

Recommendations of the SEC (Reproductive and Urology) made in its 66th meeting held on 24.12.2021 at CDSCO HQ, New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/20/000008 Topiroxostat tablets 20mg, 40mg and 60mg	M/s. Precise Bio Pharma Pvt.Ltd.	<p>The firm presented their Phase III CT report before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should submit the following:</p> <ol style="list-style-type: none"> 1. PMS safety data from the country of origin along with the published literature. 2. Chronological analysis of side effects of the drug in their study w.r.t dosage 20mg b.d vs 40mg b.d vs 60mg b.d. <p>Accordingly, the firm should submit the above information/documents to CDSCO for further review by the committee.</p>
SND Division			
2.	SND/IMP/21/000007 Testosterone Gel 1.62% w/w (pump pack containing 1.62% w/w testosterone	M/s. Besins Healthcare	<p>In light of recommendations of the earlier committee meeting held on 29.07.2021 the firm presented pharmacokinetic data of the drug product.</p> <p>After detailed deliberation, the committee recommended for grant of permission for import and marketing of Testosterone Gel 1.62% w/w (pump pack containing 1.62% w/w testosterone indicated in adults as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by the clinical features and biochemical tests.</p>
FDC Division			
3.	FDC/MA/21/000273 Vitamin D3 3000IU +Folic acid 4.5 mg +Dehydroepiandroster one 75 mg film coated tablets	M/s. Synokem Pharmaceuticals Ltd	The firm did not turn up for presentation.
4.	FDC/CT/20/000085 Metronidazole + Miconazole Nitrate (500mg+100mg) Suppositories	ICBio Clinical Research Pvt. Ltd	<p>In light of earlier SEC recommendations, the firm presented their proposal.</p> <p>The committee noted that the firm did not address any of the concerns raised by the committee. The committee also opined that the firm needs to present the rationale for presenting Metronidazole in vaginal suppository form.</p>

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			In view of above, the committee recommended that the firm should make a detailed presentation addressing all the points raised by the committee.
GCT Division			
5.	CT/129/21 Online Submission (28392) Human Recombinant (r-hFSH)900 IU (66.0 µg)/1.5 ml Solution for Injection	M/s. Bharat Serum	<p>The firm presented their Phase III Global CT Protocol for Foligraf® 900 IU (66.0 µg) / 1.5mL Solution for Injection in Prefilled Pen [Follicle Stimulating Hormone (Human Recombinant) before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study.</p>