Recommendations of the SEC (Reproductive) made in its 03rd/24 meeting held on 30.04.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/23/000196 Dydrogesterone Tablets Kit {Each kit contains: Part(A) 1 Dydrogesterone Tablet 40mg+ Part (B) 14 Dydrogesterone Tablets 10mg}	M/s. Mankind Pharma Ltd.	In light of earlier SEC recommendation dated 29.11.2023 & 30.11.2023, the firm proposed for manufacturing and marketing of combikit (Each part contains Part (A) 1 Dydrogesterone tablet 40 mg + Part (B) 06 Dydrogesterone tablets 10 mg. The firm presented Bioequivalence study report of Dydrogesterone tablet 40 mg along with Phase III clinical trial before the committee. After detailed deliberation, the committee noted that clinical trial protocol is inadequate and not in line with International clinical guidelines on threatened miscarriage and required to be revised as below: 1. The study shall be double blinded study instead of open label study as presented by the firm. 2. The protocol shall be designed in accordance to the recommendation of FOGSI / International guidelines and Inclusion criteria may be including: a) Duration of treatment shall be clearly specified with respect to above referred guidelines. b) Specify criteria for threatened miscarriage / abortion criteria. 3. In exclusion criteria mention known case of major illness will be excluded. 4. Schedule of events shall be clearly demonstrated with frequency of visit, test and follow up 5. Sample size should be scientifically calculated based on previous published data. Accordingly, the firm may be requested to submit the revised protocol for further review by the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
2.	FDC/MA/22/000421 Norethindrone Acetate USP 0.5mg + Estradiol (as Hemihydrate) USP eq. to Anhydrous Estradiol 1mg + Relugolix 40mg film coated tablet	M/s. Akums Drugs & Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 21.02.2024, the firm presented the proposal along with Phase III clinical trial protocol before the committee. After detailed deliberation, the committee opined the following modification in the Phase III clinical trial protocol: 1. Basic literacy status of subjects should be defined in Inclusion criteria. 2. Women with HbA1C ≥ 6.5 should be excluded from Inclusion criteria. 3. Standard rescue medication should be clearly defined and should be uniform for all sites. 4. The firm should include the references for sample size calculation. 5. Details of rating scale should be mentioned for Pelvic pain discomfit score and quality of life. Proof of validity and availability in local language proof to be provided. 6. Calcium and Vitamin D3 needs to be given for both the study arms. 7. The firm should define whether the study drug will be continued for Amenorrheic patients Accordingly, revised Phase III clinical trial protocol should be submitted to CDSCO for further review by the committee.