

Recommendations of the SEC (Oncology) made in its 06th/26 meeting held on 25.02.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/185/25 Online Submission (53836) Rilvegostomig (AZD2936) Concentrate for solution for infusion 50 mg/mL (750 mg/vial) Durvalumab (MEDI4736) Concentrate for solution for infusion 50 mg/mL (500 mg/vial)	M/s. AstraZeneca Pharma India Limited	The firm presented phase III clinical study protocol no. D702NC00001, version no. 1.0 dated 08 August 2025 and Local CSP Addendum 1.0 India, Version 1.0 dated 07 Oct 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the more geographically distributed government site shall be included in the study. Dr. Kaushal Kalra didn't participate in the discussion.
2.	CT/186/25 Online Submission (53887) Trastuzumabderuxtecan (T-DXd; DS-8201a) Powder for concentrate for solution for infusion 100 mg/vial Rilvegostomig (AZD2936) Concentrate for solution for infusion 50 mg/mL (750 mg/vial)	M/s. AstraZeneca Pharma India Limited	The firm presented phase III clinical study protocol no. D7815C00001, version no. 1.0 dated 11 August 2025 (Master) and sub-study 1, version 1.0 dated 11 August 2025 and Local CSP Addendum 1.0 India, Version 1.0 dated 16 Sep 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
3.	E-93432 Durvalumab Solution for Infusion 500 mg/10 mL and 120 mg/2.4mL	M/s. AstraZeneca Pharma India Limited	In reference to earlier SEC meeting dated 09.01.2025; the committee had recommended for grant of approval of additional indication where "Durvalumab is indicated for the treatment of patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemo radiation therapy (CRT)" and accordingly on 07.03.2025 subject approval was granted with the condition to conduct Phase IV clinical trial in India. Now, firm has presented their proposal for the waiver of Phase-IV condition in the NOC for additional indication dated 06.03.2025. The committee noted the status of global

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			<p>& India specific Phase-IV & PSUR for all the approved indications of the subject drug.</p> <p>After detailed deliberation, the committee reiterated its earlier recommendation to conduct a Phase IV clinical trial in order to generate additional safety data in the Indian population</p> <p>Accordingly, the protocol to conduct the Phase IV study shall be submitted to CDSCO as per the condition mentioned in the NOC for additional indication dated 06.03.2025.</p>
4.	<p>BIO/CT04/FF/2025/50535</p> <p>Pembrolizumab Concentrate for Solution for Infusion 100 mg /4 mL Vial (25 mg/mL).</p>	<p>M/s. Intas Pharmaceuticals Ltd.</p>	<p>The firm presented the proposal for grant of permission to conduct a Phase I/III clinical trial titled, “A Randomized, Double-Blind, Active-Controlled, Parallel, Three Arm, Multicentre Study Comparing Pharmacokinetics, Efficacy, Safety and Immunogenicity of INT58 and Keytruda, both Administered in Combination with Platinum – Pemetrexed Chemotherapy for the First-Line Treatment in Patients with Metastatic Non-Squamous Non-Small Cell Lung Cancer vide Protocol No.: 0265-24, Version No.: 1.0, Dated 20-Jun-2025 meant for USFDA and EMA submission only”</p> <p>The proposal of firm was earlier discussed in SEC (Oncology) dated 16.10.2025, wherein committee has made certain recommendations.</p> <p>The committee noted that the subject study has been approved by USFDA for export consideration.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct Phase I/III clinical trial as per the protocol presented by the firm subject to following conditions:</p> <ol style="list-style-type: none"> 1. All PIs shall be Medical Oncologist. 2. Day care facilities & Nursing Homes shall not be used as a clinical trial site.

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			<p>3. Clinical trial sites shall be geographically distributed.</p> <p>4. Number of patients shall be proportionate between government and private clinical trial sites.</p> <p>5. Post-trial access of the study drug shall be provided to the subjects till disease progression.</p> <p>6. Data generated on the basis of subject study is for registration in foreign country and shall not be claimed for registration in India.</p>
SND Division			
5.	<p>SND/MA/24/000251</p> <p>Enzalutamide oral solution 160mg/6ml</p>	<p>M/s. Ferring Pharmaceuticals Pvt. Ltd</p>	<p>In the light of earlier SEC recommendations dated 04.11.2025, firm presented the proposal for grant of permission to manufacture and market of Enzalutamide oral solution 160mg/6ml along with results of BE study conducted in fasting and fed conditions.</p> <p>The Committee noted that revised prescribing information of Enzalutamide 40mg soft Capsule of M/s.Astellas Pharma India Pvt. Ltd is considered in the SEC (Oncology) meeting dated 07.01.2026.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Enzalutamide Oral Solution (160mg/6ml) for already approved Indications i.e.</p> <ol style="list-style-type: none"> 1) In the treatment of adult men with metastatic castration resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. 2) For the treatment of adults with metastatic castration resistant prostate cancer (mCRPC) whose disease has progressed on or after

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			Docetaxel therapy.
6.	SND/MA/25/000264 Ondansetron Extended Release Injectable Suspension 100 mg/ 1 mL	M/s. Shilpa Medicare Limited	Under Discussion
FDC Division			
7.	FDC/IMP/22/000028 Valine 5.2gm+Serine 6gm+Aspartic acid 3gm+ Alanine 9.7gm+Sodium acetate trihydrate 1.088gm+LysineHCl 5.68gm+Potassium acetate 5.886gm+Tryptophan 1.14gm+Glycine 3.3gm+Magnesium acetate tetrahydrate 1.288gm+Isoleucine 4.68gm+Arginine 5.4gm+Phenylalanine 7.02gm+ Threonine 3.64gm+Methionine 3.92gm+Histidine 3.38gm+sodium dihydrogen phosphate dihydrate 2.34gm+sodium hydroxide 1.6gm+Proline 6.8gm+Glutamic acid 7gm+Leucine 6.26gm+sodium chloride 2.162gm+zinc acetate dehydrate 0.0132gm+medium chain triglycerides 100gm+calcium chloride dehydrate 0.8820gm+soya-bean oil, refined 100gm+Glucose monohydrate 176gm Parenteral preparations	M/s. B.Braun Medical India Pvt Limited	<p>The firm presented the proposal before the committee.</p> <p>Committee noted that the firm is already holding Registration Certificate for Import of Drug in India Under Drugs and Cosmetics Rules 1945 with the condition that “Firm shall submit “NOC”/ Regularisation permission for the product Nutriflex Lipid Peri.”</p> <p>Firm stated that the product is already approved in Brazil, EU Region, China, etc.</p> <p>After detailed deliberation, the committee recommended that the product should not be used in oncology patients due to lack of credible scientific data.</p> <p>Further, the firm should submit the Phase IV Clinical trial protocol with internationally (ICH region) approved indication to CDSCO for further review by the committee.</p>

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8.	FDC/IMP/22/000031 Sodium acetate trihydrate 3.27gm+ magnesium chloride hexahydrate 0.2gm+Sodium Chloride5.55gm+Succinylated gelatine 40gm+Potassium Chloride 0.3gm+Calcium Chloride dehydrate 0.15gm Parenteral Preparations	M/s. B.Braun Medical India Pvt Limited	<p>The firm presented the proposal before the committee.</p> <p>Committee noted that the firm is already holding Registration Certificate for Import of Drug in India Under Drugs and Cosmetics Rules 1945 with the condition that “New drug import permission for Gelaspan 4% solution shall be submitted”</p> <p>Firm stated that the product is already approved in United Kingdom, EU Region, Singapore, etc.</p> <p>After detailed deliberation, the committee recommended that the firm should submit the Phase IV Clinical trial protocol with internationally (ICH region) approved indication to CDSCO for further review by the committee.</p>