Recommendations of the SEC (Reproductive & Urology) made in its 79th meeting held on 28.02.2023 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/22/000171 Relugolix Film coated tablet 40mg	M/s. Synokem	The firm did not turn up for presentation.
Biological Division			
2.	BIO/CT/21/000144 Follicle Stimulating Hormone (Hormone Recombinant)	M/s. Veeda Clinical Research	The firm presented the amendment in the protocol titled "A randomized, open label, balanced, two-treatment, two-period, two-sequence, single dose, crossover, bioequivalence study of Foligraf® 900 IU (66.0 µg)/1.5mL solution for injection in prefilled pen [Follicle Stimulating Hormone (Human Recombinant)] of Bharat Serums and Vaccines Limited,India and GONAL-f® 900 IU (66.0 µg)/1.5 mL solution for injection in prefilled pen of Merck Serono at a dose of 300 IU in healthy, adult, female, human subjects" vide protocol version 01 vide amendment 002 dated 31-Dec-2022. After detailed deliberation, the committee recommended for grant of approval for theamendmentvide protocol version 01 vide amendment 002 dated 31-Dec-2022.
SND Division			
3.	SND/MA/22/000299 Dyhydogestrone film coated sustained release Tablets 20/30mg	M/s. Synokem Pharmaceuticals	The firm presented its proposal for manufacture and marketing permission of Dydrogesterone film coated sustained release tablets 20/30mg for the indication of "Luteal support as part of an Assisted Reproductive Technology (ART) treatment" alongwith Phase III clinical trial protocol and BE protocol respectively as mentioned below, before the committee. A multicenter, randomized, double blind, active controlled, three-arm, parallel group, Phase III clinical trial to evaluate efficacy and safety of Dydrogesterone SR Tablets 20mg/30mg for Luteal support as part of assisted reproductive technology (ART) treatment.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			An open label, randomized, balanced, two treatment, two sequence, two period, cross-over, single dose, oral bioequivalence study of Dydrogesterone film coated sustained release 30mg tablets (T) manufactured by Synokem Pharmaceuticals Ltd., India with Duphaston® (Dydrogesterone tablets IP 10mg (Dose: 3x10mg) (R) manufactured by Abbott India Limited in normal healthy, adult female subjects under fasting condition. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study and Phase III clinical trial as per the protocols presented by the firm subject to condition that the age group of the study population in Phase III clinical trial should be ≥ 21 and ≤ 42 years of age and are planning to undergo ART.
FDC Division			
4.	FDC/MA/23/000020 Tamsulosin Hydrochloride 0.4mg/0.4mg+ Mirabegron 25mg/50mg tablets	M/s. Windlas	The firm presented its proposal before the committee along with BE study protocol. After detailed deliberation, the committee recommended for conducting the BE study. The result of the BE study shall be presented before the committee along with Phase III clinical trial study protocol.
5.	FDC/MA/23/000003 Mirabegron (As prolonged Release) 25mg/50mg/25mg/ 50mg + Tamsulosin Hydrochloride (As Prolonged Release) 0.2mg/0.2mg/0.4mg/ 0.4mg tablets	M/s. Ravenbhel Healthcare	The firm presented its proposal before the committee along with BE study protocol. After detailed deliberation, the committee recommended for conducting the BE study. The result of the BE study should be presented before the committee along with Phase III clinical trial protocol.
6.	FDC/MA/18/000074 L-Methylfolate 1mg + Dehydroepiandrosterone 75 mg + vitamin D3 2000IU Tablets	M/s. Synokem Pharmaceuticals	The firm did not turn up for presentation.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
7.	4-66/2018-DC (Pt. Akums) Alfuzosin Hydrochloride IP (as Extended Release) 10mg/10mg + Tadalafil IP 2.5mg/5mg film coated tablets	M/s. Akums Drugs & Pharmaceuticals	In light of earlier SEC recommendation dated 24.05.2022, the firm presented the Phase III clinical trial study report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the product with condition to conduct the active PMS study for secondary efficacy and tolerability including ED parameters. In view of above, the active PMS study protocol should be submitted to CDSCO within a month for review by committee.
Medical Device Division			
8.	MFG/MD/2022/ 61423 Pessary	M/s. Ziller Medical INC	The firm presented its proposal before the committee. After detailed deliberation, the committee recommended to submit pilot clinical investigation protocol & application for the proposed device.