Recommendations of the SEC (Oncology & Haematology) made in its 128th meeting held on 13.07.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	4-40/Astrazeneca/PAC-R-Durvalumab (Dy no 3415) Durvalumab	M/s. Astrazeneca Pharma India Limited	The firm did not turn up for presentation.
SND Division			
2.	SND/IMP/22/000042 Ruxolitinib Tablets 5/10/15/20 mg	M/s. Novartis Healthcare	The firm presented their proposal for additional indication of Ruxolitinib Tablets 5/10/15/20 mg with local clinical trial waiver before the committee. After detailed deliberation, the committee recommended for grant of permission for the additional indication "Ruxolitinib is indicated for the treatment of patients aged 12 years and older with acute graft versus host disease or chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies" for Ruxolitinib tablets 5/10/15/20 mg subject to following condition: (1). The firm should submit safety and efficacy data of ongoing Global study and Post Marketing data related to said indication within one year from the approval for evaluation by the committee for its continued marketing.
3.	SND/IMP/22/00007 Olaparib Film Coated Tablet 100/150 mg	M/s.AstraZenca	In light of SEC recommendation dated 12-04-2022, the firm presented interim report of the ongoing Phase IV clinical trial as per the condition of the permission (IMP-ND-189/2018) granted to the firm. The committee noted the interim results of the ongoing Phase IV clinical trial. After detailed deliberation, the committee recommended for grant of permission for the additional indication "As monotherapy for the adjuvant treatment of adult patients with BRCA-mutated HER2- negative high risk early breast cancer who have previously been

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			treated with neoadjuvant or adjuvant chemotherapy" for Olaparib film coated tablet 100/150 mg.
GCT Division			
4.	CT/50/17 Online Submission (14253) Lorlatinib (PF-06463922)	M/s. Pfizer	The firm presented clinical trial protocol amendment 5 dated 29/07/2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
5.	CT/103/21 Online Submission (18172) Trastuzumab Deruxtecans	M/s. AstraZeneca	The firm presented clinical trial protocol amendment version 2.0 dated 07/03/2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
6.	CT/72/20 Online Submission (18238) Capmatinib	M/s. Novartis	The firm presented clinical trial protocol amendment CINC280A2301, Version 02, dated 24 Feb 2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
7.	CT/81/21 Online Submission (27085) Dated 22/07/2021 Galinpepimut-S	M/s. PPD	The firm presented Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study with condition that patients with active TB/ latent TB infection should be excluded. Accordingly, India specific protocol amendment with revision of the exclusion criteria should be submitted to CDSCO.
8.	CT/77/18 Online Submission (12586) Dated 15/09/2021 Crizanlizumab	M/s. Novartis	The firm presented clinical trial protocol amendment CSEG101B2201, Version 4, dated 30.03.2021before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
9.	CT/29/21 Online Submission (17869) Dated 17/05/2022 Larotrectinib	M/s. Bayer	The firm presented clinical trial protocol amendment Version 12, dated 15.03.2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.

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Additional Proposal-New Drug Division			
10.	ND/CT/21/000090 Darolutamide 300mg Film coated tablets	M/s. Bayer Pharmaceuticals Pvt. Ltd.	In light of earlier SEC recommendation dated 09.12.2021 & 10.12.2021, the firm presented justification for sample size before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial.
Additional Proposal- Biological Division			
11.	X-11026/84/2020-BD Human Normal Immunoglobulin for Intravenous Administration IP/EP, 5% and 10% Solution Indication	M/s. Intas Pharmaceuticals Pvt. Ltd.	The firm presented their proposal along with Phase III clinical trial protocol before the committee for export purpose. After detailed deliberation, the committee recommended for grant of permission for conducting the proposed Phase III clinical trial with the following conditions: 1. The clinical trial sites should be geographically distributed and accordingly PI undertaking should be submitted. 2. Undertaking stating that the product to be used in clinical trial is same as approved in India in respect of indication (PID) and dosage schedule for which the trial is proposed, to be submitted.
12.	X-11026/85/2020-BD Human Normal Immunoglobulin for Intravenous Administration IP/EP, 5% and 10% Solution.	M/s. Intas Pharmaceuticals Pvt. Ltd.	The firm presented their proposal along with Phase III clinical trial protocol before the committee for export purpose. After detailed deliberation, the committee recommended for grant of permission for conducting the proposed Phase III clinical trial with the following conditions: 1. The clinical trial sites should be geographically distributed and accordingly PI undertaking should be submitted. 2. Undertaking stating that the product to be used in the trial is same as approved in India in respect of indication (PIT) and dosage schedule for which the trial is proposed, to be submitted.