Recommendations of the SEC (Oncology) made in its 15th/26 meeting held on 09.06.2026 at CDSCO HQ New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/05/25 Online Submission (47379) CT-P44 (Daratumumab)	M/s. IQVIA RDS (India) Private Limited.	In light of earlier SEC recommendation dated 07.04.2026, the firm presented phase I/III clinical study protocol no.: CT-P44 3.1 version no. 1.0 dated 21-OCT-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition. 1) PI/CO-PI shall be Medical Oncologist or Clinical Hematologist. 2) Day care of center should not be a part of clinical trial.
2.	CT/178/25 Online Submission (53049) JBI-802	M/s. Jubilant Therapeutics India Limited.	The firm presented phase I/II clinical trial protocol no. JBI-802-102 version no. 5.0 dated 24-OCT-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition. 1. Prior thromboembolic events and their resolution/status should be including in the inclusion criteria and response assessment criteria. 2. The frequency and timing of bone marrow examination should be clearly defined in the protocol. 3. Interim safety analysis should be made available after Six month of trial and same submitted to CDSCO. 4. The sponsor should provide Post Trial Access of the IMP to eligible participant after completion of the trial.
3.	CT/05/26 Online Submission (54097) BMS 986504	M/s. Bristol-Myers Squibb India Pvt. Ltd.	In light of earlier SEC recommendation dated 26.02.2026, the firm presented phase II/III clinical study protocol no.: CA2400029 amendment 01 dated 24-JUN-2025. After detailed deliberation, the committee recommended for grant of permission to

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			conduct the trial as presented by the firm
4.	CT/66/26 Online Submission (56598) Velzatinib/IDRX-42(GSK6042981)	M/s. GSK Pharma India Private Limited.	The firm presented phase III clinical study protocol no. 306293 version no. 1 final dated 23-MAR-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
5.	CT/67/26 Online Submission (56633) PF-08634404, 20 mg per ml, Concentrate for solution for infusion	M/s. Pfizer Limited.	The firm presented phase II clinical study protocol no. C6461010 Amendment 1 dated 16-MAR-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
New Drug Division			
6.	ND/MA/26/000020 Elacestrant Tablets 86 mg & 345 mg	M/s. BDR Pharmaceuticals International Pvt. Ltd.	The firm presented their proposal for grant of permission to manufacture and market of drug Elacestrant Tablets 86 mg & 345 mg along with BE study reports under Fed condition (SLS-BE-0012-25-ELAC; Ver.: 01 dated 16.02.26) and justification for Phase-III Clinical Trial waiver, before the committee. The Committee considered BE study results. Further, the committee noted that firm has presented the published study data of Asian patients only but not patients from South Asian region including India specifically. The committee opinioned that there is lack of sufficient efficacy and safety data to prove that there is no substantial ethnic variability. Thus, dose titration on drug in Indian population is required. After detailed deliberation, the committee did not agreed for Phase-III CT waiver and recommended that firm should conduct Phase III clinical trial of applied drug in Indian population. Accordingly, firm should submit Phase III clinical Trial protocol to CDSCO for further review by the committee.

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SND Division			
7.	SND/11011/15/2026-eoffice Trametinib Tablets 0.5 mg and 2 mg	M/s. Novartis Healthcare Pvt. Ltd.	The firm did not attend the meeting.
8.	SND/CT18/FF/2026/54173 SND/IMP/26/000007 Zanubrutinib Tablets 160 mg	M/s. Glenmark Pharmaceuticals Ltd.	The firm presented their proposal for import and marketing of Zanubrutinib Tablets 160 mg in already approved indication along with BE study reports in fasting and fed condition and request for local CT wavier. The committee noted that Zanubrutinib Capsules 80 mg is approved in the country on 08.04.2025 in the applied indication and as per approved posology, 320 mg is given in two divided doses i.e. 2 x 80 mg capsules each time. The drug is also approved in USA in same posology. The additional dosage form of 160 mg will reduce the pill burden. After detailed deliberation, the committee accepted the bioequivalence study reports and recommended for grant of permission for import and marketing of Zanubrutinib Tablets 160 mg in the already approved indication along with CT waiver.