

Recommendations of the SEC (Oncology) made in its 20th/24 meeting held on 08.10.2024 & 09.10.2024 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/40/24 Online Submission (42322) Pembrolizumab (BAT3306)	M/s. IQVIA RDS (India) Private Limited	In light of earlier SEC recommendation on 03.04.2024 and 04.04.2024, The firm presented phase I/III clinical study protocol no:BAT-3306-002-CR, Version: 1.0, dated 19 Dec 2023. After detailed deliberation, the committee opined that the firm should submit preclinical study data in animal, Phase-I complete study data including all pharmacokinetic and immunogenicity data for further review by the committee.
2.	CT/47/24 Online Submission (42604) AZD0901 Powder for Solution for infusion	M/s. AstraZeneca	In light of earlier SEC recommendation on 02.05.2024, The firm presented Phase III clinical study protocol No. D9802C00001 version 1.0 dated 13 October 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/48/24 Online Submission (42691) MK-2870	M/s. MSD	In light of earlier SEC recommendation on 02.05.2024, The firm presented Phase III clinical study protocol No. MK-2870-009 Version No. 00 dated 24-Jan-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
4.	CT/119/23 Online Submission (32896) SB27 (proposed pembrolizumab biosimilar)	M/s. Fortrea Development India Private Limited	The firm presented protocol amendment version 3.0 dated 11 April 2024 protocol no. SB27-3004. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm with the condition that PI shall be medical oncologist.
5.	CT/36/23 Online Submission (34878) LEE011	M/s. Novartis Healthcare Private Limited	The firm presented protocol amendment version 01 dated 01 December 2023 protocol no. CLEE011A2412B After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.

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6.	CT/167/23 Online Submission (34917) Osimertinib	M/s. Fortrea Development India Private Limited	The firm presented Protocol amendment version 2.0 dated 18 June 2024 Protocol no. D516AC00003. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
7.	CT/115/24 Online Submission (45237) JNJ-61186372, (Amivantamab SC)	M/s Johnson & Johnson Pvt. Ltd	The firm presented phase III clinical study protocol no: 61186372COR3002 version no. original, dated 26-JUL-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. Dr. Kaushal Kalra didn't participate
8.	CT/117/24 Online Submission (45349) JNJ-61186372, (Amivantamab SC)	M/s. Johnson & Johnson Pvt. Ltd.	The firm presented phase III clinical study protocol no: 61186372COR3001 version no. 00, dated 18-JUL-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
9.	BIO/CT04/FF/2024/ 44534 Pegfilgrastim 6 mg/.0.6 mL solution in single use PFS	M/s. CuraTeQ Biologics Private Limited	The firm presented the proposal to conduct Phase III clinical trial of Pegfilgrastim (BP14) Injection 6 mg/ 0.6 mL titled "An Open-Label, Randomized, Multi-Center, Active controlled, Clinical Study to Assess Efficacy, Safety and Immunogenicity of BP14 (Pegfilgrastim) Versus Neulasta® as an Adjunct to Chemotherapy in Patients with Non-Myeloid Malignancies" vide Protocol no. ICS/CUR/2024-004; Version No.: 1.0; Dated: 06 JUL 2024 along with results of Phase I study conducted in India. After detailed deliberation, the committee has recommended for approval of the Phase III CT protocol presented by the firm with the following conditions- 1. Study design should be changed to "Double blind" study instead of "open label" study. Accordingly, the firm is required to submit revised protocol to CDSCO. 2. The firm is also required to submit comparative preclinical data to CDSCO.

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			Note: Dr. Kaushal Kalra did not participate in the discussion.
10.	BIO/CT18/FF/2024/44952 Atezolizumab Injection 1200mg/20ml Vial and 840mg/14ml vial [Tecentriq].	M/s. Roche Products (India) Private Limited	<p>The firm presented the proposal for grant of approval of additional indication for Atezolizumab Injection i.e. “Tecentriq as monotherapy is indicated for the first-line treatment of adult patients with advanced NSCLC who are ineligible for platinum-based therapy” based on the global clinical trial safety and efficacy results where India is also a part of the study.</p> <p>The committee noted that the proposed additional indication is approved by EMA.</p> <p>After detailed deliberation, the committee recommended for approval of the proposed additional indication with the condition to conduct Phase IV study in India for the proposed indication.</p> <p>Accordingly, the firm should submit Phase IV study protocol to CDSCO within 03 months of approval of additional indication.</p>
11.	E-27299 Enfortumabvedotin (Powder for concentrate for solution (20mg and 30mg)	M/s. Astellas Pharma India Pvt. Ltd.	<p>The firm presented the proposal for update in Package Insert and Patient Information Leaflet for PADCEV™ Enfortumab vedotin (Powder for concentrate for solution (20mg and 30mg) to include ILD/pneumonitis safety signal in sections of posology and method of administration, special warning and precautions for use, undesirable effects, mechanism of action, pharmacodynamics/pharmacokinetic properties and patient counselling information based on CCDS version 6.0 dated 02 Dec 2022.</p> <p>After detailed deliberation, the committee recommended for approval of updated PI and PIL Version no. 3.0 dated 01.04.2024 for the proposed changes.</p>
12.	E-47330 Cetuximab 5mg/mL solution for infusion	M/s. Merck Specialities Private Limited	<p>The firm presented the proposal for update in dosage regimen of drug product Cetuximab 5 mg/mL Solution for Infusion (Erbix) with the changes in Dosage and administration section of package insert.</p>

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			<p>The committee noted that the proposed dosage regimen is approved in US, Japan, Singapore and other countries.</p> <p>After detailed deliberation, the committee recommended for approval of update in the dosage regimen and update of Package insert Version V3.0 dated April 2024.</p>
BA/BE Division			
13.	BABE/CT05/FF/2024/43212 Nabilone Capsules 1 mg	M/s. Lambda Therapeutic Research Limited	<p>The firm presented the Protocol No.: 0077-24 Version No. 1.0 Date 15 April 2024 for BA/BE study for export purpose only.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study for export purpose only.</p>
New Drugs Division			
14.	ND/CT/24/000056 Venetoclax 10mg, 50mg, 100mg tablets	M/s. AbbVie Healthcare India Private Limited	<p>Firm presented their proposal for grant of permission to conduct phase IV clinical trial with new drug Venetoclax 10mg, 50mg, 100mg tablets before the committee.</p> <p>After detailed deliberation, the committee opined that the proposed sample size i.e. 50 patients is in-adequate considering the safety and efficacy endpoints of the proposed phase IV clinical trial and as India is not part of the global clinical trial conducted by the firm.</p> <p>Hence, the committee recommended that the firm should increase the sample size to 100 patients.</p>
15.	12-20/05-DC (Pt-D Phase IV) Azacitidine for injection 100mg/vial	M/s. Intas Pharmaceuticals Limited	<p>The firm presented Phase IV clinical trial report of drug Azacitidine for injection 100mg/vial (Azadine) before the committee.</p> <p>After detailed deliberation, the committee considered the result of the Phase IV clinical study.</p>