

**Recommendations of the SEC (Oncology) made in its 19<sup>th</sup>/24 meeting held on 18.09.2024 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/169/23 Online Submission (34768) PF-07220060 100mg Tablets	M/s. Pfizer Limited	The firm presented protocol amendment 1 dated 06 February 2024 protocol no. C4391022.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/36/21 Online Submission (34743) Belantamab Mafodotin	M/s. GlaxoSmithKline Pharmaceuticals Limited	The firm presented protocol amendment 03 dated 25 June 2024 protocol no. 209628.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/34/24 Online Submission (34705) Olaparib	M/s. Fortrea Development India Private Limited	The firm presented protocol amendment version 6.0 dated 31 May 2024 protocol no. D9102C00001.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/143/21 Online Submission (34677) Hydrogen Peroxide	M/s. IQVIA RDS (India) Private Limited	The firm presented proposal for Increase in number of subjects from India protocol no. CCR5119  After detailed deliberation, the committee recommended for approval for Increase in number of subjects from 60 to 111 in India.
5.	CT/17/24 Online Submission (34514) ISB 2001	M/s. Glenmark Pharmaceuticals Ltd.	The firm presented protocol amendment 02 version 3.0 dated 06 August 2024 protocol no. ISB 2001-101.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.