Recommendations of the SEC (Reproductive) made in its 06th/26 meeting held on 18.06.2026 at CDSCO HQ New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2026/ 55158 Choriogonadotropin alfa (r-DNA Human Chorionic Gonadotropin) solution for injection 250 mcg/0.5 mL in Pre-filled Syringe	M/s. INTAS PHARMACEUTICALS LTD	The firm presented the proposal to conduct a Phase I/III Clinical Trial titled "A Randomized, Assessor-Blind, Active-Controlled, Parallel Group, Two-Arm Study to Compare Efficacy, Safety, Pharmacokinetics and Immunogenicity of Recombinant Human Chorionic Gonadotropin (r-hCG) Injection of Intas Pharmaceuticals Ltd., with Ovitrelle (r-hCG) Injection of Merck Europe B.V. in Adult Female Participants Undergoing Controlled Ovarian Stimulation for Assisted Reproductive Technology" vide Protocol No.: 0299-25, Version No.: 1.0, Dated 23 January 2026 After detailed deliberation, the committee recommended for grant ofpermission to conduct the Phase I/III Clinical Trial as per the protocol presented by thefirm.
New Drugs Division			
2.	ND/CT/26/000039 Fezolinetant 45 mg film-coated tablet	M/s. Astellas Pharma India Private Limited.	In light of earlier recommendation dated 20.05.2025, firm has presented the Phase III Clinical Trial Protocol (Protocol No: 2693-CL-0315 dated 18.03.2026) of Fezolinetant 45 mg film-coated tablet before the committee. After detailed deliberation, the committee recommended for conduct of Phase III clinical trial as per the protocol presented by the firm with the condition that the protocol shall be revised for following: • Inclusion criteria shall be revised to Include Indian female participant (both surgical as well as natural menopausal) instead of Indian female participant of ≥ 40 years of age. • Definition of menopausal women needed to be included in the study protocol. Accordingly, firm should submit revised Phase-III CT protocol to CDSCO.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
3.	ND/MA/25/000149 Linzagolix Tablets 200 mg	M/s.Exemed Pharmaceuticals	In light of earlier recommendation dated 18.12.2025, firm has presented the BE report Linzagolix Tablets 200 mg before the committee. After detailed deliberation, the committee considered the BE study results of Linzagolix Tablets 200 mg as presented by the firm. Further, the firm should submit Phase III clinical trial results to CDSCO for further review by the committee.