Recommendations of the SEC (Oncology & Haematology) made in its 126th meeting held on 26.05.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	12-01/19-DC (Pt-337) Docetaxel	NCC-PvPI, IPC, Ghaziabad	The SRP recommendation received from PvPI was discussed by the committee. After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to include Docetaxel associated Candidiasis as an adverse event in the corresponding prescribing information leaflet.
SND Division			
2.	SND/IMP/20/000015 Olaparib Film Coated Tablets 100/150 mg	M/s. AstraZeneca Pharma	The firm didn't turn up for presentation.
3.	SND/CT/22/000032 Ondansetron Extended release Injectable suspension 100mg/ml	M/s. Shilpa Medicare	The firm presented protocol to conduct Phase I dose-escalation, comparative pharmacokinetic, safety and tolerability study of Ondansetron extended release injectable suspension 100mg/ml. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial of Ondansetron extended release injectable suspension 100mg/ml as per the protocol presented.
4.	SND/MA/21/000504 Hydroxyurea capsules 500 mg	M/s. Cipla Limited	The firm didn't turn up for presentation.
GCT Division			
5.	CT/17/22 Online Submission (30585) Durvalumab plus Domvanalimab	M/s. AstraZeneca	The firm presented the proposed Phase III clinical trial protocol no. D9075C00001, Ver:3.0 dated 17Dec2021 (PACIFIC-8) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as per the protocol presented.
6.	CT/29/22 Online Submission (31152) Durvalumab	M/s. AstraZeneca	The firm presented the proposed Phase III trial protocol no. D910SC000001, Ver:2.0 dated 16Nov2021 (KUNLUN) before the committee. After detailed deliberation, the committee recommended for grant of permission to

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			conduct the clinical trial with the condition that: 1) The study Principal Investigator (Medical Oncologist) and his team should have Radiotherapy expert as co-investigator or sub-investigator at each site. 2) The committee also suggested that randomization stratification should be worked out for those subjects included in the trial, who medically have resectable oesophageal squamous cell carcinoma (ESCC), however refused surgery (inclusion criteria 5).
7.	CT/30/22 Online Submission (31079) Capivasertib + Docetaxel	M/s. Labcorp	The firm presented the proposed Phase III clinical trial protocol no. D361EC00001, Ver:2.0 dated 09Dec2021 (CAPItello-280) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as per the protocol presented.
8.	CT/36/22 Online Submission (31027) Selpercatinib(LY3527 723)	M/s. Eli Lilly	The firm presented the proposed Phase III clinical trial protocol no. J2G-MC-JZJX, amendment (e), dated 08Mar2022 (LIBRETTO-432) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as per the protocol presented.
9.	CT/41/22 Online Submission (31863) Oregovomab	M/s. Raptim Research	The firm presented the proposed Phase II clinical trial protocol no. QPT-ORE-006, version 1.0 dated 14/04/2022 before the committee. **Risk versus Benefit**: The safety profile from pre-clinical toxicity studies and clinical Phase I and Phase II studies, may justify the conduct of the study. **Innovations Vs existing therapeutic option**: The objective of this study is to confirm that the presence of primary tumor and its immune suppressive biology does not interfere with chemoimmunotherapy when Oregovomab is administered with initiation (Cycle 1) of chemotherapy and

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			not delayed to after the debulking procedure. **Unmet medical need in the country**: Neoadjuvant chemotherapy with Oregovomab may be a better treatment option in patient with Advanced Epithelial Ovarian, Fallopian Tube or Peritoneal Carcinoma. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase II clinical trial as per the protocol presented.
10.	CT/02/22 Online Submission (16697) Fitusiran	M/s. Sanofi Healthcare	The firm presented the proposed protocol no. EFC15467, amendment 02, version 1, dated 16-Dec-2021 (ATLAS-PEDS) and to increase the number of subjects from 12 to 18 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment and also recommended for increase of number of subjects from 12 to 16 in India as per the protocol presented.