

Recommendations of the SEC (Oncology) made in its 15th/25 meeting held on 06.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT21/BO/2024/46843 BIO/CT21/FF/2024/46877 Trastuzumab 150 mg/440 mg (PGS formulation)	M/s. Biocon Biologics Ltd	<p>The firm presented the proposal for grant of permission to manufacture and market Trastuzumab lyophilized powder for injection 150mg vial and 440 mg vial (PGS formulation) for the indications of Adjuvant breast cancer, Metastatic Breast Cancer and Metastatic Gastric Cancer based on the results of global clinical trial including Indian patients.</p> <p>The committee noted that Trastuzumab lyophilized powder for injection 150mg vial and 440 mg vial (PGS formulation) is approved in 90 countries including USA, EU, Canada, Australia, Singapore etc.</p> <p>The committee further noted that Trastuzumab 150 mg/440 mg (RPF formulations) is approved in India for domestic market and Trastuzumab 150 mg/440 mg (PGS formulation) is approved for export market.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market Trastuzumab lyophilized powder for injection 150mg vial and 440 mg vial (PGS formulation) with the condition to conduct PMS study in India.</p> <p>Accordingly, the firm shall submit the protocol to conduct PMS study within 03 months of approval.</p>