

Recommendations of the SEC (Oncology) made in its 29th/24 meeting held on 11.09.2025 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/17/22 Online Submission (40747) Durvalumab (MEDI4736) 500mg/Vial + Domvanalimab (AB154) 300 mg/ vial	M/s. AstraZeneca Pharma India Limited	The firm presented protocol amendment 6.0 dated 14 May2025 protocol no. D9075C00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/111/25 Online Submission (51145) PF-08046054	M/s. Pfizer Limited	The firm presented phase III clinical study protocol no. C5851005 final dated 28 May 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
3.	BIO/CT18/FF/2024/4 5080 Trastuzumab Deruxtecan100 mg Powder for Concentrate for Solution for Infusion	M/s. AstraZeneca Pharma India Limited	In light of earlier SEC recommendation dated 12.11.2024, the firm presented additional data of Trastuzumab Deruxtecan 100 mg Powder for Concentrate for Solution for Infusion with a request for waiver of local clinical trial. The committee noted that the proposed indication has been approved in countries including the USA, Canada, and Australia. After detailed deliberation, the committee recommended approval of the additional indication: “indicated for the treatment of adult patients with unresectable or metastatic HER2-positive (IHC3+) solid tumors who have received prior systemic treatment or who have no satisfactory alternative treatment options” with a condition to conduct Phase IV study in India. Accordingly, the firm shall submit the India specific Phase IV study protocol to CDSCO within 03 months of the grant of permission for this additional indication.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
4.	BIO/CT04/FF/2025/4 9869 Nivolumab Injection 100 mg/10mL vial	M/s. Enzene Biosciences Ltd	<p>The firm presented the proposal for grant of permission to conduct Phase III clinical trial titled “A phase III, prospective, multicenter, randomized, double blind, parallel group study to compare the efficacy and safety of proposed biosimilar Nivolumab versus innovator Nivolumab in patients with recurrent locoregional or metastatic squamous cell carcinoma of the head and neck (SCCHN) in adults progressing on or after platinum-based therapy” vide Protocol No. ALK43/ENZ132-NIVO1 Version 1.0, Dated 14/Feb/2025.</p> <p>After detailed deliberation, the committee recommended for the following changes in the proposed protocol:</p> <ol style="list-style-type: none"> 1. The DCR should be assessed at 12 week. 2. The non-inferiority margin used for sample size calculation should be narrowed. 3. The PK study should be adequately powered. 4. Long-term efficacy endpoints should be assessed for a minimum duration of 24 weeks. 5. The protocol should include provision for the reporting of safety data from the initial 20% of sample size. <p>Accordingly, the firm shall submit revised protocol for further evaluation by the SEC.</p>
5.	BIO/CT04/FF/2024/4 6815 Nivolumab 40mg/4mL, 100mg/ 10ml, 120 mg/12 mL and 240 mg/24 mL in vial, (10mg/ml)	M/s. Reliance Life Sciences Pvt. Ltd.	<p>In light of earlier recommendation of SEC (oncology) dated 20.03.2025, firm has presented the protocol to conduct a Phase I/III clinical trial titled “A Prospective, Multicenter, Randomized, Double-Blind, Parallel-Group, Two-Arm Comparative Phase I/III Clinical Study to Evaluate the Efficacy, Safety, Pharmacokinetics and Immunogenicity of R-TPR-067 (RLS-Nivolumab) and Opdivo®/ Opdyta® administered by intravenous route in Patients previously treated for Locally Advanced or Metastatic Non-Small Cell Lung Cancer vide Protocol No.: RLS/ONC/2024/05 Version 2.0 Dated 09</p>

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			Apr 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I/III clinical trial as per the protocol presented by the firm.
BA/BE Division			
6.	BABE/CT05/FF/2025 /47401 Lenalidomide TDS 8% -LLD-TDS-009 patch (50 cm ² with 81 cm ² overlay)	M/s. Raptim Research Pvt. Ltd.	In light of the earlier SEC recommendation dated 08/07/2025, the firm presented its justification for proposed clinical study before the committee. However, the data / justification presented were insufficient to establish safety & tolerability of proposed drug in the normal, healthy, adult male subject. After detailed deliberation, the committee again opined that firm should submit safety data of low strength Lenalidomide TDS 5% using Derma Roller technology before initiating higher strength Lenalidomide TDS 8% using Derma Roller technology in healthy human subjects. Accordingly, the firm should submit above data for further review by the committee.
SND Division			
7.	SND/MA/23/000061 Methotrexate Oral Solution 2mg/mL	M/s. Beta Drugs Ltd	In light of earlier SEC recommendation dated 02.04.2025, the firm presented BE study report in fed condition for grant of permission to manufacture and market Methotrexate Oral Solution 2mg/mL for proposed indications before the committee. The Committee noted that Methotrexate Oral Solution 2mg/ml approved in United Kingdom and various EU countries. After detailed deliberation, the Committee accepted the Fed BE study report and recommended for the grant of permission to manufacture and market Methotrexate Oral Solution 2mg/ml for

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			proposed indication.
8.	SND/MA/23/000028 Abiraterone Acetate Oral Suspension 1000mg/5ml	M/s. BDR Pharmaceuticals International Pvt Ltd	<p>In light of earlier SEC recommendation dated 15.05.2024, firm presented BE Fasting and Fed study reports of Abiraterone Acetate Oral Suspension 1000 mg/5ml Vs Abiraterone Tablets 500mg x 2) for grant of manufacturing & marketing of Abiraterone Acetate Oral Suspension 1000 mg/5ml in already approved indication for Tablets before the committee.</p> <p>After detailed deliberation, the committee recommended to accept BE Fasting and Fed study results and recommended for grant of permission to manufacture and market Abiraterone Acetate Oral Suspension 1000 mg/5ml for the applied indication subject to condition that firm should conduct Phase IV Clinical Trial in 400-500 subjects.</p> <p>Accordingly, firm should submit Phase IV Clinical Trial protocol within 3 months from the date of approval of the product to CDSCO for further review by the committee.</p>