Recommendations of the SEC (Reproductive) made in its 01st/24 meeting held on 21.02.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/IMP/20/000082 Estradiol 1.53mg/ Actuation transdermal spray, solution (Additional dosage form and additional indication)	M/s. Themis Medicare Limited	In light of earlier recommendation dated 26.08.2021, the firm presented the revised Active Post marketing Surveillance (PMS) Study protocol (Protocol No. TML/LEN-01 Version No. 02 dated 14.09.2023) before the committee. After detailed deliberation, the Committee recommended for grant of permission for conduct of Post Marketing surveillance study with subject to condition that the methodology needs to include use of monotherapy only for hysterectomised patients and progesterone to be added as per standard of care in women with intact uterus.
New Drugs Division			
2.	ND/CT/20/000064 Follicle-stimulating Hormone (Endogen) and Human Chorionic Gonadotropin (Pubergen)	M/s. Sanzyme Pvt. Ltd.	The firm has presented the Phase III Clinical Trial study report of Follicle-Stimulating Hormone (FSH) and Human Chorionic Gonadotropin (HCG) before the committee. After detailed deliberation, the committee reviewed the Phase III Clinical study report and opined that the report submitted by the firm is acceptable.
FDC Division			
3.	FDC/IMP/20/000045 Dydrogesterone IP 2.5mg + Estradiol 0.5mg tablets	M/s. Abbott India Ltd.	In the light of earlier SEC recommendation dated 30.08.2023, firm presented revised Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial as per the revised protocol. The firm should submit Phase IV clinical trial report to CDSCO for further review by the committee.
4.	FDC/MA/23/000330 Relugolix 40 mg +	M/s. Macmillon Pharmaceuticals Pvt. Ltd.	The firm presented its proposal before the committee along with BE study protocol.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Estradiol Hemihydrate Eq. to Estradio USP 1 mg + Norethindrone Acetate 0.5 mg Tablets		After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. Accordingly, the firm should submit the BE study report to CDSCO for review by the committee and taking decision on the Phase III Clinical Trial protocol.
5.	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 19.12.2023, the firm presented the proposal for Phase III CT waiver based on international approval status, NICE Guidelines, Unmet Medical need for long term use etc. before the committee. After detailed deliberation, the committee reiterated its earlier recommendation dated 19.12.2023 and recommended to submit Phase III Clinical Trial protocol to CDSCO for review by the committee.