Recommendations of the SEC (Renal) made in its 12th/25 meeting held on 22.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2025/ 52219 Eculizumab Concentrate for solution for infusion 300 mg (10 mg/ml) (r-DNA origin)	M/s. AstraZeneca Pharma India Limited	The firm presented the proposal for grant of permission to conduct a Phase IV clinical trial titled "A Prospective, Multicenter, Open-Label Phase-IV Clinical Trial to Assess the Safety & Effectiveness of Eculizumab in Indian Patients with atypical Hemolytic Uremic Syndrome (aHUS)" vide Protocol No. D7413L00002, Version No.1.0 dated 20-Aug-2025. After detailed deliberation, the committee recommended the firm to submit six monthly data on the drug usage in each patient, including proof of justified indication, appropriate vaccination, antibiotic prophylaxis and clinical outcome including infections as per earlier recommendation dated 30.07.2025 along with revised Phase IV study protocol with following changes to CDSCO for further evaluation before the committee- 1. Chronic kidney disease (CKD) stage should be replaced with Acute Kidney Injury (AKI) stage or acute kidney disease (AKD) in the outcome measure of the study objective. 2. Clarification is required on whether immunosuppression will be withheld or be permitted for patients with anti-FH antibody associated aHUS during study period. 3. The protocol should specify that testing for genetic and autoimmune basis of disease, which is not required to confirm eligibility, will be performed as part of investigations at baseline. 4. The firm should consider supporting the continued use of eculizumab beyond the defined study period, on compassionate grounds, in patients diagnosed with genetic form of a HUS.