Recommendations of the SEC (Reproductive & Urology) made in its 65th meeting held on 30.11.2021 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/19/000124 Medroxy progesterone Acetate Sustained Release (SR) Tablet 30 mg	M/s. Synokem	In light of earlier SEC (Reproductive) recommendation dated 26.02.2020 the firm presented Phase III clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Medroxy progesterone acetate Sustained Release (SR) tablets 30mg for the indication "Mild to Moderate Endometriosis".
2.	SND/MA/21/000477 Vardenafil Oral Jelly 20 mg per 5 g	M/s. Ajanta	The firm presented the proposal along with BE protocol and requested for clinical trial waiver. After detailed deliberation, the committee recommended for grant of permission for conduct of the BE study as per the protocol presented. Based on the results of the BE study the request of the firm for product approval may be considered.
3.	SND/IMP/21/000091 Estriol vaginal Cream 1mg/gm	M/s. Torrent Pharma	The firm presented the proposal for import and marketing of Estriol vaginal cream 1mg/gm. After detailed deliberation, the committee recommended for grant of permission for import and marketing of Estriol Vaginal Cream 1mg/gm, for vaginal symptoms due to estrogen deficiency in menopause.
4.	SND/IMP/21/00007 Testosterone Gel 1.62% w/w (pump pack containing 1.62% w/w testosterone)	M/s. Besins Healthcare	The firm didn't turn up for presentation.
5.	SND/MA/21/000418 Carbetocin Injection 100mg/ml (Room Temperature Stable formulation)	M/s. Percise Biopharma	The firm presented the proposal for Carbetocin Injection 100mg/ml claimed to be stable at room temperature with a change in the excipient composition. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing the Carbetocin Injection 100mg/ml subject to

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			condition that the firm should conduct a Phase IV clinical trial. Accordingly, the firm should submit the Phase IV CT protocol within 3 months of approval of the product.
FDC Division			
6.	FDC/MA/21/000254 Silodosin 8mg/8mg + Mirabegron(ER) 25mg/50mg tablets	M/s. Windlas	The firm presented their proposal along with CT and BE study protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE and clinical trial. The committee also recommended that more sites should be included in the study and BE study results should be presented in the SEC before initiating the Phase III clinical trial.
7.	FDC/MA/21/000074 Tamsulosin Hydrochloride IP 0.4mg (as prolonged release pellets) + Tadalafil IP 5mg (as film coated tablet)	M/s. Sun Pharma	The firm presented their proposal along with Phase IV study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical study subject to the following conditions: i) Sexually active patient with LUTS should be included ii) All parameters should be evaluated upto 12 weeks. Revised protocol should be submitted to CDSCO before initiation of the study.
Medical Device Division			
8.	CI/MD/2021/41062 Female condom	M/s. Cupid Limited	In light of earlier SEC recommendations dated 29.07.2021, the firm presented their proposal for post marketing clinical investigation before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the post marketing clinical investigation with the proposed device in India.