

Recommendations of the SEC (Reproductive) made in its 10th meeting held on 05.11.2024 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	r-DNA-11011/1/2024-e-office Follicle Stimulating Hormone Injection I.P. 300IU and 600IU	M/s Organon India Pvt. Ltd.	The firm did not turn up for the presentation
SND Division			
2.	SND/MA/23/000140 Dydrogesterone Modified Release Tablet 20mg	M/s. Abbott India Limited	Under Discussion.
FDC Division			
3.	FDC/MA/24/000228 Dehydroepiandrosterone 75 mg (MR) + Melatonin 3 mg + Ubidecarenone (Coenzyme Q10) 100 mg Soft Gelatin Capsule	M/s Sun Pharma Laboratories Limited	<p>The firm presented the proposal before the committee.</p> <p>The committee noted that CDSCO has not approved dehydroepiandrosterone 75mg (MR). Further, the three molecules of the proposed FDC, individually or in combination, are not approved for the indication, i.e., treatment of diminished ovarian reserve.</p> <p>After detailed deliberation, the committee opined that:</p> <ol style="list-style-type: none"> 1. The firm did not present rationality and justification from scientific literature in peer-reviewed journals or any proof of concept study w.r.t applied FDC for the proposed indication, i.e., for treating diminished ovarian reserve. 2. The proposed FDC is not approved internationally. 3. The firm did not present justification and supporting literature for the proposed indication (for the treatment of diminished ovarian reserve) of the FDC vis-a-vis approved indication of individual drugs of FDC. 4. The firm did not present any

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			<p>data/literature w.r.t Dosage compatibility, adverse event profile, and Drug-Drug-Interactions (known and/or expected) among the active ingredients in the FDC.</p> <p>5. There is no unmet need for the proposed FDC.</p> <p>Because of the above, the committee did not recommend the proposal for the proposed FDC.</p>