Recommendations of the SEC (Oncology) made in its 11th/24 meeting held on 15.05.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/88/23 Online Submission (32249) Durvalumab	M/s. Parexel	The firm presented protocol amendment 2 version 3.0 dated 04.03.2024 protocol no. D4191C00137. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/109/23 Online Submission (32251) Talquetamab	M/s. Johnson and Johnson	The firm presented protocol amendment 2 dated 21.03.2024 protocol no. 64407564MMY3009. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/155/22 Online Submission (32220) Vibostolimab with Pembrolizumab	M/s. MSD	The firm didn't turn up for presentation.
4.	CT/141/22 Online Submission (32138) Ianalumab	M/s. Novartis	The firm presented protocol amendment version 04 dated 17. 01.2024 protocol no. CVAY736O12301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
5.	CT/171/21 Online Submission (32151) Entrectinib	M/s. Roche	The firm presented protocol amendment version 6 dated 02.10.2023 protocol no. MO41552. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
6.	CT/25/23 Online Submission (31011) Camizestrant	M/s. Fortrea	In light of earlier SEC recommendation dated 05.03.2024, the firm presented waive –off CTNOC conditions (1) & (2) vide protocol no. D8531C00002 Condition No: (1) Heart rate shall be continuously monitored rather than once in two months (2) SOP for proper management of bradycardia shall be mentioned in the study protocol.

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			After detailed deliberation, the committee accepted the justification as presented by the firm to waive –off CT NOC condition no. (1) and (2) .
Biological Division			
7.	BIO/CT18/FF/2024/41545 Daratumumab solution for Injection 1800 mg (120 mg/ml)	M/s. Johnson & Johnson Pvt. Ltd.	The firm has presented the proposal for approval of additional indication i.e, for treatment of Light chain (AL) amyloidosis in combination with cyclophosphamide, bortezomib and dexamethasone for the treatment of adult patients with newly diagnosed systemic AL amyloidosis along with request for local clinical trial waiver. The committee noted that treatment of Light chain (AL) amyloidosis comes under the category of orphan drug and applied indication is approved in US, EU, Canada, Brazil, Switzerland, U.K. and China. After detailed deliberation, the committee recommended for approval of proposed additional indication with waiver of local clinical trial with condition to conduct the Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months for SEC deliberation.
8.	BIO/CT18/FF/2023/39717 (E-30357) Atezolizumab Injection (1875mg/15ml vial)	M/s. Roche Products (India) Pvt. Ltd.	In light of the earlier SEC recommendations dated 09.01.2024 and 19.03.2024 & 20.03.2024, the proposal of the firm was redeliberated for grant of permission to import and market Atezolizumab injection (1875mg/15ml vial) (Tecentriq) by new route of administration i.e., subcutaneous route for indications of Atezolizumab injection approved for intravenous (IV) route for sale or for distribution in India with local Phase III clinical trial waiver under unmet need in India and commitment to conduct Phase IV study". The committee noted that the i.v. formulation of Atezolizumab is already available in market. Further, the

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			committee noted that the formulation and dose of proposed S.C. route is different from i.v. route and also India was not part of the GCT conducted to establish safety and efficacy data for new route of administration i.e., S.C. route. After detailed deliberation, the committee did not consider the firm's request for approval of Atezolizumab injection (1875mg/15ml) (Tecentriq) for proposed S.C. route of administration with waiver of Phase III Clinical Trial by claiming the unmet need in India. The committee recommended that the firm should conduct phase III study in Indian population to establish safety and efficacy of the product for the proposed S.C. route. The protocol should be presented before SEC for further review.
SND Division			
9.	SND/MA/23/000028 Abiraterone Acetate Oral Suspension 1000mg/5 ml	M/s. BDR Pharmaceuticals Private Limited	In light of the earlier SEC recommendation dated 07.02.2024 & 08.02.2024, the firm represented their justification for waiver of Phase III clinical trial before the committee. The firm has informed that the proposed drug formulation Abiraterone Acetate Oral Suspension 1000mg/5ml has no change in route of administration and no change in dosing regimen. Also, Abiraterone Acetate 1000mg tablets approved in EU by 2021. After detailed deliberation, the committee has opined for grant of manufacturing and marketing of Abiraterone Acetate Oral Suspension 1000mg/5 ml along with Phase III CT waiver with the condition to conduct Phase IV Clinical Trial in 400-500 subjects. Accordingly, firm should submit Phase IV Clinical Trial protocol within 3 months from the date of approval of the product to CDSCO for further review by the committee.