

Recommendations of the SEC (Oncology) made in its 35th/25 meeting held on 11.11.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2025/50 819 Tislelizumab Injections 100mg (10ml/Vial)	M/s. Glenmark Pharmaceuticals Ltd	<p>The firm presented the proposal to conduct Phase IV clinical trial titled "An Open Label, Phase IV, Single Arm, Multicentric, Prospective study to evaluate the safety and efficacy of Tislelizumab in patients with Esophageal Squamous Cell Carcinoma (ESCC) or Non-Small Cell Lung Cancer (NSCLC)" vide Protocol No. GPL TISLE-401, Version 1.0 dated 05-Jun-2025.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial as per the protocol presented by the firm, with the following revision:</p> <ul style="list-style-type: none"> • ECG and renal function tests shall be assessed at every 3-week visit. <p>Accordingly, the firm shall submit the revised protocol to CDSCO.</p>
2.	BIO/CT18/FF/2025/50 603 Dostarlimab concentrate for solution for infusion 500 mg/10mL (10ml Vial)	M/s. GSK Pharma India Private Limited	<p>The firm presented a proposal for grant of approval of additional indication of Dostarlimab concentrate for solution for infusion 500 mg/10mL (10ml Vial) in combination with carboplatin and paclitaxel for the first-line treatment of adult patients with primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy</p> <p>The committee noted that the subject drug is approved in India since April, 2023 as 2L monotherapy for the treatment of dMMR/MSI-H recurrent or advanced endometrial cancer (EC) and with respect to 1L treatment in proposed indication of endometrial cancer (EC) is currently approved in key countries including European Union, United States, United Kingdom, Canada and Australia. The committee further noted that despite high efficacy, early toxicity concerns were observed in the presented data which require close monitoring.</p> <p>After detailed deliberation, the committee</p>

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			<p>recommended for grant of approval for the proposed additional indication subject to the condition to conduct Phase IV clinical trial in the proposed indication in significant number of subjects.</p> <p>Accordingly, the protocol to conduct the Phase IV study shall be submitted to CDSCO within 3 months of grant of approval for the proposed indication.</p>
3.	<p>BIO/CT04/FF/2025/51788</p> <p>Pembrolizumab Injection 100 mg/ 4 mL (25 mg/mL in a single vial)</p>	M/s. Sun Pharmaceutical Industries Limited	<p>The firm presented the proposal for grant of permission to conduct Phase III clinical trial titled “A Prospective, Multicenter, Randomized, Parallel Group, Double-Blind, Comparative, Active-Controlled, Phase 3 Study to Evaluate the Efficacy, Safety, Pharmacokinetic and Immunogenicity of Intravenous Infusion of Pembrolizumab (Sun Pharmaceutical Industries Limited) in comparison with Reference Medicinal Product (Keytruda) in treatment of Patients with Non-Squamous Metastatic Non-Small Cell Lung Carcinoma” vide Protocol No. ICR/25/012, Version No. 1.0; Dated 17/JUL/2025.</p> <p>After detailed deliberation, the Committee recommended the grant of permission to conduct the Phase III clinical trial as per the presented protocol subject to the following conditions:</p> <ul style="list-style-type: none"> • The DSMB report for the first 15 subjects shall be presented before the SEC. • The statistical calculation defining the number of subjects in the PK study shall be provided to the CDSCO. <p>Accordingly, the firm shall submit the above to CDSCO for further evaluation.</p> <p>Note: <i>Dr. Kaushal Kalra did not participate in the deliberation.</i></p>
4.	<p>BIO/CT21/BO/2023/38170</p> <p>Cetuximab 100 mg/20 ml (r-DNA Origin) Solution for Intravenous Infusion in</p>	M/s. Enzene Biosciences Ltd	<p>In reference to the earlier SEC recommendation dated 09.01.2024 & 10.01.2024, firm has presented Phase-IV CSR dated 19.09.2025 for the study “A prospective, multicenter, Phase IV study to evaluate the safety and efficacy of biosimilar Cetuximab either alone or in</p>

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	vial		<p>combination with investigator choice chemotherapy/ radiotherapy in patients with loco regionally advanced or recurrent loco regional or metastatic squamous cell carcinoma of the head and neck (SCCHN).</p> <p>After detailed deliberation, the committee noted the results of referenced Phase-IV study and recommended for grant of approval for the proposed additional indications in-line with the Eu SmPC as per similar biologics guideline.</p> <ol style="list-style-type: none"> 1) Head and Neck cancer: Treatment of patients with squamous cell cancer of the head and neck in combination with radiation therapy for locally advanced disease. 2) Colorectal Cancer: Treatment of patients with epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer <ul style="list-style-type: none"> • in combination with Irinotecan-based chemotherapy • In first-line in combination with FOLFOX • As a single agent in patients who have failed oxaliplatin and irinotecan-based therapy and who are intolerant to irinotecan.