Recommendations of the SEC (Reproductive & Urology) made in its 86th meeting held on 20.09.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/22/000353 Dydrogesterone Sustained Release Tablets 20 & 30mg	M/s. Ravenbhel Healthcare Pvt. Ltd.	In light of earlier SEC recommendations dated 31.01.2023, the firm presented Bioequivalence study report of Dydrogesterone sustained release tablets 20 & 30mg before the committee. After detailed deliberation, the committee recommended for grant of permission to initiate Phase III clinical trial study as per approved Phase III clinical trial protocol of Dydrogesterone sustained release tablets 30mg for which NOC was issued on dated 15.02.2023.
2.	SND/MA/20/000368 Dydrogesterone Extended Release Tablet 20mg	M/s. Zydus Healthcare Pvt. Ltd.	In light of earlier SEC recommendations dated 21.10.2023 and 31.01.2023. The firm presented Bioequivalence study report and Phase III clinical trial study report of Dydrogesterone Extended Release tablet 20mg before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of the Dydrogesterone Extended Release tablet 20mg.
3.	SND/MA/23/000166 Dydrogesterone Modified Release Tablets 30mg (Additional Strength)	M/s. Abbott India Limited	The firm presented Phase III clinical trial protocol before the committee. The committee noted that the firm is already holding BE NOC. After detailed deliberation, the committee recommended that additional objective should be included as secondary objective stating that " In women diagnosed to be having endometrioma on sonography at the time of recruitment, any change in the size of endometrioma will be noted at the end of the study". The committee recommended grant of permission to conduct the Phase III clinical trial subject to the above condition and that the firm should submit Bioequivalence report and get evaluated by the SEC committee before initiating the Phase III clinical trial.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
4.	SND/MA/22/000317 Dydrogesterone SR Tablet 20mg	M/s. Synokem Pharmaceuticals Limited	In light of earlier SEC recommendations dated 26.04.2023. The firm presented Bioequivalence study report of Dydrogesterone sustained release tablets 20 before the committee. After detailed deliberation, the committee recommended for grant of permission to initiate Phase III clinical trial study as per Phase III clinical trial protocol approved vide clinical trial NOC dated 23.06.2023 for Dydrogesterone sustained release tablets 20mg.
5.	SND/MA/23/000137 Dydrogesterone SR Tablet 20mg	M/s. Acme Formulations Pvt. Ltd.	In light of earlier SEC recommendations dated 25.05.2023, the firm presented Bioequivalence study report of Dydrogesterone sustained release tablets 20 before the Committee. After detailed deliberation, the committee recommended for grant of permission to initiate Phase III clinical trial study as per Phase III clinical trial protocol approved vide clinical trial NOC dated 23.06.2023 for Dydrogesterone sustained release tablets 20mg.
FDC Division			
6.	FDC/MA/23/000014 Combikit of Silodosin Capsules 8mg/8mg + Mirabegron ER Tablets 25mg/50mg	M/s. MSN Laboratories Pvt. Ltd.	The firm presented their proposal along with request for Phase III clinical trial & BE study waiver before the committee. After detailed deliberation the committee noted that:- 1) The firm has not presented any scientific justification and need for the proposed Combikit. 2) The single drug of the proposed strength is already approved and FDC of Silodosin 8mg/8mg + Mirabegron ER 25mg/50mg tablet is also recommended for CT study, the firm did not present any benefit over the FDC and approved single drugs. 3) There is no unmet need. Accordingly, the committee didn't recommend for approval of the proposed Combikit.