Recommendations of the SEC (Oncology) made in its 19th/26 meeting held on 21.07.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/94/26 Online Submission (57720) PF-08634404, 20mg/ml, Concentrate for solution for Infusion.	M/s. Pfizer Limited.	The firm presented phase III clinical study protocol no.: C6461018 Final Protocol Amendment 2 dated 04- JUN- 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. The sample size shall be increased to minimum 40 from India. 2. More government sites shall be includ ed in the study.
2.	CT/91/26 Online Submission (57624) Mocertatug Rezetecan (GSK5733584)	M/s. GSK Pharma India Private Limited.	The firm presented phase III clinical study protocol no.: 224040 version no. 1 Finaldated 19-MAY-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. Dr. Kaushal Kalra did not participate in the discussion.
Biological Division			
3.	BIO/CT18/FF/2026/55003 Daratumumab 1800 mg (120 mg/mL) solution for SC injection (r-DNA origin) (DARZALEX Faspro).	M/s. Johnson & Johnson Pvt. Ltd.	The firm presented the proposal for grant of permission to import and market Daratumumab 1800 mg (120 mg/mL) solution for SC injection (r-DNA origin) (DARZALEX Faspro) for the following additional indication; "In combination with bortezomib, lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma but who are INELIGIBLE for autologous stem cell transplant." The proposal was presented which includedresults from a Phase 3 Global Clinical Trial conducted comparing Daratumumab, Bortezomib, Lenalidomide, and Dexamethasone (D-VRd) with Bortezomib, Lenalidomide and Dexamethasone (VRd) in Subjects with Untreated Multiple Myeloma and for Whom

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			Hematopoietic Stem Cell Transplant was Not Planned as Initial Therapy. After detailed deliberation, the committee recommended the grant of permission to import and market Daratumumab 1800 mg (120 mg/mL) solution for SC injection (r-DNA origin) with a waiver of the local Phase III clinical trial under the provisions of Rule 101 of the New Drugs and Clinical Trials Rules, 2019,for the following indication; "In combination with bortezomib, lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma but who are INELIGIBLE for autologous stem cell transplant." Subject to the condition that the firm shall conduct a Phase IV clinical trial in the Indian population with Daratumumab 1800 mg (120 mg/mL) solution for SC injection. Accordingly, the firm shall submit Phase IVClinical Trial protocol to CDSCO within 03 months of grant of marketing authorization permission.
4.	BIO/CT18/FF/2026/55205 Pembrolizumab Injection 100 mg/4 ml (25 mg/ml solution in a single vial).	M/s. MSD Pharmaceutical Private Limited.	The firm presented thePhase III Clinical Study Report of CSR Identification-P689V01MK3475 for grant of additional Indication of Squamous Cell Carcinoma of Head and Neck which was conducted at 192 centers in 24 countries excluding Indian Patients. After detailed deliberation, the committee recommended for grant ofpermission for the following additional indication-"Pembrolizumab as monotherapy is indicated for the treatment of resectable locally advanced head and neck squamous cell carcinoma as neoadjuvant treatment, continued as adjuvant treatment in combination with radiation therapy with or without concomitant cisplatin and then as monotherapy in adults whose tumours express PD-L1 with a CPS ≥1". Subject to conduct of Post Marketing Surveillance Study.

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New Drug Division			
5.	ND-11011(13)/1/2026-eoffice Vorasidenib Tablets 10mg and 40mg	M/s. Seriver India Private Limited.	The Firm did not attend the meeting.
6.	ND/MA/26/000039 Momelotinib Tablets 100 mg, 150 mg and 200mg.	M/s. Glaxosmithkline Pharmaceuticals Limited.	The firm presented the proposal for grant of permission for import and marketing of the drug, Momelotinib Tablets 100 mg, 150mg and 200mg along with justification for local Phase III Clinical Trial waiver, before the committee. The committee noted that the drug is approved in USA, EU, Canada, Australia, Japan and other countries. The committee also noted that there is unmet medical need for the proposed indication (i.e. treatment of disease-related splenomegaly or symptoms in adult patients with moderate to severe anaemia who have primary myelofibrosis, post polycythaemiaveramyelofibrosis or post essential thrombocythaemiamyelofibrosis and who are Janus Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib), in the country. Further, the committee reviewed the justification presented by the firm regarding no ethnic variability. The committee also reviewed India specific package insert. After detailed deliberation, the committee recommended for the grant of permission for the import and marketing of the drug, Momelotinib Tablets 100 mg, 150mg and 200mg with the condition that: 1. The firm should conduct Phase IV clinical trial for which the protocol should be submitted within 3 months of approval of the drug for review by the committee. 2. Drug to be sold by retail under the prescription of Medical oncologist and Hematologist only.

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SND Division			
7.	SND/CT18/FF/2025/53616 Olaparib tablets 100 and 150 mg.	M/s. AstraZeneca Pharma India Limited.	The firm presented their proposal for amendment of already approved indication of Olaparib tablets 100 and 150 mg to update the indication in line with EMA approved indication. The committee noted that the applied indication is approved in EMA and firm is also conducting Phase IV CT. After detailed deliberation, the committee recommended amendment in already approved indication of Olaparib tablets 100 and 150 mg to update the indication in line with EMA approval.
8.	SND/MA/26/000076 Niraparib Tablets 100 mg, 200mg, 300mg.	M/s. Sun Pharmaceutical Industries Limited.	Firm presented proposal for manufacturing & marketing of Niraparib Tablets 100mg/200mg/300mg along with BE study report and request for Phase-III Clinical Trial waiver and proposal to conduct post marketing Phase-IV clinical study, before the committee. The committee noted that Niraparib Tablet 100mg is approved in India and 100mg/200mg/300mg tablets are approved in USA. As per approved posology, the recommended dose is 200mg taken orally once daily and 300mg for patients weighing ≥77 kg AND a platelet count ≥150,000/mcL. After detailed deliberation, the committee recommended grant of permission to manufacture & marketing of Niraparib Tablets 100mg/200mg/300mg along with Phase-III Clinical Trial waiver with condition to conduct post marketing Phase-IV clinical study.