Recommendations of the SEC (Oncology & Haematology) made in its 151st meeting held on 22.06.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT/23/000037 Tenalisisb Tablets 400mg	M/s. Syngene International Limited	The proposal was deferred for next SEC meeting.
2.	ND/IMP/22/000015 Selpercatinib 40 mg & 80 mg	M/s. Eli-Lilly	The firm did not turn up for presentation.
3.	ND/IMP/19/000039 Dacomitinib Tablets 15mg, 30mg & 45mg	M/s. Pfizer Product India Pvt. Ltd.	The proposal was deferred for next SEC meeting.
Biological Division			
4.	BIO/CT18/FF2022/ 34766 Polatuzumab Vedotin for Injection, 30mg/vial and140 mg/vial	M/s. Roche Products(I) Pvt. Ltd	The firm presented their proposal of warning statement for inclusion of Hematologist in the label, PI. After detailed deliberation, the committee recommended for the proposed amendment as follows. "Warning: To be sold by retail on the prescription of a Registered Oncologist, /Haematologist only".
5.	BIO/CT18/FF/2022/ 34250 Teclistamab Sterile Liquid in Vials, 30 mg/vial (10 mg/ml) and 153 mg/vial (90 mg/ml)	M/s. Johnson & Johnson Pvt. Ltd.	In light of the earlier SEC recommendations dated 09.12.2022, the firm presented the additional information for the proposal for import and marketing of the drug Teclistamab sterile liquid in vials 30mg/vial and 90mg/vial indicated for treatment of adult patients with relapsed or refractory multiple myeloma who have received at least three prior therapies including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody with local clinical trial waiver. After detailed deliberation, the committee recommended for grant of permission to import and market the drug with waiver of Phase III clinical trial in the country with the condition that the firm should conduct Phase IV trial. Accordingly, Phase IV clinical trial protocol should be submitted within 3 months of import and marketing

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			permission granted.
6.	BIO/CT21/FF/2023/ 36429 Nimutuzumab Injection 50 mg/ 10 mL	M/s. Biocon Biologics Limited	The firm presented the proposal for grant of permission for additional indication for the treatment of patients suffering from Advanced Esophageal Squamous Cell Carcinoma (ESCC) with waiver of local clinical trial. The committee observed that there is no convincing data available for proposed additional indication. After detailed deliberation, the committee recommended that the firm should conduct Phase III clinical trial in India in the proposed indication.
SND Division			
7.	SND/MA/22/000246 Eribulin Mesylate Solution for Injection 2.5mg in 5ml vial	M/s. Emcure Pharmaceuticals Limited	The proposal was deferred for next SEC meeting.
GCT Division			
8.	CT/38/23 Online Submission (37151) Serpin PC	M/s. Inventive International Pharma Services	The firm presented their proposal for Phase IIb clinical trial protocol number AP-0102, Protocol Version: 3.0 dated 05-Dec-2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study with conditions- 1. The firm should submit safety data of adults subjects along with Independent Data Monitoring Committee (IDMC) recommendations for review by the committee prior to randomization of adolescent subjects (Age 12-18 years) from India in the study. 2. The firm should provide post trial access treatment to trial subjects who will be benefitted from the study drug.
9.	CT/35/23 Online Submission (36619) CC-92480 (BMS-986348) Mezigdomide	M/s. Bristol-Myers	The firm presented Phase III clinical trial protocol no- CA057008, Version- 1 dated 10 Nov. 2022, before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study.

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10.	CT/131/22 Online Submission (25294) Marstacimab Prophylaxis	M/s. Pfizer	The firm presented their proposal to increase the number of subjects from 4 to 10 in India, before the committee. After detailed deliberation, the committee recommended for approval of increase of number of trial subjects i.e. 4 to 10 from India.
11.	CT/15/20 Online Submission (22812) Azacitidine with or without MBG453	M/s. Novartis	The firm presented their proposal for protocol amendment version 03 dated 23-06-2022, before the committee. The committee noted that the subject enrollment is completed at this stage and now it is proposed for amendment in protocol w.r.t to AE/SAE reporting and statistical analysis part. After detailed deliberation, the committee recommended that the firm should submit certificate from Biostatistician for the proposed changes in protocol for further review by the committee.
12.	CT/33/23 Online Submission (36892) Pacritinib	M/s. PSI CRO	The firm presented their proposal for Phase III clinical trial protocol number PAC303 before the committee. After detailed deliberation, the committee recommended for grant of permission with condition that 1. The firm should submit Safety data of first 10 subjects from India for further review by the committee. 2. Cardiologist should be a part of study team at each clinical trial site for the proposed study.
13.	CT/83/22 Online Submission (25324) BCD-201-2	M/s. IR Innovate Research	The firm presented their proposal for protocol amendment version no 3.0 dated 17-02-2023 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment as presented by the firm.
14.	CT/17/22 Online Submission (25272) Durvalumab (MEDI4736) Domvanalimab	M/s. AstraZeneca	The firm presented the protocol amendment version 4.0 dated 27-Feb-2022, protocol- addendum IND-1 version 2.0 dated 15-Mar-2023 before the committee. After detailed deliberation, the committee

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	(AB154)		recommended for approval of the proposed protocol amendment version 4.0 dated 27-Feb-2022, and protocol-addendum IND-1 version 2.0 dated 15-Mar-2023 as presented by the firm.
15.	CT/166/21 Online Submission (25957) Achylabrutinib	M/s. Labcorp	The firm presented the protocol amendment version 5.0 dated 22-June-2022 and version 6.0 dated 22-Nov-2022 before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment version 5.0 dated 22-June-2022 and version 6.0 dated 22-Nov-2022 as presented by the firm.
16.	CT/39/23 Online Submission (37172) Serpin PC	M/s. Inventive International	The proposal was deferred for next SEC meeting.
17.	CT/176/22 Online Submission (34952) Atezolizumab Injection 1200mg/20ml Sorafenib 200 mg Lenvatinib	M/s. Roche	The proposal was deferred for next SEC meeting.
18.	CT/23/23 Online Submission (36506) Pertuzumab	M/s. CliniRx	The proposal was deferred for next SEC meeting.
19.	CT/7/23 Online Submission (35658) HT-6184 (2mg, Caps)	M/s. CBCC	The proposal was deferred for next SEC meeting.
Medical Device Division			
20.	CI/MD/2023/86807 Hydrating oral Patch	M/s. Bylin Meditec Pvt. Ltd.	The proposal was deferred for next SEC meeting.