Recommendations of the SEC (Oncology) made in its 37th/25 meeting held on 16.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/143/25 Online Submission (52260) Trastuzumab Deruxtecan	M/s IQVIA RDS (India) Private Limited	The firm presented phase III clinical study protocol no.: DS8201-854, Version 2.0 dated 30- JUN-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. More government site shall be included in the study. 2. A day care Centre is not an appropriate or acceptable clinical trial site as it does not provide the required infrastructure for emergency management and regulatory compliance. Dr. Kaushal Kalra and Dr. Harsha Panchal didn't participate.
2.	CT162 /25 Online Submission (53029) N-803	M/s CBCC Global Research LLP	The firm presented phase III clinical study protocol no.: ResQ201A-NSCLC version no. 3.0 dated 24-MAR-25. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. More government site shall be included in the study. 2. PI shall be Medical Oncologist Only. 3. A day care Centre is not an appropriate or acceptable clinical trial site as it does not provide the required infrastructure for emergency management and regulatory compliance.

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Biological Division			
3.	BIO/CT18/FF/2025/51116 Serplulimab Concentrate for Solution for Infusion 100 mg/10 ml Vial (10 mg/ ml) (r-DNA origin)	M/s Intas Pharmaceuticals Ltd	The firm did not turn up for the presentation.
4.	BIO/CT18/FF/2025/51522 Brentuximab vedotin 50 mg powder for concentrate for solution for infusion in vial.	M/s Takeda Biopharmaceuticals India Pvt. Ltd.	The firm presented a proposal for grant of approval of modification & expansion in approved indication of Brentuximab vedotin 50 mg powder for concentrate for solution for infusion (r-DNA Origin). The committee noted that the subject drug is approved in India since 20-Oct-2021 for the treatment of adult patients with previously untreated Stage III or IV cHL, in combination with doxorubicin, vinblastine, and dacarbazine. After detailed deliberation, the committee recommended for grant of approval for the proposed modification & expansion of indication where subject drug is indicated for adult patients with previously untreated CD30+ Stage IIB with risk factors, Stage III or Stage IV HL in combination with etoposide, cyclophosphamide, doxorubicin, dacarbazine, dexamethasone (BrECADD)".; in-line with EMA approval subject to the condition to conduct Phase-IV clinical Trial in the proposed modified & expanded indication in significant number of subjects. Accordingly, the protocol to conduct the Phase-IV clinical Trial shall be submitted to CDSCO within 3 months of grant of approval for the proposed indications.

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BA/BE Division			
5.	BABE/CT05/FF/2025/47401 Lenalidomide TDS 8% -LLD-TDS-009 patch (50 cm^2 with 81 cm^2 overlay)	M/s Raptim Research Pvt. Ltd.	In light of the earlier SEC recommendation dated 11/09/2025, the firm presented its justification for proposed study before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study for export purpose only.
6.	BABE/CT05/FF/2025/52089 Venetoclax tablet 400 mg	M/s. Cliantha Research Limited Sarkhej Ahmedabad (India)	The firm presented BA/BE study Protocol No.: C1B06036, Version: 01, dated 28.08.2025 (For Export purpose only), before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study for export purpose only.
New Drugs Division			
7.	ND-12011/10/2025-eoffice Venetoclax Based Combination Therapies	Tata Memorial Hospital	The study investigator presented protocol titled" Evaluation of Venetoclax-Based Combination Therapies in Childhood Acute Myeloid Leukemia: A Phase II Randomized Controlled Trial" (Study Protocol Version 2.0 dated 1 July 2025)" before the committee. After detailed deliberation, the committee recommended that proposed academic research study may be allowed as per proposal presented by the applicant.
SND Division			
8.	SND/CT04/FF/2025/51289 SND/CT/25/000092 Ondansetron Extended Release Injectable Suspension 100 mg/ml.	M/s. Shilpa Medicare Limited	In light of earlier SEC recommendation dated 09.10.2025, the firm presented the additional information for the rationality of applied dosage form with respect to oral dose calculation from the Phase I study. Firm also apprised the committee the outcome of the ongoing Phase III Clinical trial of the applied product. (IV Vs IM ER injection). After detailed deliberation, considering the submitted therapeutic window of the applied product, the committee recommended to grant the permission to

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			conduct the Phase III clinical trial for the applied product as per the protocol presented by the firm.