Recommendations of the SEC (Reproductive & Urology) made in its 71st meeting held on 24.06.2022 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/22/000119 Clotrimazole vaginal Film 50 mg	M/s Hetero Healthcare Limited	The firm did not turn up for presentation.
2.	12-109/2017-DC (Pt-Akums-SND) Febuxostat ER Tablet 40/80mg	M/s. Akums	The firm submitted proposal for manufacturing and marketing of Febuxostat ER Tablet 40/80mg along with the results of BE study conducted in fasting and fed conditions. Committee noted the results of the BE study. After detailed deliberation, the committee recommended to conduct phase III clinical trial , accordingly protocol should be submitted to CDSCO for further review by the committee.
FDC Division			
3.	FDC/MA/20/000162 Silodosin 8mg/8mg + Mirabegron (SR) 25mg/50mg tablets	M/s. Mascot	The firm presented their proposal along with BE & CT study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE and CT study with following condition: 1. Criteria of ultrasound and uroflometry should be included. 2. Endoscopy should not be done at base line. 3. All urothelial cancer should be in the exclusion criteria. Accordingly, revised CT protocol and results of BE study be submitted before initiating CT study.
4.	FDC/MA/20/000099 Solifenacin Succinate IP 5mg/5mg + Mirabegron (ER)25mg/50mg tablets	M/s. Pure & Cure	The firm was granted permission on 16.07.2021 with condition to conduct the Phase IV CT study. Accordingly, the firm presented their proposal along with Phase IV CT protocol before the committee. After detailed deliberation, the committee

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
			recommended for grant of permission to conduct the proposed Phase IV CT study on minimum 200 subjects.
5.	04-01/2019-DC(Misc. 53) Aceclofenac100mg + Drotaverine Hydrochloride80mg	M/s. Mapra	The firm did not turn up for the presentation.
GCT Division			
6.	CT/129/21 Online Submission (17406) Human Recombinant (r-hFSH) 900 IU (66.0 µg)/1.5 mL Solution	M/s. Bharat Serum	The firm presented Phase –III Clinical Trial Protocol amendment version 02 dated 02-March-2022 before the committee. After detailed deliberation, the committee recommended to grant approval for the clinical trial protocol amendment.