

**Recommendations of the SEC (Reproductive) made in its 01<sup>st</sup>/25 meeting held on 15.01.25 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drugs Division</b>			
1.	ND/CT/24/000089 Elagolix Tablets 150mg/200mg	M/s Sun Pharmaceuticals Industries Limited.	In line with the condition of the permission for the manufacturing and marketing of the drug Elagolix Tablets 150mg/200mg, the firm presented Phase IV clinical trial protocol for drug Elagolix Tablets 200mg before the committee.  After detailed deliberation, the committee recommended for the grant of permission to conduct Phase IV clinical trial as per protocol presented.  The result of the Phase IV CT study should be presented before SEC for further review by the committee.
<b>SND Division</b>			
2.	SND/MA/22/000203 Estradiol Vaginal Inserts USP 4mcg and 10 mcg	M/s West-Coast Pharmaceutical Works Limited	The firm did not turn up for presentation.
3.	SND/MA/22/000168 Estradiol vaginal cream 0.01%	M/s West-Coast Pharmaceutical Works Limited	The firm did not turn up for presentation.