Recommendations of the SEC (Reproductive & Urology) made in its 74th meeting held on 28.09.2022 at CDSCO (HQ), New Delhi:

Sr. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	12-01/21-DC (Pt-203) Melatonin	Bhaktivednta Hospitals	The Principal Investigator presented the academic clinical trial protocol before the committee. After detailed deliberation, the committee recommended that the applicant should submit: 1. Rationale for use of melatonin as post operative analgesic agent with scientific literature and animal studies data. 2. Rationale for including the patients only undergoing caesarean section 3. Methodology section is incomplete. It should be clear and must include randomization, blinding details, number of subjects in each group, etc. 4. Justification for sample size calculation. 5. Exclusion criteria should include Preeclampsia and eclampsia conditions. 6. Effect of the drug on lactation and breast feeding with supportive literature 7. Rationale for 18 months duration of the study Accordingly the applicant should submit revised protocol and above information/data to CDSCO for further consideration.
2.	12-01/2022-DC (PU-003) Levonorgestrol 52 mg (20µg/ 24 hours intra Uterine Delivery System)	M/s. Bayer Pharmaceuticals Pvt. Ltd.	The firm didn't turn up for presentation.
3.	ND/MA/22/000105 Elagolix Tablets 150mg and 200mg	M/s Sun Pharmaceutical Industries Ltd.	In light of earlier SEC recommendation dated 28.07.2022, the firm presented revised Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented

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			protocol subject to condition that the firm should include both T-score and Z-score for monitoring of Bone marrow Density (BMD).
4.	12-05/07-DC (Pt-Emcure) Atosiban Acetate Injection 7.5mg/ml	M/s Emcure	The firm presented Phase-IV clinical study report for Atosiban Acetate injection 7.5mg/ml. After detailed deliberation, the committee recommended for continued marketing of the drug Atosiban Acetate Injection 7.5mg/ml in the country.
SND Division			
5.	SND/MA/21/000547 Progesterone SR Tablet 200/300/400mg	M/s. Sun Pharma	The firm presented their proposal alongwith BE study report of Progesterone SR Tablet 400mg before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of the applied drug products for already approved indication.
6.	SND/CT/04/22/ 000043 Thymosin Alpha for injection 1.56mg	M/s Gufic Bioscience	In light of recommendation of the SEC committee held on 28-07-2022, the firm presented revised Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial as per protocol presented with the condition that follow up treatment arm should be 3 months after last dosing of Thymosin Alpha for Injection and more government sites should also be include.
Medical Device Division			
7.	IMP/MD/2021/38932 Portia Vaginal Ring Pessary	M/s. Morulaa Health Tech Pvt. Ltd.	In light of earlier SEC recommendation dated 24.05.2022, the firm presented their proposal for import and marketing of the proposed device before the committee. The committee observed that the firm was unable to present the efficacy and long term safety data on proposed device even after request/advise two times. After detailed deliberation, the committee recommended that the firm should conduct a pivotal clinical investigation (Phase III clinical trial) of the proposed device on Indian population.