orphan in the Indian context. Further, the committee opined that Rare disease division of the Ministry of Health may be requested to explore whether the said disease is to be considered as a rare disease or not.