Recommendations of the SEC (Reproductive & Urology) made in its 77th meeting held on 23.12.2022 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 150 mg/200 mg	M/s MSN Laboratories Limited	The firm did not turn up for the presentation.
2.	ND/MA/21/000061 Fesoterodine Fumarate Extended Release Tablets 4 mg and 8 mg	M/s MSN	Firm presented Phase III clinical trial report of Fesoterodine Fumarate extended release tablets 4 mg and 8 mg before the committee. After detailed deliberation, the committee noted that; 1. Total of 216 patients were randomized into two different groups for efficacy outcome. 2. The efficacy analysis between two treatment groups has no statistical significant difference ($p>0.05$) which showed that Fesoterodine Fumarate extended release tablets 4 mg and 8 mg and Solifenacin Succinate Tablets 5 mg and 10 mg have similar efficacy in reduction in mean number of micturitions, urgency episodes, urgency urinary incontinence and Night time micturitions per 24 hrs. 3. Fesoterodine Fumarate extended release tablets 8 mg has shown clinically meaningful reduction in number of micturitions, urgency episodes, urgency urinary incontinence and night time micturitions per 24 hrs in patients who did not respond to Fesoterodine Fumarate extended release tablets 4 mg. 4. Overall, the results of efficacy analysis demonstrated that Fesoterodine Fumarate extended release tablets 4 mg and 8 mg have non-inferior efficacy compared to Solifenacin Succinate Tablets 5 mg and 10 mg in the treatment of Overactive Bladder Symptoms.

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			5. There were no SAE reported. All reported AE were mild/moderate in nature and similar to innovator. In view of the above, the committee recommended for grant of permission to manufacture and market drug Fesoterodine Fumarate extended release tablets 4 mg and 8 mg.
SND Division			
3.	SND/MA/22/000276 Tadalafil Oral Jelly 20 mg (Orange Flavour)	M/s Ajanta Pharma	The firm presented its proposal of manufacture and marketing permission of Tadalafil Oral Jelly 20 mg (Orange Flavour) for the indication as "It is indicated for the treatment of erectile dysfunction in adult men" alongwith BE protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct BE study of Tadalafil Oral Jelly 20 mg (Orange Flavour) as per the protocol presented subject to condition that physician opinion should be taken before enrolment the subjects in the study. The committee also recommended that firm should submit BE study report for further review by the committee and consideration of clinical trial of the applied drug product.
4.	SND/MA/22/000168 Estradiol Vaginal Cream USP 0.01%	M/s West Cost Pharmaceuticals	The firm presented its proposal for the permission for manufacturing and marketing of the drug Estradiol Vaginal Cream USP 0.01% (additional dosage form) for the treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause. After detailed deliberation the committee recommended that the firm should submit the following documents for further deliberation in the next SEC meeting: 1 Toxicology study report. 2 Detailed Indian study data. 3 Formulation details and patient information documents. 4 Nature of applicator used for delivery of the Cream.
5.	SND/MA/22/000282	M/s Zydus Healthcare	The proposal was deferred for next meeting.

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	Dydrogesterone film coated Sustained Release Tablets 20 mg		
6.	SND/MA/22/000299 Dydrogesterone film coated Sustained Release Tablets 20 mg/30mg	M/s Synokem Pharmaceutical	The proposal was deferred for next meeting.
FDC Division			
7.	FDC/MA/22/000343 Tamsulosin HCl IP (as extended release tablet) 0.4mg + Tadalafil IP (as film coated tablet) 2.5mg capsules	M/s. Akums	The firm presented their proposal before the Committee along with justification for BE and CT study waiver. The committee noted that higher strength of proposed FDC was already approved by CDSCO on 02.07.2021. The firm informed Committee that the application has been submitted separately in higher strength for which NOC for conducting the BE study is awaited. After detailed deliberation, committee recommended that firm should present the BE report in higher strength as well as submit the Phase IV CT protocol to CDSCO for further review by the committee.
Biological Division			
8.	BIO/CT/21/000039 Recombinant Anti Rho-D Immunoglobulin Injection 300 mcg (Liquid Injection)	M/s. Bharat Serums and Vaccines Limited	The firm presented the Phase IV clinical study titled "A Prospective, Multi-centre, Phase IV study for Post-Marketing Safety Evaluation of Recombinant Anti-Rho(D) immunoglobulin in the prevention of Maternal Rh-isoimmunization" conducted as per Protocol No. BSV_ANTID_21_03 Version 3.0 dated 26.08.2021 as per condition of manufacture and marketing of the drug. After detailed deliberation, the committee noted the results of this safety study & recommended that- 1. Safety data including all adverse events reported in the Phase IV study should be included in the prescribing information of the drug

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			The use of the drug should be avoided in patients with tachycardia (more than 100 beats/mins).