

**Recommendations of the SEC (Reproductive) made in its 02<sup>nd</sup>/25 meeting held on 18.02.2025. at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>Biological Division</b>			
1.	BIO/CT18/FF/2024/46051  Follitropin Delta Solution for Injection in a prefilled pen 12mcg per 0.36ml,36mcg per 1.08ml and 72mcg per 2.16ml	M/s Ferring Pharmaceuticals Pvt. Ltd	The firm presented the proposal for grant of permission to import and market the drug product Follitropin Delta Solution for Injection in a prefilled pen 12mcg per 0.36ml,36mcg per 1.08ml and 72mcg per 2.16ml for the indication i.e. “Controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies (ART) such as an in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) cycle” based on the results of the Phase III clinical studies conducted in India.  The committee noted that the drug is approved in 78 countries including Europe, Australia, Japan, Korea., etc After detailed deliberation, the committee recommended for the grant of permission to import and market the drug product Follitropin Delta Solution for Injection in a prefilled pen 12mcg per 0.36ml, 36mcg per 1.08ml and 72mcg per 2.16ml for the proposed indication with the condition to conduct Active PMS study in the country. Accordingly, the firm should submit the active PMS study protocol to CDSCO within three months of grant of marketing authorization
<b>SND Division</b>			
2.	SND/MA/22/000203  Estradiol Vaginal Inserts USP 4mcg and 10 mcg	M/s West-Coast Pharmaceutical Works Limited	Under Discussion
3.	SND/MA/22/000168  Estradiol vaginal cream 0.01%	M/s West-Coast Pharmaceutical Works Limited	Under Discussion