

Recommendations of the SEC (Reproductive) made in its 09th/24 meeting held on 23.10.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2024/44882 R-hFSH (Follitropin alfa) Solution for Injection 900 IU/ 1.44 mL	M/s Intas Pharmaceuticals Ltd.	<p>The firm presented the clinical study protocol to conduct Phase III clinical trial titled “A Randomized, Assessor-Blind, Active-Controlled, Parallel Group, Two-Arm, Phase-3 Study To Compare Safety, Efficacy and Immunogenicity of R-hFSH (Recombinant Human Follicle Stimulating Hormone (Follitropin Alfa) Injection of Intas Pharmaceuticals Ltd., With Recombinant Human Follicle Stimulating Hormone (r-hFSH) Follitropin Alfa (Gonal-F) of Merk Serono Ltd. in Adult Females Undergoing Assisted Reproductive Technology” vide Protocol no. 0232-4 Version 1.0 dated 17.07.2024.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial as per protocol presented by the firm with a condition to include more tertiary care centers and Government sites in the study.</p>
New Drugs Division			
2.	ND/MA/23/000129 Elagolix Tablets 150mg and 200mg	M/s Exemed Pharmaceuticals	<p>In the light of earlier recommendation dated 29.11.2023, the firm presented the BE study report of the drug Elagolix 200 mg tablets before the committee.</p> <p>After detailed deliberation, the committee considered the BE study result and recommended for market authorization of Elagolix tablet. The committee also noted that the said drug is approved by CDSCO on 09.08.2024.</p> <p>Further, the firm should conduct Phase IV clinical trial on Elagolix 150 mg and 200 mg tablets for which Phase IV clinical trial protocol should be submitted to the CDSCO within 3 months of approval for further deliberation before subject expert committee.</p>