Recommendations of the SEC (Reproductive & Urology) made in its 75th meeting held on 21.10.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-01/2022-DC(PU-003) Levonorgestrol 20ug/24 hours intra Uterine Delivery System	M/s. Bayer Pharmaceutical	The firm presented the updation in prescribing information of Levonorgestrol 120µg/24 hr. After detailed deliberation, the committee recommended for proposed updation in prescribing information.
SND Division			
2.	SND/MA/22/000282 Dydrogesterone Extended Release Tablet 20mg	M/s. Zydus Life Science	The firm has presented the bioequivalence study protocol no: BIOS/2022/267 of Dydrogesterone extended release tablet 20mg. After detailed deliberation, the committee recommended to conduct the bioequivalence study with following conditions: 1. Subject should be screened for the gynaecological disorder by physical examination or by investigation by the Investigator. 2. Hemoglobin level of the subject should be more than 12gm. 3. Dose of the product should be given within 10 days of LMP (last menstruation period).
3.	SND/MA/20/000024 Mifepristone 10/25mg Tablet	M/s. Akums Drugs & Pharmaceuticals Limited	The firm presented their proposal of present status of ongoing Phase III clinical trial of Mifepristone 10/25mg tablet with Mifepreistone Tablets 10mg and 25mg alongwith challenges being faced in subject recruitments before the committee. After detailed deliberation, the committee recommended that there is no particular reason significant for considering the submission of interim study report of the clinical study and opined that the firm might be allowed to present any changes required in the approved protocol with respect to recruitment window period or additional study site to complete the study.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
4.	FDC/MA/22/000081 Dutesteride 0.5mg/0.5mg + Silodosin 4mg/8mg tablets	M/s.Akums Drugs & Pharmaceuticals Limited	In light of earlier SEC recommendation dated 27.04.2022, the firm presented the proposal along with BE study report. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC with condition that active PMS report should be submitted to CDSCO for review by the committee.