Recommendations of the SEC (Reproductive and Urology) made in its 72nd meeting held on 28.07.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/21/000151 Topiroxosatat Tablet 20/40/60 mg	M/s. Synokem Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 27.04.2022, the firm presented their proposal for grant of permission to manufacture and market drug Topiroxosatat Tablet 20/40/60 mg along with bioequivalence study results. After detailed deliberation, the committee noted that the drug Topiroxosatat is already approved in the country and opined that the Topiroxosatat Tablet 60 mg of M/s. Synokem Pharmaceuticals Ltd and reference Topiroxosatat Tablet 60 mg are bioequivalent. Hence, the committee recommended for grant of permission to manufacture and market drug Topiroxosatat Tablet 20/40/60 mg.
Biological Division			
2.	BIO/CT21/FF/2022/32155 Recombinant Follicle stimulating Hormone	M/s. Bharat Serums	The firm presented their proposal for manufacturing and marketing of additional presentation i.e. 300 IU/0.5ml solution for Injection in Prefilled pen. The committee noted that the firm is already holding new drug permission for r-FSH after conducting clinical trials in India and also holds new drug permission for higher strength i.e rFSH 450IU/900IU/1200IU in prefilled pen and there is no change in composition. After detailed deliberation, the committee recommended for approval of the additional presentation 300 IU/0.5ml Solution for Injection in prefilled pen.
SND Division			
3.	SND/MA/22/000119 Clotrimazole vaginal Film 50 mg	M/s. Hetero Healthcare Limited	The firm presented the revised Phase III protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the phase III clinical trial with

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			following conditions: 1. To increase the number of study centers (atleast 10 centers i.e 5 Govt Hospitals and 5 Private Hospitals) and accordingly, number of subjects to be increased. 2. To increase the safety follow up period up to 14 days instead of 7 days.
4.	SND/CT/22/000043 Thymosin Alpha 1 for injection 1.6 mg	M/s. Gufic Biosciences	The firm submitted proposal to conduct Phase III clinical trial before the committee. The committee opined that the SOC used in control as well as test arm is not clearly defined in the protocol. After detailed deliberation, the committee recommended that the firm should revise protocol with clearly defined SOC for further review by the committee.
FDC Division			
5.	04-01/2019-DC(Misc. 53) Aceclofenac100mg + Drotaverine Hydrochloride80mg	M/s. Mapra	The firm didn't turn up for presentation.
6.	FDC/MA/21/000254 Silodosin 8 mg/8mg + Mirabegron 25 mg/50 mg tablets	M/s. Windlas	In light of earlier SEC recommendation dated 30.11.2021, the firm presented the BE study results before the committee. After detailed deliberation, the committee recommended for initiation of Phase III clinical trial study for which permission was already granted to the firm on 16.12.2021. The results of clinical trial should be presented before the committee.
Medical DeviceDivision			
7.	CI/MD/2018/4626 Condom	M/s. Ethicare Clinical Trial Services	The firm presented final clinical study report before the committee. After detailed deliberation, the committee recommended for approval of final

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			clinical study report.
Additional Proposal- New Drug Division			
8.	ND/MA/22/000105 Elagolix tablets 150mg and 200mg	M/s. Sun Pharma	The firm presented their proposal to manufacture and market the drug Elagolix 150 mg and 200mg tablets by conducting Phase-III clinical trial in the county. After detailed deliberation, the committee recommended to conduct Phase III clinical trial for test arm 1(Elagolix 150 mg tablets) by monitoring Bone marrow density for 06 months and with the follow up of serum estrogen level of the subjects. Further, the committee raised safety concern with subjects at higher doses and did not consider the request to conduct Phase III study with test arm 2(Elagolix 200mg Tablets) Accordingly, revised protocol to be submitted to CDSCO.