

Recommendations of the SEC (Reproductive) made in its 04th/25 meeting held on 17.04.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/24/000249 Relugolix Tablets 40mg	M/s. Hetero Labs Limited	<p>Firm presented the proposal for grant of permission to manufacture and marketing of Relugolix Tablets 40mg along with Bioequivalence study Protocol no. BIOS/2024/249 version. 01 dated 05.12.2024 and CT Protocol no. HCR/III/RGEDNTEM/10/2024 version. 1.0 dated 30.10.2024 before the committee.</p> <p>Firm has informed that the formulation of Relugolix Tablets 40mg is approved in Japan.</p> <p>After detailed deliberation, the committee recommended to conduct BE study and Phase III clinical trial as per protocol presented by the firm with subject to condition that the firm should submit BE Study report to CDSCO and BE report should be evaluated from the committee before initiation of Phase-III clinical trial.</p>
FDC Division			
2.	FDC/MA/25/000049 Relugolix, 40mg + Estradiol 1mg + Norethindrone Acetate 0.5 Tablets.	M/s Hetero Labs Limited	<p>The firm presented the proposal along with BE study report and Phase III CT study protocol before the committee.</p> <p>After detailed deliberation, the committee considered BE study report based on BE NOC for export purpose.</p> <p>As regard to Phase III clinical trial protocol, the committee recommended for grant of permission to conduct the proposed Phase III clinical trial with the condition as mentioned below:</p> <ol style="list-style-type: none"> 1. Reproductive age group of female patients aged of 18-49 years should be mentioned in the inclusion criteria. 2. Firm should take Leuprolide acetate 3.75 mg IM injection followed by placebo tablet in comparator arm. <p>Accordingly, the revised phase III CT Protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Phase III</p>

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			CT report for further review by the committee