Recommendations of the SEC (Reproductive) made in its 02nd/24 meeting held on 20.03.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/23/000171 Relugolix Tablets 40 mg	M/s. Macmillon Pharmaceuticals Pvt. Ltd.	The firm presented the proposal for grant of permission to manufacture and market drug Relugolix tablet 40 mg along with permission to conduct Bioequivalence study and request for Phase III CT waiver. After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study with drug Relugolix tablet 40 mg as per the protocol presented. However, the committee did not recommend the Phase III CT waiver and recommended that the firm should submit Phase III clinical trial protocol for further consideration.
2.	ND/MA/20/000005 Flinbanserin 100mg Tablets	M/s. Zydus	The firm presented the proposal for grant of permission to manufacture and market drug product Flibanserin 100 mg tablets along with BE study report and request for local Phase III clinical trial waiver. The committee observed that proposed indication is not an unmet medical need. After detailed deliberation, the committee did not recommend local Phase III clinical trial waiver and recommended that firm should submit Phase III clinical trial protocol for further consideration.
3.	ND/MA/23/000113 FDC of Relugolix, Estradiol and Norethindrone Acetate Tablets (40 mg + 1 mg + 0.5 mg)	M/s. Sun Pharmaceutical Industries Limited	The firm presented the proposal before the committee for CT waiver and also presented the published safety and efficacy data. However, the committee did not agree for clinical trial waiver and the firm was asked to present Phase III CT protocol in continuation with earlier SEC recommendation dated 19.12.2023. After detailed deliberation, the committee recommended for conduct of Phase III clinical trial as per the protocol presented by the firm.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
4.	ND/MA/22/000105 Elagolix Tablets 150 mg and 200 mg	M/s. Sun Pharma Industries Ltd.	The firm has presented the Phase III CT report of Elagolix 150mg tablet and therapeutic justification and rationale for Elagolix 200 mg tablets. After detailed deliberation, the committee recommended for grant of manufacturing and marketing of Elagolix 150mg and 200mg for the proposed indication subject to the condition that (a) The firm should conduct Phase IV CT on Elagolix 200 mg tablet for which Phase IV CT protocol to be submitted to CDSCO within 3 months of approval for further evaluation by the committee. (b) To be sold by retail under the prescription of Gynaecologist only.
FDC Division			
5.	04-01/2019-DC (Misc. 53) Aceclofenac 100mg + Drotaverine Hydrochloride 80mg tablet	M/s. IPCA Laboratories Ltd.	In light of earlier SEC recommendation dated 29.08.2019, the firm presented the proposal along with Active PMS report before the committee. After detailed deliberation, the committee opined that the firm should submit source data of the Active PMS study to CDSCO for further review.
SND Division			
6.	SND/MA/22/000353 Dydrogesterone Sustained Release Tablets 20 and 30 mg	M/s. Ravenbhel Healthcare Private Limited	This is reference to earlier SEC minutes of the meeting dated 20/09/2023 and 29/11/2023 & 30/11/2023, the present proposal is for correction in the SEC minute held on 29/11/2023 & 30/11/2023 for Agenda no. 8 of M/s Ravenbhel Healthcare Private Limited. The name of the product is inadvertently mentioned as Dydrogesterone extended release tablets 30 mg/ Dydrogesterone sustained release 30mg as against Dydrogesterone sustained release tablet 20mg & 30 mg which is in line with earlier SEC minutes for the meeting held on 20/09/2023 and as per the Form CT-21.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			The committee noted above correction and recommended to make necessary correction in the minutes in F. No., Drug Name & Strength and Recommendation columns respectively for name of product is Dydrogesterone sustained release tablet 20mg & 30 mg.