Recommendations of the SEC (Reproductive) made in its 06th/24meeting held on 04.07.2024 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/24/000101 Dydrogesterone Injection 5mg/ml	M/s. Mankind Pharma Private Limited	The firm present the proposal for grant of permission to manufacture and marketing of Dydrogesterone injection 5mg/ml (Additional Dosage form) along with Phase-III clinical trial protocol before the committee. The firm informed that the formulation Dydrogesterone injection 5mg/ml is not yet approved anywhere in the world. The firm also presented 28 repeated dose intramuscular toxicity data in female Wistar rat and Female New Zealand White Rabbit. After detailed deliberation, the committee opined that the firm should submit Phase-I/Phase-II clinical trial data including PK/PD study data to established safe and effective dose in IM (intramuscular) route to CDSCO for further review by the committee. Further, animal toxicity data shall be carried out in accordance with para 2 of the second schedule of the ND&CT Rules.
2.	SND/MA/23/000195 Relugolix Tablets 40mg (Additional strength and Additional indication)	M/s. Alkem Laboratories Limited	The firm present the proposal for grant of permission to manufacture and marketing of Relugolix 40mg tablets (Additional Strength) along with BE study protocol and justification for waiver of Phase-III clinical trial before the committee. The firm informed that Relugolix 40mg tablets is approved in Japan in year 2019 and FDC of Relugolix 40mg estradiol 1mg and Norethindrone acetate 0.5mg approved in USA in the year 2022. The committee noted that the firm did not present sufficient clinical trial data in female population for applied indication.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
			After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study as per protocol presented by the firm and submit Bioequivalence study report along with clinical trial data on Indian patients or Phase-III clinical trial protocol to CDSCO for further consideration by the committee.
FDC Division			
3.	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 30.04.2024, firm presented the proposal along with revised Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III clinical trial with the condition as mentioned below: 1. Subject to be educated for filing of Pictorial Blood Loss Assessment Chart. 2. Record of the training document should be maintained for each subject. 3. Pictorial Blood Loss Assessment Chart (PBAC) should be available in a vernacular language with reference images to each subject. Accordingly, the firm should submit Phase III clinical trial report to CDSCO for further review by the committee.
4.	FDC/MA/23/000184 Levonorgestrel 0.15mg + Ethinyloestradiol 0.03mg Tablets	M/s. Pfizer Limited	As per the condition mentioned in Form CT-23 dated 18.12.2023, the firm presented Active PMS protocol before the committee. After detailed deliberation, the committee recommended for conducting the Active PMS study. The result of the study should be submitted to CDSCO for review by the committee.
5.	04-01/2019-DC (Misc. 53)	M/s Akums Drugs & Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 29.08.2019, the firm presented the proposal along with Active PMS protocol

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Aceclofenac 100mg + Drotaverine Hydrochloride 80mg tablet		before the committee. After detailed deliberation, the committee recommended for conducting the Active PMS study. The result of the study should be submitted to CDSCO for review by the committee.