Recommendations of the SEC (Oncology) made in its 17th/26 meeting held on 24.06.2026 at CDSCO HQ New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2026/55101 Glofitamab concentrate for solution for infusion 2.5 ml and 10 ml single dose vial (1mg/ml) • 2.5 mg of Glofitamab/2.5 mL at a concentration of 1 mg/mL • 10 mg of Glofitamab/10 mL at a concentration of 1 mg/mL	M/s. Roche Products (India) Private Limited	The firm presented the proposal for grant of permission to import and market Glofitamab concentrate for solution for infusion 2.5 ml and 10 ml single-dose vial (1mg/ml) • 2.5 mg of Glofitamab/2.5mL at a concentration of 1mg/mL • 10 mg of Glofitamab/10 mL at a concentration of 1 mg/mL for the treatment for the treatment of following indications: • Glofitamab in combination with gemcitabine and oxaliplatin is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are notcandidatesfor autologous stem cell transplant (ASCT). • Glofitamab is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and primary mediastinal large B-cell lymphoma (PMBCL) after two or more lines of systemic therapy. The committee noted that the subject drug product has been approved in USA, United Kingdom, Japan, Australia, Canada and EU etc.based on the clinical data generated through global clinicaltrials where India was not a participating country. Further, committee observed that significant therapeutic advancementof proposed drug over existing therapies isnot established. After detailed deliberation, the committee did not consider the local Phase-III and Phase-IV clinical trial waiver for both the proposed indications and accordingly recommended to submit the Phase III Clinical Trial protocol to CDSCO for both the proposed indications as mentioned above.
2.	BIO/CT21/BO/2025/50982	M/s CuraTeQ Biologics Private	The firm presented the proposal for grant of permission to manufacture and market

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	Pegfilgrastim 6 mg solution for injection (10 mg/ml) in PFS	Limited	the Pegfilgrastim 6mg solution for injection (10mg/ml) in pre filled syringe based on the results of Phase-I clinical trial (BP14-102) conducted to establish the comparative pharmacokinetic, pharmacodynamic, safety and immunogenicity of the drug product using absolute neutrophil count (ANC) as validated PD marker. The committee noted the following: 1. Firm had conducted similar study BP14-101 with the subject drug Pegfilgrastim 6mg/0.6ml in Australia where primary PK parameters study results did not meet the pre-approved protocol criteria. 2. Subsequently, present study BP14-102 with Pegfilgrastim 6mg/0.6ml was conducted as repeat study in India with increased number of subjects as mandated by EMA. 3. Subject drug Pegfilgrastim is fundamentally a Pegylated form of Filgrastim. Phase-I clinical trial (BP13-102) which was conducted in India on Filgrastim 300 mcg/0.5ml;also failed to meet the pre-approved protocol criteria for the primary PD parameters study results. 4. Firm was granted permission in Form CT-06 to conduct the Phase-III clinical trial (BP14-301) for Pegfilgrastim 6mg/0.6ml; however same has not been initiated till date. After detailed deliberation, the committee did not consider the Phase-III clinical trial waiver for the proposed indication and accordingly recommended to conduct the Phase-III clinical trial in India.
SND Division			
3.	SND-12012/1/2026-eoffice Osimertinib Tablets 40 mg & 80mg	M/s. AstraZeneca Pharma India Limited	The firm presented their proposal forsafety update in prescribing information ofOsimertinib tablets 40 mg & 80 mg to update side effects. The committee noted that Osimertinib tablets 40 mg & 80 mg is already approved in India since 2017.

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			The firm stated that skeletal muscle toxicities were observed in patients treated with Osimertinib monotherapy in the ADURA, FLAURA, FLAURA2 and AURA global studies and the said update in PI is already approved in New Zealand and Brazil. After detailed deliberation, the committee considered the update of side effects in PI of Osimertinibas proposed by the firm.