

Recommendations of the SEC (Oncology) made in its 10th/24 meeting held on 07.05.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	12-78/2010-DC Degarelix Injection	M/s. Ferring	The firm didn't turn up for presentation.
2.	ND/MA/23/000094 Erdafitinib Tablet 3mg, 4mg & 5mg	M/s. Natco Pharma Ltd.	<p>The firm presented the proposal for grant of permission to manufacture and market Erdafitinib tablets 3mg, 4mg and 5mg along with bioequivalence study data as well as Phase III clinical trial study waiver.</p> <p>After detailed deliberation, the committee did not recommend the waiver of Phase III clinical trial.</p> <p>Accordingly, the firm should submit the Phase III clinical trial protocol before the committee for further consideration.</p>
3.	ND/MA/22/000166 Relugolix Tablets 120 mg	M/s. Alkem Laboratories Ltd.	<p>In light of earlier recommendation dated 21.12.2023 & 22.12.2023, the firm presented the BE study report along with other documents:</p> <ol style="list-style-type: none"> 1. Justification/clarification regarding significant inter subject variability in presented BE study data. 2. Published PK/PD data 3. Data on ratio of serum to CSF concentration 4. Minimum effective concentration in CSF required for pharmacological action of proposed drug. <p>The committee noted that the drug is already approved in country on 16.10.2023.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market of drug Relugolix tablets 120mg with condition that the firm should conduct Phase IV clinical trial for which the protocol should be submitted within 3 months of</p>

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			approval of the drug for review by the committee.
GCT Division			
4.	CT/25/24 Online Submission (42032) ALT-803 (N-803)	M/s. CBCC Research Globa	<p>In light of earlier SEC recommendations dated 05.03.2024, wherein the firm presented Phase IIb clinical study protocol No. CA-ALT-803-01-14, QUILT-2.005 version 14 dated 15/Feb/2024 and the committee opined that more stratified data of adverse events including SAE along with causality assessment shall be submitted for further review by the committee.</p> <p>Now, the firm presented data as recommended by SEC in earlier meeting dated 05.03.2024.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm.</p>