Recommendations of the SEC (Reproductive) made in its 11th/25 meeting held on 18.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/25/000149 Linzagolix Tablets 100 mg/200 mg Tablets	M/s. Exemed Pharmaceuticals	The firm presented the proposal for grant of permission to conduct the BE study (Protocol ID: 077-25, Version No; 00, dated: 18.09.2025) and Phase III Clinical Trial (Protocol ID. CT/2025/25, Version No: 00, Dated: 20.09.2025) for Linzagolix Tablets 100 mg/200 mg before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct bioequivalence study as per the protocol presented by the firm. Further, the committee opined that firm should revise Phase III CT protocol including the following points: 1. Firm should include add-back therapy (ABT) in Leuprolide arm to make all three arms comparable. 2. Firm should revise the inclusion criteria to restrict the age range to 25-45 years. 3. The inclusion criteria related to menstrual status shall be revised alongwith menstrual bleeding definition rather than duration and interval. 4. Firm should monitor at least one bone remodeling marker and one bone reabsorption marker at the time of recruitment and at end of the study. Accordingly, the firm should submit revised Phase III CT protocol to CDSCO for further review by the committee.
FDC Division			
2.	FDC/MA/22/000319, E. office No. 118013	M/s. Akums Drugs and Pharmaceuticals	The firm presented the Active PMS study protocol before the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Progesterone IP 100mg + Estradiol USP (as hemihydrates) eq. to Anhydrous Estradiol 1mg soft gelatin capsules	Ltd.	After detailed deliberation, the committee recommended for grant of permission to conduct the Active PMS study with the condition that firm should include follow-up visit after completion of 4 weeks of the study. Accordingly, revised Active PMS study protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Active PMS study report for further review by the committee.