Recommendations of the SEC (Reproductive & Urology) made in its 76th meeting held on 30.11.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT/22/000102 Follitropin alfa (r-FSH) Injection in multidose pre-filled glass cartridges (300 IU, 450 IU, 900 IU) or single use Vial (75 IU)	M/s. Zydus Life Sciences Limited	The firm presented the proposal for conduct of Phase IV clinical trial titled "A Phase IV, single arm, open-label, multicenter study to evaluate the safety and efficacy of recombinant human FSH (Briogyn™) in female patients undergoing assisted reproductive technology" vide protocol no. FOLI.21.001, Version No.: 02; dated 20 September 2021. After detailed deliberation, the committee approved the protocol for conduct of Phase IV trial as presented.
SND Division			
2.	SND/MA/22/000276 Tadalafil Oral Jelly 20 mg (Orange Flavour)	M/s. Ajanta Pharma	The firm did not turn up for presentation.
3.	SND/MA/22/000168 Estradiol Vaginal Cream USP 0.01%	M/s. West Cost Pharmaceuticals	The firm did not turn up for presentation.
4.	SND/MS/22/000299 Dydrogesterone Film Coated Sustained Release Tablets 20mg/30 mg	M/s. Synokem Pharmaceuticals	The firm presented their proposal alongwith rationality of the drug product, BE and Phase III clinical trial protocol before the committee. Dydrogesterone 10mg Tablets is already approved in India on 06.04.2018, indicated for luteal support as part of an assisted reproductive technology (ART) treatment. Further, Dydrogesterone and Dydrogesterone tablet 10mg are official in IP 1996. Estradiol-2mg + Dydrogesterone 10mg is also approved in India on 01.02.2000 for treatment of women with intact uterus for the symptoms of estrogen deficiency as consequence of the menopause or after overectomy and for the prevention of post menopausal osteoporosis.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			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.
FDC Division			
5.	FDC/MA/22/000055 26 hormone -containing film coated tablets in the following order: 2 dark yellow tablets each containing 3mg estradiol valerate EP 5 medium red tablets each containing 2mg estradiol valerate EP and 2mg dienogest IP 17 light yellow tablets each containing 2mg estradiol valerate EP and 3mg dienogest IP 2 dark red tablets each containing 1mg estradiol valerate EP Film Coated tablet	M/s. Bayer Pharmaceuticals Pvt. Ltd.	The firm presented their proposal along with justification for BE/CT study waiver. The firm informed the committee that the product (Combipack) is already approved in countries like US, UK, Australia, EU, etc. After detailed deliberation, the committee recommended for grant of permission to import and market the product with condition to conduct the Phase IV clinical trial study. The study protocol should be submitted within 03 months from the date of approval to CDSCO for review by the SEC.
6.	FDC/MA/22/000318 Solifenacin Succinate 6mg + Tamsulosin HCl 0.4mg	M/s. Cipla Ltd.	The firm presented their proposal along with BE study report conducted for export purpose 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 Europe & UK. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the product with condition to conduct the Phase IV clinical trial study. The study protocol should be submitted within 03 months from the date of approval to CDSCO for review by the SEC.
7.	FDC/MA/22/000319	M/s. Akums Drugs and Pharmaceuticals Ltd.	The firm presented their proposal along BE study protocol as well as justification for Phase III clinical trial study waiver.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Estradiol USP (as hemihydrate) eq to anhydrous Estradiol 1mg + Progesterone IP 100mg soft gelatin capsule		The firm informed the committee that the product is already approved in countries like US, Australia, UK, Canada, EU etc. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. The result of BE study should be presented before the SEC for further review.
Medical Device Division			
8.	MFG/MD/2022/ 71440 Graphene condom	M/s. HLL Lifecare Limited	The firm presented their proposal before the committee. After detailed deliberation, the committee recommended for the manufacturing permission of the product Graphene condom to M/s. HLL Lifecare Limited for manufacturing and marketing in the country.