Recommendations of the SEC (Oncology) made in its 05th/26 meeting held on 11.02.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/93/25 Online Submission (50656) Sacituzumab tirumotecan	M/s MSD Pharmaceuticals Private Limited	In light of earlier SEC Recommendation dated 28.08.2025, the firm presented phase III clinical study protocol no. MK2870-032, version no. 00 dated 18 Feb 2025. Now the firm presented 1. Control arm is not the Standard of care, need rationale for that. 2. The proposed sample size of only 60 patients represents less than 3% of the global study population (N=2400). This appears relatively small and may limit the result findings at our population. It is therefore recommended that the sample size be increased to ensure adequate representation and statistical reliability. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1) Increase the Number of subjects from India. 2) More geographically distributed government site shall be included in the study. 3) Day care center should not be a part of clinical trial.
Biological Division			
2.	E-70438 Atezolizumab Injection 1200 mg/20 ml & 840 mg/14 ml vials [Tecentriq®]	M/s. Roche products India Pvt. Ltd.	The firm presented the proposal for update in the Package Insert Version 32.0 of Atezolizumab Injection 1200 mg/20 mL & 840 mg/14 mL vials [Tecentriq®]. The proposed update included revisions to Section 2.4.1 (General) under Section 2.4 – Warnings and Precautions and Section 2.6.1 – Clinical Trials under Section 2.6 – Undesirable Effects, based on the updated Company Core Data Sheet (CCDS), analysis of clinical trial data, published literature and post-marketing safety data, including Drug Safety Reports (DSRs). After detailed deliberation, the committee recommended approval of the updated Package Insert Version 32.0 dated Nov 2025 incorporating the proposed changes.

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3.	BIO/CT04/FF/2025/ 49114 Nivolumab Concentrate for Solution for Infusion 100 mg/10 mL Vial	M/s Intas Pharmaceuticals Ltd.	In light of earlier recommendation of SEC (Oncology) dated 29.07.2025, the firm presented revised protocol to conduct a Phase I/III clinical trial titled "A Phase 1/3, Randomized, Multicentre, Assessor-Blind, Two-Arm, Parallel-Group, Comparative Clinical study to Investigate the efficacy, Immunogenicity, Safety and Pharmacokinetics of Intas Nivolumab Versus Reference Nivolumab in Patients with Previously Treated Locally Advanced or Metastatic Non-Small Cell Lung Cancer" as per Protocol No. 0139, Version 2.0 dated. 02.09.2025. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I/III clinical trial as per the presented protocol subject to following conditions**:** 1. All PIs should be Medical Oncologist. 2. Day care facilities should not be used as a clinical trial site 3. Clinical trial sites should be geographically distributed. 4. Number of patients shall be proportionate between government and private clinical trial sites. 5. Post-trial access of the study drug shall be provided to the subjects until disease progression.
New Drug Division			
4.	ND/CT/25/000068 Zanubrutinib capsules 80 mg	M/s Glenmark Pharmaceuticals Ltd	In light of earlier recommendations dated 25.08.2025, the firm has submitted revised Phase-IV CT study protocol of Zanubrutinib capsules 80 mg (Protocol Number: GPL ZANU-401, Version 2.0 Dated 29-Dec-2025) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase IV clinical trial as per the protocol presented by the firm. The firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.

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5.	ND/CT/25/000126 Erdafitinib Tablets 3 mg, 4 mg and 5 mg	M/s Natco Pharma Limited	In line with the condition of manufacturing and marketing permission granted to the firm for drug, Erdafitinib Tablets 3 mg, 4 mg and 5 mg, the firm presented Phase IV clinical trial protocol of drug Erdafitinib Tablets 3mg, 4mg, and 5mg (Protocol No.: ERDANAT4, Version No.: 1.0, Dated: 15.12.2025), before the committee. After detailed deliberation, committee recommended for grant of permission to conduct Phase IV Clinical Trial subject to the condition that- 1. The firm should increase the sample size with at least 60 patients in the proposed study. 2. The firm should submit validation documents for the test for FGFR3 to be carried out at central lab to CDSCO.
SND Division			
6.	SND/CT21/FF/2023/38264 SND/CT21/FF/2023/38264 Ibrutinib Tablet 140 mg, 280 mg, 420 mg & 560 mg tablets	M/s Natco Pharma Limited	Under Discussion
FDC Division			
7.	FDC/IMP/22/000026 Modified Fluid Gelatin 4 gm + Sodium Hydroxide 0.1360 gm + Sodium Chloride 0.7010 gm Parenteral Preparations	M/s. B. Braun Medical India Pvt Limited	The firm presented the proposal before the committee. 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 Regularisation permission of the product Gelofusine (Modified fluid Gelatin) 500 ml in due course of time." Firm stated that the product is already approved in United Kingdom, EU Region, Australia, etc. After detailed deliberation, the committee recommended that the firm should submit the Phase IV Clinical trial protocol with internationally approved indication to

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8.	FDC/IMP/22/000027 Tryptophan 2 gm+ Threonine 6.35 gm+ Aspartic acid 5.25 gm+ Zinc acetate dehydrate 0.0176 gm+ Histidine HCl 9.45 gm+ Glucose monohydrate 396 gm+ Sodium dihydrogen Phosphate dehydrate 6.24 gm+ Serine 10.5 gm+ Magnesium acetate tetrahydrate 2.2740 gm+ Glutamic acid +12.27 gm+ Tyrosine 0.0 gm+ Proline 11.9 gm+ Glycine 16.98 gm+ Alanine 16.98 gm+ Lysine hydrochloride 9.95 gm+ Soya-bean oil 80 gm+ Omega-3 acid triglycerides 20 gm + Arginine 9.45 gm + Sodium acetate trihydrate 0.9460 gm + Sodium hydroxide 2.9280 gm + Sodium chloride 0.9460 gm+ isoleucine 8.21 gm + Medium chain triglycerides 100 gm+ Potassium acetate 9.2220 gm+ Phenylalanine 12.29 gm+ Methionine 6.84 gm+Calcium chloride dehydrate 1.558 gm+Valine 2 gm+Leucine 10.96 gm Parenteral preparation	M/s. B. Braun Medical India Pvt Limited	The firm presented the proposal before the committee. 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 Omega Special." Firm stated that the product is already approved in United Kingdom, EU Region, Singapore, etc. After detailed deliberation, the committee recommended that the product should not be used in cancer patients due to lack of credible scientific data. Further, the firm should submit the Phase IV Clinical trial protocol with internationally approved indication to CDSCO for further review by the committee.