

**Recommendations of the SEC (Oncology) made in its 34<sup>th</sup>/25 meeting held on 04.11.2025 at CDSCO HQ New Delhi:**

<b>S. No</b>	<b>File Name &amp; Drug Name, Strength</b>	<b>Firm Name</b>	<b>Recommendations</b>
<b>GCT Division</b>			
1.	CT/152/25 Online Submission (52565)  Izalontamab Brenigitecan	M/s Bristol-Myers Squibb India Pvt. Ltd	The firm presented phase II/III clinical study CA2440010 version no. original dated 15 May 2025.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following conditions:  <ol style="list-style-type: none"> <li>1. More number of subjects shall be recruited from India.</li> <li>2. More geographically distributed sites shall be included in the study.</li> <li>3. Day care center (site no. 73) should not be a part of clinical trial.</li> <li>4. After completion of phase II study, safety data along with selected dose for phase III shall be submitted to CDSCO.</li> </ol>
<b>BA/BE Division</b>			
2.	BABE/CT05/FF/2025/ 50482  Venetoclax Tablets 200 mg	M/s Lambda Therapeutic Research Limited	The firm presented BA/BE study Protocol No. 0208-25, Version: None, dated 17.06.2025 (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.
<b>Biological Division</b>			
3.	BIO/CT18/FF/2024/46 258  Talquetamab solution for injection 2 mg/ml and 40 mg/ml	M/s Johnson & Johnson Pvt. Ltd.	In light of earlier SEC recommendation dated 21.05.2025, the firm presented the additional justification for the unmet need of the drug for the proposed indication in India, efficacy results from the extended global clinical trials and the commitment to conduct a Phase IV study in India in support of their proposal for seeking permission to import and market Talquetamab solution for injection 2 mg/ml and 40 mg/ml with Phase III local clinical trial waiver.  The committee noted that the drug product is having a significant therapeutic

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			<p>advance in India over the current standard of care for the treatment of adult patients with relapsed or refractory multiple myeloma who has previously received at least 3 prior therapies.</p> <p>After detailed deliberation, the committee recommended for grant of permission to the firm to import and market the drug product Talquetamab solution for injection 2 mg/ml and 40 mg/ml for the “treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least 3 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy” in line with EMA approved indication subject to the condition that the firm should conduct Phase IV clinical trial in significant number of patients in India.</p> <p>Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within three months of grant of MA approval.</p>
4.	<p>BIO/CT21/BO/2025/49420</p> <p>Lyophilized Recombinant L-Asparaginase-II bulk &amp; Injection 10000 IU</p>	<p>M/s Gennova Biopharmaceuticals Limited</p>	<p>The firm presented the proposal for grant of permission to manufacture and market Recombinant L-Asparaginase-II Bulk and Lyophilized Recombinant L-Asparaginase-II for Injection 10000 IU for the indication “as a component of antineoplastic combination therapy for the treatment of Acute Lymphoblastic Leukaemia (ALL) in paediatric patients and adults” based on the results of the Phase-I (PK-PD) study using validated PK-PD biomarker in healthy subjects.</p> <p>Further, the firm also presented the data of modelling and simulation for extrapolation of indication to pediatric population.</p> <p>The committee noted that the recombinant L-Asparaginase of innovator is not approved in India and there is no sufficient safety data available in Indian patients for the said recombinant product.</p> <p>After detailed deliberation, the committee recommended the firm to conduct a Phase</p>

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			III clinical trial to establish the safety, efficacy, and immunogenicity in adults and pediatric Indian patient population.
<b>New Drugs Division</b>			
5.	ND/CT/25/000013  Nelarabine Injection 250 mg/50 ml	M/s Zydus Lifesciences Limited	<p>In light of earlier recommendations dated 09.04.2025, the firm has submitted revised Phase-IV CT Protocol of Nelarabine Injection 250 mg/50ml (Protocol no. C2B05522, version 02 dated 08 May 2025) before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct Phase IV clinical trial as per the protocol presented.</p> <p>The results of Phase IV Clinical Trial should be submitted to CDSCO for further review by the committee.</p>
6.	ND/CT/25/000071  Nelarabine Injection 250 mg/50 ml (5 mg/ml)	M/s MSN Laboratories Private Limited	<p>In line with the condition of permission for manufacturing and marketing of drug Nelarabine Injection 250mg/50 ml (5 mg/ml), the firm presented Phase IV clinical trial protocol titled “A Phase IV, Open-label, Multicenter Study to Evaluate the long-term safety and Effectiveness of Nelarabine Injection 250 mg/50 mL (5 mg/mL) in Adult Patients with Relapsed or Refractory T- Acute Lymphoblastic Leukaemia (T-ALL)/ Lymphoblastic Lymphoma (T-LBL)”, vide protocol no. 014/NLRN/MSN/2025 Version 1.0 Dated 27/MAY/2025 for Nelarabine Injection 250mg/50 ml (5 mg/ml) before the committee.</p> <p>After detailed deliberation, the committee recommended that firm should revise protocol with the following points:</p> <ol style="list-style-type: none"> <li>1) Firm should include paediatric population in the proposed Phase IV CT protocol</li> <li>2) Firm should define washout period between CAR-T cell therapy and Nelarabine injection treatment</li> <li>3) Firm should revise the follow-up period considering the median</li> </ol>

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			<p>time interval for SAE after last dose.</p> <p>Accordingly, the firm should submit the revised protocol within one month for further review by the committee.</p>
<b>SND Division</b>			
7.	<p>SND/MA/24/000251</p> <p>Enzalutamide oral solution 160 mg/6 ml</p>	<p>M/s Ferring Pharmaceuticals Pvt. Ltd.</p>	<p>The firm presented the proposal for grant of permission to manufacture and market of Enzalutamide oral solution 160 mg/6 ml Based on the results of the Bioequivalence study conducted in fasting and fed state.</p> <p>The committee noted that the Phase IV clinical trial report of Enzalutamide 40 mg soft Capsule along with SAEs reported (M/s. Astellas Pharma India Pvt. Ltd) was deliberated in the SEC (Oncology) meeting dated 28.08.2025 and committee recommended that M/s. Astellas Pharma India Pvt. Ltd should update the results of the Phase IV study and SAEs outcomes in the prescribing information and revised prescribing information should be submitted to CDSCO for further review by the committee.</p> <p>After detailed deliberation, committee recommended that this proposal may be taken up before the committee after consideration of revised prescribing information of Enzalutamide 40 mg soft Capsule of M/s. Astellas Pharma India Pvt. Ltd.</p>
8.	<p>SND-16011(11)/106/2025-eoffice</p> <p>Osimertinib tablets 40 mg and 80 mg (Tagrisso®)</p>	<p>M/s AstraZeneca Pharma India</p>	<p>The firm presented the proposal for waiver of Phase IV clinical trial requirement for Osimertinib tablets 40 mg &amp; 80 mg and request for approval to conduct a Post Marketing Surveillance before the committee.</p> <p>The committee has noted that the firm had been granted import and marketing permission for Osimertinib tablets 40 mg &amp; 80 mg for current additional indication based on Global Clinical Trial data, wherein only 3 Indian patients were participated.</p> <p>After detailed deliberation, the committee</p>

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			<p>has reiterated the earlier SEC recommendation dated 11.03.2025 and recommended to submit the Phase IV clinical trial study protocol within one month.</p> <p>Accordingly, firm should submit the protocol to conduct Phase IV clinical trial study.</p>