Recommendations of the SEC (Reproductive & Urology) made in its 78th meeting held on 31.01.2023 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000161 Elagolix Tablets 150mg & 200mg	M/s. MSN Laboratories Private Limited	The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Elagolix Tablets 150mg & 200mg along with the result of BE Study and Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III clinical trial as per protocol presented.
SND Division			
2.	SND/MA/22/000282 Dydrogesterone film coated Sustained Release Tablets 20 mg	M/s. Zydus Healthcare	The firm represented the Phase III clinical trial protocol BIOS/2022/267, version No. 01 dated 06.10.2022. "Prospective, randomized, double-blind study, single dummy, two – arm, active controlled, parallel, multicentre, Phase III clinical trial to assess the efficacy and safety of Dydrogesterone film coated sustained release tablets 20 mg as compared to Dydrogesterone tablets 10mg for treatment of endometriosis in women." After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial. The committee also suggested to monitor the size of endometrioma during the study.
3.	SND/MA/22/000299 Dydrogesterone film coated Sustained Release Tablets 20/30 mg	M/s. Synokem Pharmaceuticals	The proposal will be redeliberated in upcoming SEC.
4.	SND/MA/22/000317 Dydrogesterone film coated Release Tablet 20 mg	M/s. Synokem Pharmaceuticals	The firm presented their proposal along with rationality of the drug product, BE and Phase III clinical trial protocol to assess the efficacy and safety of Dydrogesterone film coated sustained release tablets 20mg versus

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			Dydrogesterone tablets 10mg for treatment of confirmed endometriosis in women before the committee. After detailed deliberation, the committee opined that Phase III clinical trial protocol is inadequate with respect to objective of the study, inclusion and exclusion criteria and justification for sample size calculation. In the presented BE study protocol the indication of proposed product is mentioned which is not as per the proposed indication i.e for treatment of confirmed endometriosis in women. After detailed deliberation, the committee recommended that the firm should submit revised clinical trial protocol and BE study protocol for further review of the committee.
5.	SND/MA/22/000253 Dydrogesterone film coated Sustained Release Tablets 20/30 mg	M/s. Ravenbhel Healthcare	The firm presented their proposal alongwith rationality of the drug product, BE protocol and Phase III clinical trial protocol to assess the efficacy and safety of Dydrogesterone film coated sustained release tablets 30mg versus Dydrogesterone tablets 10mg for treatment of confirmed endometriosis in women before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct BE study and Phase III clinical trial as per protocols presented by the firm.
FDC Division			
6.	FDC/MA/22/000366 Pyridoxine HCl IP (ER) 20mg + Doxylamine succinate (ER) 20mg	M/s. Akums	The firm presented their proposal along with BE study protocol as well as justification for Phase III clinical trial study waiver. The committee noted that the product is already approved in countries like USA, Canada, etc. After detailed deliberation, the committee recommended for grant of permission for conducting the BE study.

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			The result of the study shall be presented before the committee for further review.
7.	FDC/MA/22/000418 Estradiol (as hemihydrate) USP Eq. to Anhydrous Estradiol 0.5mg/1.0mg + Drospirenone IP 0.25mg/0.5mg tablets	M/s. Akums	The firm presented their proposal along with BE study protocol as well as justification for Phase III clinical trial study waiver. The firm informed the committee that the product is already approved in countries like USA, Canada, UK, etc. After detailed deliberation, the committee recommended for grant of permission for conducting the BE study. The result of the study shall be presented before the committee along with Phase IV clinical trial protocol for further review.
8.	FDC/MA/22/000421 Norethindrone acetate USP 0.5mg + Estradiol (as hemihydrate) eq. to Estradiol 1.0mg + Relugolix 40mg tablets	M/s. Akums	The firm presented their proposal along with BE study protocol as well as justification for Phase III clinical trial study waiver. The firm informed the committee that the product is already approved in countries like USA, EU, UK, etc. After detailed deliberation, the committee recommended for grant of permission for conducting the BE study and revise the indication in line of approved indication by USFDA i.e it is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. The result of the study should be presented before the committee for further review. Further, there should not be waiver of Phase III local clinical trial.
Medical Device Division			
9.	CI/MD/2022/80312 Robotic Surgery System	M/s Crossly Remedies Limited	The firm presented their proposal to conduct a Pilot Clinical Investigation of the proposed product before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct the Pilot Clinical Investigation with the proposed device on Indian population.