Recommendations of the SEC (Reproductive &Urology) made in its 67th meeting held on 27.01.2022 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/20/000088 Topiroxostat Tablets 20mg/40mg and 60mg	M/s. Precise Biopharma Pvt. Ltd.	In light of earlier recommendation of SEC dated 16.06.2020, the firm presented the Phase III CT report before the Committee. After detailed deliberation, the Committee recommended for grant of permission to manufacture and market Topiroxostat 20 mg/40 mg and 60 mg tablets.
Biological Division			
2.	BIO/CT04/FF/2021/28604 Follicle Stimulating Hormone (Human Recombinationt) 900 IU	M/s. Veeda Clinical Research Limited	The firm presented the proposal for conduct of (PK-PD) study in the country for generation of data for export registration. The Committee noted that the drug is already approved in the country. After detailed deliberation, the Committee recommended for grant of permission for conduct of the study as per the protocol presented.
SND Division			
3.	SND/MA/21/000542 Magnesium Sulphate Intravenous Infusion 4% w/v	M/s Precise Biopharma	The firm presented the proposal along with published data. The Committee noted that the proposed product is already available in USA. After detailed deliberation, the Committee recommended for grant of permission for manufacturing and marketing of Magnesium Sulphate Intravenous Infusion 4% w/v for IV use only.
4.	SND/CT/21/000095 Flavoxate HCl controlled release tablet 600mg	M/s Martin and Harris	The firm presented the BE study protocol of Flavoxate HCl controlled release tablet 600mg before the Committee for approval. After detailed deliberation, the Committee recommended for grant of permission for conduct of the BE study as per the protocol presented.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
5.	SND/IMP/21/000546 Tamsilosin HCl MR Capsules 400mcg	M/s Cipla Limited	The firm presented the proposal along with published data. The Committee noted that the proposed additional indication was not approved in any other country. After detailed deliberation, the Committee recommended that the firm should conduct Phase III clinical trial. Accordingly, the firm should submit the Phase III clinical trial protocol for review by the committee.
FDC Division			
6.	FDC/MA/21/000032 Dutasteride IP 0.5 mg + Silodosin 4mg Capsule	M/s Akums Drug and Pharmaceuticals Ltd.	In light of the earlier SEC recommendations dated 26.08.2021, the firm presented active PMS report on higher strength. After detailed deliberation, the Committee recommended for grant of permission for manufacturing and marketing of proposed strength with condition to conduct the Active PMS study as below: 1. Qualified urologists shall be included in the study as a Principal investigator. 2. Adverse effect of Silodosin as well as Dutasteride should be recorded during the study.